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CODE OF FEDERAL REGULATIONS

Title 21
Food and Drugs

Parts 500 to 599

Revised as of April 1, 2018

Containing a codification of documents
of general applicability and future effect

As of April 1, 2018

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Cite this Code: CFR

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OLIVER A. POTTS,
Director,
Office of the Federal Register.
April 1, 2018.

THIS TITLE

Title 21—FOOD AND DRUGS is composed of nine volumes. The parts in these volumes are arranged in the following order: Parts 1–99, 100–169, 170–199, 200–299, 300–499, 500–599, 600–799, 800–1299 and 1300 to end. The first eight volumes, containing parts 1–1299, comprise Chapter I—Food and Drug Administration, Department of Health and Human Services. The ninth volume, containing part 1300 to end, includes Chapter II—Drug Enforcement Administration, Department of Justice, and Chapter III—Office of National Drug Control Policy. The contents of these volumes represent all current regulations codified under this title of the CFR as of April 1, 2018.

For this volume, Ann Worley was Chief Editor. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

Title 21—Food and Drugs

(This book contains parts 500 to 599)

Part

CHAPTER I—Food and Drug Administration, Department of Health and Human Services (Continued) 500

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter I appear at 69 FR 13717, Mar. 24, 2004, and 69 FR 18803, Apr. 9, 2004.

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500.1410 N-methyl-2-pyrrolidone.

AUTHORITY: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13802, Mar. 27, 1975, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b) of this chapter, the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

[80 FR 56337, Sept. 17, 2015]

§ 500.24 Emergency permit control.

The provisions of part 108 of this chapter shall apply to the issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers, and intended for use as food for animals.

[61 FR 37681, July 19, 1996]

§ 500.25 Anthelmintic drugs for use in animals.

(a) The Commissioner of Food and Drugs has determined that, in order to assure that anthelmintic drugs, including animal feeds bearing or containing such drugs, which do not carry the prescription statement are labeled to provide adequate directions for their effective use, labeling of these anthelmintic drugs shall bear, in addition to other required information, a statement that a veterinarian should be consulted for

assistance in the diagnosis, treatment, and control of parasitism.

(b) The label and any labeling furnishing or purporting to furnish directions for use, shall bear conspicuously the following statement: ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.''

(c) For drugs covered by approved new animal drug applications, the labeling revisions required for compliance with this section may be placed into effect without prior approval, as provided for in § 514.8(c)(3) of this chapter. For drugs listed in the index, the labeling revisions required for compliance with this section may be placed into effect without prior granting of a request for a modification, as provided for in § 516.161(b)(1) of this chapter.

(d) Labeling revisions required for compliance with this section shall be placed into effect by February 25, 1975, following which, any such drugs that are introduced into interstate commerce and not in compliance with this section will be subject to regulatory proceedings.

[40 FR 13802, Mar. 27, 1975, as amended at 71 FR 74782, Dec. 13, 2006; 72 FR 69120, Dec. 6, 2007]

§ 500.26 Timed-release dosage form drugs.

(a) Drugs are being offered in dosage forms that are designed to release the active ingredients over a prolonged period of time. There is a possibility of unsafe overdosage or ineffective dosage if such products are improperly made and the active ingredients are released at one time, over too short or too long a period of time, or not released at all. Drugs marketed in this form, which are referred to by such terms as timed-release, controlled-release, prolonged-release, sustained-release, or delayed-release drugs, are regarded as new animal drugs within the meaning of section 201(v) of the Federal Food, Drug, and Cosmetic Act.

(b) Timed-release dosage form animal drugs that are introduced into interstate commerce are deemed to be adulterated within the meaning of section 501(a)(5) of the act and subject to regulatory action, unless such animal drug is the subject of an approved new animal drug application, or listed in the index, as required by paragraph (a) of this section.

(c) The fact that the labeling of this kind of drug may claim delayed, prolonged, controlled, or sustained-release of all or only some of the active ingredients does not affect the new animal drug status of such articles. A new animal drug application or index listing is required in any such case.

(d) New animal drug applications for timed-release dosage form animal drugs must contain, among other things, data to demonstrate safety and effectiveness by establishing that the article is manufactured using procedures and controls to ensure release of the total dosage at a safe and effective rate. Data submitted in the new animal drug application must demonstrate that the formulation of the drug and the procedures used in its manufacture will ensure release of the active ingredient(s) of the drug at a safe and effective rate and that these release characteristics will be maintained until the expiration date of the drug. When the drug is intended for use in food-producing animals, data submitted must also demonstrate that, with respect to possible residues of the drug, food derived from treated animals is safe for consumption.

[42 FR 8635, Feb. 11, 1977, as amended at 60 FR 38480, July 27, 1995; 72 FR 69120, Dec. 6, 2007]

§ 500.27 Methylene blue-containing drugs for use in animals.

(a) New information requires a reevaluation of the status of drugs containing methylene blue (tetramethylthionine chloride) for oral use in cats or dogs.

(1)(i) It has been demonstrated that two orally administered urinary antiseptic-antispasmodic preparations that contained methylene blue cause Heinz body hemolytic anemia in cats when used according to label directions. The specific cause of the reaction was determined to be the methylene blue contained in the preparations. The reaction can be severe enough to cause death of treated animals.

(ii) The Heinz body hemolytic anemia reaction to methylene blue has also

been demonstrated in dogs under laboratory conditions. The precise mechanism by which methylene blue produces the characteristic erythrocytic inclusion bodies (Heinz bodies) and associated hemolytic anemia is unclear.

(2) The effectiveness of orally administered methylene blue as a urinary antiseptic is open to question. It appears that following oral administration, methylene blue is poorly and erratically absorbed and also slowly and erratically excreted in the urine. Studies in the dog indicate it is excreted in the urine essentially as leukomethylene blue stabilized in some manner. Methylene blue itself is stepwise demethylated in alkaline solutions (alkaline urine being a frequent consequence of urinary infection) to Azure B, Azure A, and Azure C. The antiseptic efficacy of all of these excretion products is unsubstantiated.

(3) In view of the foregoing, the Commissioner has concluded that animal drugs containing methylene blue for oral use in cats or dogs are neither safe nor generally recognized as effective within the meaning of section 201(v) of the act and are therefore considered new animal drugs. Accordingly, all prior formal and informal opinions expressed by the Food and Drug Administration that such drugs are ''not new drugs'' or ''no longer new drugs'' are hereby revoked.

(b) Animal drugs that contain methylene blue for oral use in cats or dogs and not the subject of an approved new animal drug application (NADA) are deemed to be adulterated under the provisions of section 501(a) (5) and/or (6) and/or misbranded under section 502(a) of the act and subject to regulatory action as of April 10, 1978.

(c) Sponsors of animal drugs that contain methylene blue for oral use in cats or dogs and not the subject of an approved new animal drug application (NADA) may submit an application in conformity with § 514.1 of this chapter. Such applications will be processed in accordance with section 512 of the act. Submission of an NADA will not constitute grounds for continued marketing of this drug substance until such application is approved.

(d) New animal drug applications required by this regulation pursuant to section 512 of the act shall be submitted to the Food and Drug Administration. Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

[43 FR 9803, Mar. 10, 1978; 43 FR 12310, Mar. 24, 1978, as amended at 54 FR 18279, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992; 60 FR 38480, July 27, 1995]

§ 500.29 Gentian violet for use in animal feed.

The Food and Drug Administration has determined that gentian violet is not generally recognized as safe for use in animal feed and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act), unless it is intended for use as a new animal drug, in which case it is subject to section 512 of the act. The Food and Drug Administration has determined that gentian violet is not prior sanctioned for any use in animal feed.

[56 FR 40506, Aug. 15, 1991]

§ 500.30 Gentian violet for animal drug use.

The Food and Drug Administration (FDA) has determined that gentian violet is not generally recognized as safe and effective for any veterinary drug use in food animals and is a new animal drug subject to section 512 of the Federal Food, Drug, and Cosmetic Act. FDA has determined that gentian violet is not exempted from new animal drug status under the ''grandfather'' provisions of the Drug Amendments of 1962 (21 U.S.C. 342).

[56 FR 40507, Aug. 15, 1991]

§ 500.45 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their

use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Investigations by the Food and Drug Administration have revealed that heat exchange fluids for certain pasteurization equipment used in processing animal feed contain PCB's. Although heat exchange fluids in such equipment are considered to be in *closed systems*, leakage has occurred that resulted in direct contamination of animal feed with PCB's and subsequently resulted in the transfer of PCB's to human food produced by animals consuming the contaminated feed. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows consuming the contaminated silage. Since PCB's are toxic chemicals, the PCB contamination of food as a result of these and other incidents represent a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of animal feed.

(b) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing feed in or around an establishment producing animal feed shall not contain PCB's.

(3) On or before Sept. 4, 1973, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any PCB-containing lubricants for equipment or machinery used for handling or processing animal feed.

(iii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such materials could cause animal feed to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement should be used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; (*d*) and its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) For the purpose of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

(d) For the purpose of this section, the term *animal feed* includes all articles used for food or drink for animals other than man.

§ 500.46 Hexachlorophene in animal drugs.

(a) The Commissioner of Food and Drugs has determined that there are no adequate data to establish that animal drugs containing hexachlorophene are safe and effective for any animal use other than in topical products for use on non-food-producing animals as part of a product preservative system at a level not to exceed 0.1 percent; that there is no information on the potential risk to humans from exposure to hexachlorophene by persons who apply animal products containing the drug at levels higher than 0.1 percent; and that there is likewise no information on human exposure to animals on which these animal drugs have been used and no information on possible residues of hexachlorophene in edible products of food-producing animals treated with new animal drugs that contain any quantity of hexachlorophene.

(b) Animal drugs containing hexachlorophene for other than preservative use on non-food-producing animals at levels not exceeding 0.1 percent are considered new animal drugs and shall be the subject of new animal drug applications (NADA's).

(c) Any person currently marketing animal drugs that contain hexachlorophene other than as part of a product preservative system for products used on non-food-producing animals at a level not exceeding 0.1 percent shall submit a new animal drug application, supplement an existing application, or reformulate the product by September 29, 1977. Each application or supplemental application shall include adequate data to establish that the animal drug is safe and effective. If the animal drug is currently subject to an approved new animal drug application, each reformulation shall require an approved supplemental application. The interim marketing of these animal drugs may continue until the application has been approved, until it has been determined that the application is not approvable under the provisions of § 514.111 of this chapter, or until an existing approved application has been withdrawn.

(d) After September 29, 1977, animal drugs that contain hexachlorophene other than for preservative use on non-food-producing animals at a level not exceeding 0.1 percent that are introduced into interstate commerce shall be deemed to be adulterated within the meaning of section 501(a)(5) of the act (21 U.S.C. 351(a)(5)) unless such animal drug is the subject of a new animal drug application submitted pursuant to paragraph (c) of this section. Action to withdraw approval of new animal drug applications will be initiated if supplemental new animal drug applications have not been submitted in accordance with this section.

(e) New animal drug applications submitted for animal drugs containing hexachlorophene for use in or on food-producing animals shall include adequate data to assure that edible products from treated animals are safe for human consumption under the labeled conditions of use.

[42 FR 33725, July 1, 1977; 42 FR 37975, July 26, 1977]

§ 500.50 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food is not generally recognized as safe and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The Food and Drug Administration also has determined that this use of propylene glycol is not prior sanctioned.

[61 FR 19544, May 2, 1996]

Subpart C—Animal Drug Labeling Requirements

§ 500.51 Labeling of animal drugs; misbranding.

(a) Among the representations on the label or labeling of an animal drug which will render the drug misbranded are any broad statements suggesting or implying that the drug is not safe and effective for use when used in accordance with labeling direction, or suggesting or implying that the labeling does not contain adequate warnings or

adequate directions for use. Such statements include, but are not limited to:

(1) Any statement that disclaims liability when the drug is used in accordance with directions for use contained on the label or labeling.

(2) Any statement that disclaims liability when the drug is used under ''abnormal'' or ''unforeseeable'' conditions.

(3) Any statement limiting the warranty for the products to a warranty that the drug in the package contains the ingredients listed on the label.

(b) This regulation is not intended to prohibit any liability disclaimer that purports to limit the amount of damages or that sets forth the legal theory under which damages are to be recovered.

(c) Any person wishing to obtain an evaluation of an animal drug liability disclaimer under this regulation may submit it to Division of Compliance, (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. A supplemental NADA providing appropriately revised labeling shall be submitted for any approved new animal drug the labeling of which is not in compliance with this regulation.

[41 FR 8473, Feb. 27, 1976, as amended at 54 FR 18279, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

§ 500.52 Use of terms such as "tonic", "tone", "toner", or "conditioner" in the labeling of preparations intended for use in or on animals.

(a) The use of terms such as *tonic, tone, toner,* and similar terms in the labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act. The unqualified use of such terms in a product's labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The terms *tonic, tone, toner,* and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product.

(b) The unqualified use of the term *conditioner* and similar terms in the labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the act. The unqualified use of such terms in a product's labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The term *conditioner* and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product. A product labeled as a ''conditioner'' or with a similar term can be either a food or drug depending upon the manner in which the term is qualified in the labeling to reflect the product's intended use.

(c) An article so qualified as to be represented as a drug must be the subject of an approved new animal drug application unless the use of the article under the conditions set forth in its labeling is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs.

§ 500.55 Exemption from certain drug-labeling requirements.

(a) Section 201.105(c) of this chapter provides that in the case of certain drugs for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law, such information may be omitted from the dispensing package. Under this proviso, the Commissioner of Food and Drugs will offer an opinion, upon written request, stating reasonable grounds therefore on a proposal to omit such information from the dispensing package.

(b) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs when intended for those veterinary uses for which they are now generally employed by the veterinary medical profession, should be exempt from the requirements of

§ 201.105(c) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Atropine sulfate. As an injectable for cattle, goats, horses, pigs, and sheep, not in excess of 15 milligrams per dosage unit; as an injectable for cats and dogs, not in excess of 0.6 milligram per dosage unit.

Barbital sodium. For oral use in cats and dogs, not in excess of 300 milligrams per dosage unit.

Epinephrine injection. 1:1,000. For cats, dogs, cattle, goats, horses, pigs, and sheep (except as provided in § 500.65).

Morphine sulfate. As an injectable for dogs, not in excess of 15 milligrams per dosage unit.

Pentobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Phenobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Procaine hydrochloride injection. Containing not in excess of 2 percent procaine hydrochloride, with or without epinephrine up to a concentration of 1:50,000. For use in cats, dogs, cattle, goats, horses, pigs, and sheep.

Thyroid. For oral use in dogs, not in excess of 60 milligrams per dosage unit.

Subpart D—Requirements for Specific Animal Drugs

§ 500.65 Epinephrine injection 1:1,000 in 10-milliliter containers for emergency treatment of anaphylactoid shock in cattle, horses, sheep, and swine.

(a) Anaphylactoid reactions in cattle, horses, sheep, and swine occur occasionally from the injection of antibiotics, bacterins, and vaccines. Adequate directions for use of these antibiotics, bacterins, and vaccines can generally be written for use by the laity and thus are available to livestock producers. Epinephrine injection is effective for the treatment of anaphylactoid reactions in animals and would be of value in saving lives of animals if it were readily available at the time of administration of the causative agents. In connection with this problem the Food and Drug Administration has obtained the views of the Advisory Committee on Veterinary Medicine, and other experts, and has concluded that adequate directions for over-the-counter sale of epinephrine injection 1:1,000 can be prepared.

(b) In view of the above, the Commissioner of Food and Drugs has concluded that it is in the public interest to make epinephrine injection 1:1,000 available for sale without a prescription provided that it is packaged in vials not exceeding 10 milliliters and its label bears, in addition to other required information, the following statements in a prominent and conspicuous manner: ''For emergency use only in treating anaphylactoid shock. Usual Dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously''.

(c) The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibiotic.

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

SOURCE: 52 FR 49586, Dec. 31, 1987, unless otherwise noted.

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs) that no residue of that compound will be found in the food produced from those animals

under conditions of use reasonably certain to be followed in practice. This subpart identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidance documents contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidance documents are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for these guidance documents should be identified with Docket No. 1983D–0288.

(b) If FDA concludes on the basis of the threshold assessment that a sponsor shall conduct carcinogenicity testing on the sponsored compound, FDA will also determine whether and to what extent the sponsor shall conduct carcinogenicity testing on metabolites of the sponsored compound. The bioassays that a sponsor conducts must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.

(c) If FDA concludes on the basis of the threshold assessment or at a later time during the approval process that the data show that the sponsored compound and its metabolites should not be subject to this subpart, FDA will continue to consider the compound for approval under the general safety provisions of the act for risks other than cancer.

(d) This subpart does not apply to essential nutrients.

[52 FR 49586, Dec. 31, 1987, as amended at 59 FR 14365, Mar. 28, 1994; 62 FR 66983, Dec. 23, 1997; 65 FR 56480, Sept. 19, 2000; 67 FR 78174, Dec. 23, 2002; 68 FR 24879, May 9, 2003; 69 FR 17292, Apr. 2, 2004]

§ 500.82 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this subpart.

(b) The following definitions apply to this subpart:

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).

Essential nutrients means compounds that are found in the tissues of untreated, healthy target animals and not produced in sufficient quantity to support the animal's growth, development, function, or reproduction, e.g., vitamins, *essential* minerals, *essential* amino acids, and *essential* fatty acids. These compounds must be supplied from external sources.

FDA means the Food and Drug Administration.

Limit of detection (LOD) means the lowest concentration of analyte that can be confirmed by the approved regulatory method.

Marker residue means the residue selected for assay whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its S_m.

Preslaughter withdrawal period or *milk discard time* means the time after cessation of administration of the sponsored compound at which no residue is detectable in the edible product using the approved regulatory method (i.e., the marker residue is below the LOD).

Regulatory method means the aggregate of all experimental procedures for measuring and confirming the presence of the marker residue of the sponsored compound in the target tissue of the target animal.

R_m means the concentration of the marker residue in the target tissue when the residue of carcinogenic concern is equal to S_m.

Residue means any compound present in edible tissues of the target animal which results from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

Residue of carcinogenic concern means all compounds in the total residue of a demonstrated carcinogen excluding any compounds judged by FDA not to present a carcinogenic risk.

S_m means the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this S_m will correspond to the concentration of residue in a specific edible tissue that corresponds to a

maximum lifetime risk of cancer in the test animals of 1 in 1 million.

S_o means the concentration of a residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this S_o will correspond to the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

Sponsor means the person or organization proposing or holding an approval by FDA for the use of a sponsored compound.

Sponsored compound means any drug or food additive or color additive proposed for use, or used, in food-producing animals or in their feed.

Target animals means the production class of animals in which a sponsored compound is proposed or intended for use.

Target tissue means the edible tissue selected to monitor for residues in the target animals, including, where appropriate, milk or eggs.

Test animals means the species selected for use in the toxicity tests.

Threshold assessment means FDA's review of data and information about a sponsored compound to determine whether chronic bioassays in test animals are necessary to resolve questions concerning the carcinogenicity of the compound.

[52 FR 49586, Dec. 31, 1987, as amended at 67 FR 78174, Dec. 23, 2002; 77 FR 50593, Aug. 22, 2012]

§ 500.84 Conditions for approval of the sponsored compound.

(a) On the basis of the results of the chronic bioassays and other information, FDA will determine whether any of the substances tested are carcinogenic.

(b) If FDA concludes that the results of the bioassays do not establish carcinogenicity, then FDA will not subject the sponsored compound to the remainder of the requirements of this subpart.

(c) For each sponsored compound that FDA decides should be regulated as a carcinogen, FDA will either analyze the data from the bioassays using a statistical extrapolation procedure as outlined in paragraph (c)(1) of this section or evaluate an alternate procedure proposed by the sponsor as provided in § 500.90. In either case, paragraphs (c)(2) and (3) of this section apply.

(1) For each substance tested in separate bioassays, FDA will calculate the concentration of the residue of carcinogenic concern that corresponds to a maximum lifetime risk to the test animal of 1 in 1 million. FDA will designate the lowest value obtained as S_o. Because the total diet is not derived from food-producing animals, FDA will make corrections for food intake. FDA will designate as S_m the concentration of residue in a specific edible tissue corresponding to a maximum lifetime risk of cancer in test animals of 1 in 1 million.

(2) From the appropriate residue chemistry data FDA will calculate the R_m as described in § 500.86(c). The sponsor must provide a regulatory method in accordance with § 500.88(b). FDA will calculate the LOD of the method from data submitted by the sponsor under § 500.88. The LOD must be less than or equal to R_m.

(3) FDA will conclude that the provisions of this subpart are satisfied when no residue of the compound is detectable (that is, the marker residue is below the LOD) using the approved regulatory method under the conditions of use of the sponsored compound, including any required preslaughter withdrawal period or milk discard time.

[52 FR 49586, Dec. 31, 1987, as amended at 67 FR 78174, Dec. 23, 2002; 77 FR 50593, Aug. 22, 2012]

§ 500.86 Marker residue and target tissue.

(a) For each edible tissue, the sponsor shall measure the depletion of the residue of carcinogenic concern until its concentration is at or below S_m.

(b) In one or more edible tissues, the sponsor shall also measure the depletion of one or more potential marker residues until the concentration of the residue of carcinogenic concern is at or below S_m.

(c) From these data, FDA will select a target tissue and a marker residue and designate the concentration of

marker residue (R_m) that the regulatory method must be capable of measuring in the target tissue. FDA will select R_m such that the absence of the marker residue in the target tissue above R_m can be taken as confirmation that the residue of carcinogenic concern does not exceed S_m in each of the edible tissues and, therefore, that the residue of carcinogenic concern in the diet of people does not exceed S_o.

(d) When a compound is to be used in milk- or egg-producing animals, milk or eggs must be the target tissue in addition to the tissue selected to monitor for residues in the edible carcass.

(Approved by the Office of Management and Budget under control number 0910–0228)

§ 500.88 Regulatory method.

(a) The sponsor shall submit for evaluation and validation a regulatory method developed to monitor compliance with FDA's operational definition of no residue.

(b) The regulatory method must be able to confirm the identity of the marker residue in the target tissue at a minimum concentration corresponding to the R_m. FDA will determine the LOD from the submitted analytical method validation data.

(c) FDA will publish in the FEDERAL REGISTER the complete regulatory method for ascertaining the marker residue in the target tissue in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(I), and 721(b)(5)(B) of the act.

(Approved by the Office of Management and Budget under control number 0910–0228)

[52 FR 49586, Dec. 31, 1987, as amended at 67 FR 78174, Dec. 23, 2002]

§ 500.90 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, the requirements of this subpart except those provided under § 500.88. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why the requirements from which a waiver is requested are not reasonably applicable to the compound, and set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the basis for that determination in the regulation approving marketing of the sponsored compound.

(Approved by the Office of Management and Budget under control number 0910–0228)

§ 500.92 Implementation.

(a) This subpart E applies to all new animal drug applications, food additive petitions, and color additive petitions concerning any compound intended for use in food-producing animals (including supplemental applications and amendments to petitions).

(b) This subpart E also applies in the following manner to compounds already approved:

(1) For those compounds that FDA determines may induce cancer when ingested by man or animals, i.e., suspect carcinogens, §§ 500.80(b), 500.82, and 500.90 apply.

(2) For those compounds that FDA determines have been shown to induce cancer when ingested by man or animals, §§ 500.82 through 500.90 apply.

Subpart F—Methods for Detection of Residues of Carcinogenic Compounds Used in Food-Producing Animals

SOURCE: 76 FR 72618, Nov. 25, 2011, unless otherwise noted.

§ 500.1410 N-methyl-2-pyrrolidone.

(a) *Standard for residues.* No residues of *n*-methyl-2-pyrrolidone may be found in the uncooked edible tissues of cattle as determined by a method entitled ''Method of Analysis: *N*-methyl-2-pyrrolidone,'' September 26, 2011, Center for Veterinary Medicine, Food and Drug Administration, which is incorporated by reference with the approval of the Director of the Federal Register under 5 U.S.C. 522(a) and 1 CFR part 51. You may obtain a copy of the method from the Communications Staff (HFV–

12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9120; or go to *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm*. You may inspect a copy at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, (301) 827–6860, between 9 a.m. and 4 p.m., Monday through Friday or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) *Related conditions of use.* See §§ 522.814 and 522.955 of this chapter.

[76 FR 72618, Nov. 25, 2011, as amended at 77 FR 9528, Feb. 17, 2012]

PART 501—ANIMAL FOOD LABELING

Subpart A—General Provisions

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501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
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501.110 Animal feed labeling; collective names for feed ingredients.

AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

SOURCE: 41 FR 38619, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 501.1 Principal display panel of package form animal food.

The term *principal display panel* as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious *principal display panel* such as the top of a triangular or circular package, the area shall consist

of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 501.2 Information panel of package for animal food.

(a) The term *information panel* as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 501.4, 501.5, 501.8 and 501.17 shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than 1/16 inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 501.15 and 501.105(h)(1) and (2).

(1) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 501.1 is less than 10 square inches.

(iii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than 3/64 inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a single *obvious principal display panel* as this term is defined in § 501.1 and has no other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 501.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than 1/32 inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes a full list of ingredients in accordance with regulations in this part.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than 1/32 inch in height.

(d) All information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 501.4, 501.5, 501.8, and 501.17, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to part 10 of this chapter.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 4716, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977]

§ 501.3 Identity labeling of animal food in package form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word *imitation* and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it

meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 502.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation and may, in addition, bear a fanciful name which is not false or misleading, and established pursuant to part 502 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount.

(ii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to part 502 of this chapter.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 14091, Mar. 15, 1977; 54 FR 18279, Apr. 28, 1989]

§ 501.4 Animal food; designation of ingredients.

(a) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this part 501, except those exempted by § 501.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 501.2.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 501.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this subchapter E, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as *skim milk* or *nonfat milk*.

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as *milk*.

(5) Bacterial cultures may be declared by the word *cultured* followed by the name of the substrate, e.g., *made from cultured skim milk or cultured buttermilk*.

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk,

and dried sweetcream buttermilk may be declared as *buttermilk*.

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as *whey*.

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milkfat) may be declared as *cream*.

(9) Butteroil and anhydrous butterfat may be declared as *butterfat*.

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as *eggs*.

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as *egg whites*.

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as *egg yolks*.

(13) A livestock or poultry feed may be declared by a collective name listed in § 501.110 if it is an animal feed within the meaning of section 201(w) of the act and meets the requirements for the use of a collective name as prescribed in § 501.110 for certain feed ingredients.

(14) [Reserved]

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105, 137.200, 137.220, 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is *flour*, *white flour*, *wheat flour*, or *plain flour*; the first ingredient designated in the ingredient list of durum flour is *durum flour*; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is *whole wheat flour*, *graham flour*, or *entire wheat flour*; and the first ingredient designated in the ingredient list of whole durum wheat flour is *whole durum wheat flour*.

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as *water* in the ingredient statement.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 14091, Mar. 15, 1977; 60 FR 38480, July 27, 1995]

§ 501.5 Animal food; name and place of business of manufacturer, packer, or distributor.

(a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as ''Manufactured for _____,'' ''Distributed by _____,'' or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, state, and ZIP Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including invoice).

(e) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or

packed or is to be distributed, unless such statement would be misleading.

§ 501.8 Labeling of animal food with number of servings.

(a) The label of any package of a food which bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, cupfuls, tablespoonfuls, etc.) when such differing term is common to cookery and describes a constant quantity. Such statement may not be misleading in any particular. A statement of the number of units in a package is not in itself a statement of the number of servings.

(b) If there exists a voluntary product standard promulgated pursuant to the procedures found in 15 CFR part 10 by the Department of Commerce, quantitatively defining the meaning of the term *serving* with respect to a particular food, then any label representation as to the number of servings in such packaged food shall correspond with such quantitative definition. (Copies of published standards are available upon request from the National Bureau of Standards, Department of Commerce, Washington, DC 20234.)

§ 501.15 Animal food; prominence of required statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403(e) or (i) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information that is required by section 403(f) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.

§ 501.17 Animal food labeling warning statements.

(a) *Self-pressurized containers.* (1) The label of a food packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

Warning Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase ''except under adult supervision'' may be added at the end of the last sentence in the warning required by paragraph (a)(1) of this section.

(3) In the case of products packaged in glass containers, the word ''break'' may be substituted for the word ''puncture'' in the warning required by paragraph (a)(1) of this section.

(4) The words ''Avoid spraying in eyes'' may be deleted from the warning required by paragraph (a)(1) of this section in the case of a product not expelled as a spray.

(b) *Self-pressurized containers with halocarbon or hydrocarbon propellants.* (1) In addition to the warning required by paragraph (a) of this section, the label of a food packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

Warning Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ozs that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than ½ oz.

(c) *Animal food containing or manufactured with a chlorofluorocarbon or other ozone-depleting substance.* Labeling requirements for animal foods that contain or are manufactured with a chlorofluorocarbon or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 22033, Apr. 29, 1977; 61 FR 20101, May 3, 1996]

§ 501.18 Misbranding of animal food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name comprised in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor

that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

(3) A part of the name required by applicable Federal law or regulation.

(4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

Subpart B—Specific Animal Food Labeling Requirements

§ 501.22 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

(a)(1) The term *artificial flavor* or *artificial flavoring* means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 172.515(b) and 582.60 of this chapter except where these are derived from natural sources.

(2) The term *spice* means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in subpart A of part 582 of this chapter, such as the following:

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as *spice and coloring* unless declared by their common or usual name.

(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in § 172.510 of this chapter.

(4) The term *artificial color* or *artificial coloring* means any *color additive* as defined in § 70.3(f) of this chapter.

(5) The term *chemical preservative* means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k) of the act.

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state ''All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration.'' Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., *strawberry flavor*, *banana flavor*, or *natural strawberry flavor*. In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., *natural and artificial strawberry flavor*. In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., *artificial strawberry flavor*.

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as *spice*, *natural flavor*, or *artificial flavor*, or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of § 501.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name *salt*.

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name *monosodium glutamate*.

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as *artificial flavor* or *artificial smoke flavor*. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, *vignette*, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or

reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word *natural* and shall be immediately followed by the word *flavored* in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as *artificially flavored*.

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words *with other natural flavor* in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) *artificial* or *artificially flavored*, in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food.

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor.

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor used shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of 3 years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized officer, or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable; provided that, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: *Provided,* That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to § 501.100, bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., *preservative, to retard spoilage, a mold inhibitor, to help protect flavor* or *to promote color retention.*

(k) The label of an animal food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section.

(1) A color additive or the lake of a color additive subject to certification under section 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the ''FD&C'' prefix or the term ''No.'' in the declaration, but the term ''Lake'' shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its

common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added'' (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as ''Colored with _____'' or ''_____ color,'' the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 14091, Mar. 15, 1977; 42 FR 15675, Mar. 22, 1977; 76 FR 71254, Nov. 17, 2011]

Subparts C–E [Reserved]

Subpart F—Exemptions From Animal Food Labeling Requirements

§ 501.100 Animal food; exemptions from labeling.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(i)(2) of the act.

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(*c*) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing

the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) [Reserved]

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j) and (k) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(e) Conditions affecting expiration of exemptions.

(1) An exemption of a shipment or other delivery of a food under paragraph (d)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d)(2) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d)(2) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement as required by such paragraph.

(f) [Reserved]

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and

the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

§ 501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition pursuant to part 10 of this chapter may issue a proposal to amend § 501.4 to specify the manner in which an ingredient(s) shall be declared, i.e., by specific or class name, or § 501.100 to exempt an ingredient(s) from the requirements for label declaration.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 15675, Mar. 22, 1977]

§ 501.105 Declaration of net quantity of contents when exempt.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

(b)(1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:

(i) In the case of frozen food that is sold and consumed in a frozen state, express the volume at the frozen temperature.

(ii) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 40 °F (4 °C).

(iii) In the case of other foods, express the volume at 68 °F (20 °C).

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

(c) When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information.

(d) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(e) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(f) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a

space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as *jumbo quart* and *full gallon*) that tends to exaggerate the amount of the food in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part.

(g) The declaration shall accurately reveal the quantity of food in the package exclusive of wrappers and other material packed therewith; provided that in the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(h) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide).

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(i) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than 1/16 inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than 1/8 inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than 3/16 inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than 1/4 inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than 1/2 inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (i) (1) through (4) of this section shall be increased by 1/16 of an inch.

(j) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraphs (m) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples in paragraphs (m) (3) and (4) of this section).

(2) If the net quantity of contents declaration appears on a random package, that is a package which is one of a lot, shipment, or delivery of packages of the same consumer commodity with varying weights and with no fixed weight pattern, it may, when the net weight exceeds 1 pound, be expressed in terms of pounds and decimal fractions of the pound carried out to not more than two decimal places. When the net weight does not exceed 1 pound, the declaration on the random package may be in decimal fractions of the pound in lieu of ounces (see example in paragraph (m)(5) of this section).

(3) The declaration may appear in more than one line. The term *net weight* shall be used when stating the net quantity of contents in terms of weight. Use of the terms *net* or *net contents* in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, *Net wt. 6 oz.* or *6 oz. net wt.* and *6 fl. oz.* or *net contents 6 fl. oz.*

(k) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of fluid measure, it shall be expressed in the largest whole unit (gallons followed by common or decimal fraction of a gallon or by the next smaller whole unit or units (quarts, or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see paragraph (m)(6) of this section).

(l) [Reserved]

(m) *Examples:* (1) A declaration of 1½ pounds weight shall be expressed as *Net Wt. 24 oz. (1 lb. 8 oz.)*, *Net Wt. 24 oz. (1½ lb.)*, or *Net Wt. 24 oz. (1.5 lb.)*.

(2) A declaration of ¾ pound avoirdupois weight shall be expressed as *Net Wt. 12 oz.*

(3) A declaration of 1 quart liquid measure shall be expressed as *Net 32 fl. oz. (1 qt.)*.

(4) A declaration of 1¾ quarts liquid measure shall be expressed as *Net contents 56 fluid ounces (1 quart 1½ pints)* or as *Net 56 fluid oz. (1 qt. 1 pt. 8 oz.)*, but not in terms of quart and ounce such as *Net 56 fluid oz. (1 quart 24 ounces)*.

(5) On a random package, declaration of ¾ pound avoirdupois may be expressed as *Net Wt. .75 lb*.

(6) A declaration of 2½ gallons liquid measure shall be expressed as *Net contents 2½ gallons*, *Net contents 2.5 gallons*, or *Net contents 2 gallons 2 quarts* and not as *2 gallons 4 pints*.

(n) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight wt.	pint pt.
ounce oz.	quart qt.
pound lb.	fluid fl.
gallon gal.	

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents; provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the food contained in the package; for example, *jumbo quart* and *full gallon*. Dual or combination declarations of net quantity of contents as provided for in paragraphs (a), (c), and (j) of this section (for example, a combination of net weight plus numerical count, net contents plus dilution directions of a concentrate, etc.) are not regarded as supplemental net quantity statements and may be located on the principal display panel.

(p) A separate statement of the net quantity of contents in terms of the metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated

quantity of contents shall not be unreasonably large.

(r) [Reserved]

(s) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (j)(1) of this section. A multiunit retail package may thus be properly labeled: *6–16 oz. bottles—(96 fl. oz.)* or *3–16 oz. cans—(net wt. 48 oz)*. For the purposes of this section, *multiunit retail package* means a package containing two or more individually packaged units of the identical commodity and in the same quantity, intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units nor prevent examination of the labeling on each of the individual units are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (f) and (i) of this section.

(t) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of this chapter (except the requirement that food falling below the applicable standard of fill of container shall bear the general statement of substandard fill specified in § 564.14(b) of this chapter), the mislabeled food product, including any food product that fails to bear the general statement of substandard fill specified in § 564.14(b) of this chapter, may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments: *Provided*, That:

(1) The purchaser shall sign a statement at the time of sale stating that he is aware that the product is mislabeled to include acknowledgement of the nature and extent of the mislabeling, e.g., ''Actual net weight may be as low as ____% below labeled quantity'' and that any subsequent distribution by him of said product except for his own institutional use is unlawful. This statement shall be kept on file at the principal place of business of the manufacturer or processor for 2 years subsequent to the date of shipment of the product and shall be available to the Food and Drug Administration upon request.

(2) The product shall be labeled on the outside of its shipping container with the statement(s):

(i) When the variation concerns net weight and/or drained weight of volume—''Product Mislabeled. Actual net weight (drained weight or volume where appropriate) may be as low as ____% below labeled quantity. This Product Not for Retail Distribution,'' the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and

(ii) When the variation is in regard to a fill of container standard—''Product Mislabeled. Actual fill may be as low as ____% below standard of fill. This Product Not for Retail Distribution.''

(3) The statements required by paragraphs (t)(2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

[41 FR 38619, Sept. 10, 1976, as amended at 54 FR 18279, Apr. 28, 1989]

§ 501.110 Animal feed labeling; collective names for feed ingredients.

(a) An animal feed shall be exempt from the requirements of section 403(i)(2) of the act with respect to its

label bearing the common or usual names of the animal feed ingredients listed in paragraph (b) of this section under the following prescribed conditions:

(1) The animal feed is intended solely for livestock and poultry.

(2) The label of the animal feed bears the collective name(s) prescribed in paragraph (b) of this section in lieu of the corresponding common or usual names of the individual feed ingredients contained therein.

(3) The label of the animal feed otherwise conforms to the requirements of section 403(i)(2) of the act.

(4) The ingredients of any feed listed in paragraph (b) of this section neither contain nor are food additives as defined in section 201(s) of the act unless provided for by and in conformity with applicable regulations established pursuant to section 409 of the act.

(b) Each collective name referred to in this paragraph may be used for the purpose of labeling where one or more of the ingredients listed for that collective name are present. The animal feed ingredients listed under each of the collective names are the products defined by the Association of American Feed Control Officials. The collective names are as follows:

(1) *Animal protein products* include one or more of the following: Animal products, marine products, and milk products.

(2) *Forage products* include one or more of the following: Alfalfa meals, entire plant meals, hays, and stem meals.

(3) *Grain products* include one or more of the following: Barley, grain sorghums, maize (corn), oats, rice, rye, and wheat.

(4) *Plant protein products* include one or more of the following: Algae meals, coconut meals (copra), cottonseed meals, guar meal, linseed meals, peanut meals, safflower meals, soybean meals, sunflower meals, and yeasts.

(5) *Processed grain byproducts* include one or more of the following: Brans, brewers dried grains, distillers grains, distillers solubles, flours, germ meals, gluten feeds, gluten meals, grits, groats, hominy feeds, malt sprouts, middlings, pearled, polishings, shorts, and wheat mill run.

(6) *Roughage products* include one or more of the following: Cobs, hulls, husks, pulps, and straws.

PART 502—COMMON OR USUAL NAMES FOR NONSTANDARDIZED ANIMAL FOODS

Sec.
502.5 General principles.
502.19 Petitions.

AUTHORITY: 21 U.S.C. 321, 343, 371.

§ 502.5 General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words ''containing (or contains) ____ percent (or %) ____'' or ''____ percent (or %) ____'' with the first blank filled in with the percentage expressed as a whole number not greater

than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word ''containing'' (or ''contains''), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words ''___ percent (or %) ___''shall appear following or directly below the word ''containing'' (or ''contains''), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word ''containing'' (or ''contains'') is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words ''containing (or contains) _____'' or ''containing (or contains) _____'' or ''no _____'' or ''does not contain _____'', with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c) (1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraph (b)(2) (i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in this part, in a standard of identity, or in other regulations in this chapter.

[41 FR 38627, Sept. 10, 1976. Redesignated at 42 FR 14091, Mar. 15, 1977]

§ 502.19 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to issue, amend, or revoke, under this part, a regulation prescribing a common or usual name for a food, pursuant to part 10 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to part 10 of this chapter.

[42 FR 4716, Jan. 25, 1977; 42 FR 10980, Feb. 25, 1977. Redesignated at 42 FR 14091, Mar. 15, 1977, and amended at 42 FR 15675, Mar. 22, 1977; 42 FR 24254, May 13, 1977]

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

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AUTHORITY: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

SOURCE: 80 FR 56337, Sept. 17, 2015, unless otherwise noted.

Subpart A—General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether an animal food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Except as provided by § 507.12, if a facility is required to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term ''food'' in part 117 includes animal food.

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Calendar day means every day shown on the calendar.

Correction means an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce).

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm means farm as defined in §1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the animal food or onto surfaces that contact the animal food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes utensils and animal food-contact surfaces of equipment.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of animal food and also includes activities performed incidental to storage of an animal food (*e.g.*, activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating

raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

Lot means the animal food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term ''undesirable microorganisms'' includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (*e.g.*, activities performed for the safe or effective packing or repacking of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public (human or animal) health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 507.5(d).

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving facility means a facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated animal food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Supplier means the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving

facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged animal food means packaged animal food that is not exposed to the environment.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale).

Water activity (a_w) means a measure of the free moisture in an animal food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Written procedures for receiving raw materials and other ingredients means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 507.3, *i.e.*, have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.

(c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.

(d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

§ 507.5 Exemptions.

(a) This part does not apply to establishments, including ''farms'' (as defined in § 1.227 of this chapter), that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Subparts C and E of this part do not apply with respect to activities that are subject to § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at an animal food facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to those activities.

(2) The exemption in paragraph (b)(1) of this section is applicable only with respect to those microbiological hazards regulated under part 113 of this chapter.

(c) Subparts C and E of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, subparts C and E of this part do not apply to a qualified facility. Qualified facilities are subject to the requirements in § 507.7.

(e) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm packing or holding of processed animal food, and § 507.7 does not apply to on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations—*i.e.*, packing (or repacking) (including weighing or conveying incidental to packing or repacking); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Roughage products (*e.g.*, alfalfa meal, entire plant meal, stem meal, pomace, and pulp);

(2) Plant protein meals (*e.g.*, algae, coconut (copra), guar, and peanut);

(3) Grain by-products and processed grain products (*e.g.*, bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal);

(4) Oilseed products (*e.g.*, oil and meal of safflower, soybean, or sunflower);

(5) Molasses (*e.g.*, processed sugar cane, sugar beets, and citrus);

(6) Animal protein meals (*e.g.*, blood, feather, meat, meat and bone, and marine (*e.g.*, crab, fish, shrimp));

(7) Milk products (*e.g.*, casein, cheese rind, and lactalbumin);

(8) Animal tissue-derived products (*e.g.*, fat);

(9) Vitamins, minerals, and concentrates;

(10) Processing aids (*e.g.*, enzymes, preservatives, and stabilizers); and

(11) Any other processed animal food that does not require time/temperature control for safety.

(f) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following low-risk manufacturing/processing activity/animal food combinations:

(1) Chopping or shredding hay;

(2) Cracking, crimping, flaking, pearling, peeling, shelling, or wafering—grain (*e.g.*, barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (*e.g.*, beans, canola, cottonseed, linseed, soybeans, and sunflowers);

(3) Crushing, dry rolling, grinding, milling, pulverizing—grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled material, culled fruits and vegetables, roughage (*e.g.*, cobs, hulls, husks, and straws), or roughage products;

(4) Ensiling (including chopping, shredding, mixing, storing, or fermenting), that is, making silage or haylage from forage (*e.g.*, sorghum (milo), corn (maize), alfalfa, and grass),

grain, culled fruits and vegetables, or roughage;

(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;

(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and

(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

(g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to any of the following:

(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and

(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) *Electronic submission.* To submit electronically, go to *http://www.fda.gov/furls* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from *http://www.fda.gov/pcafrule*;

(B) Write to the U.S. Food and Drug Administration (HFS–681), 5001 Campus Dr., College Park, MD 20740; or

(C) Request a copy of this form by phone at 1–800–216–7331 or 301–575–0156.

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS–681), 5001 Campus Dr., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By *December 16, 2019* for a facility that begins manufacturing, processing, packing, or holding animal food before *September 17, 2019;*

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after *September 17, 2019;* or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from ''not a qualified facility'' to ''qualified facility'' based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from ''qualified facility'' to ''not a qualified facility'' based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from ''qualified facility'' to ''not a qualified facility,'' the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016; 81 FR 49897, July 29, 2016]

§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if:

(1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or

(ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with § 117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food facility does not further manufacture or process the by-products intended for use as animal food.

(b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with §§ 507.28 and 117.95 of this chapter.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.

(b) The methods for conforming to hygienic practices and maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.17 Plant and grounds.

(a) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

(b) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must:

(1) Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (*e.g.*, steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;

(4) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned; and

(5) Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.

(c) The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including:

(1) Using protective coverings where necessary and appropriate;

(2) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and

(3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

§ 507.19 Sanitation.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and

(2) In wet processing of animal food, when cleaning and sanitizing are necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

(d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic materials described in paragraph (d)(1) of this section (*e.g.*, cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and

(3) Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.

(e) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(f) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.20 Water supply and plumbing.

(a) The following apply to the water supply:

(1) Water must be adequate for the operations and must be derived from an adequate source;

(2) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing,

processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee handwashing facilities;

(3) Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and

(4) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

(c) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide handwashing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food:

(1) All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

(b) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.

(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.

(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.

§ 507.25 Plant operations.

(a) Management of the establishment must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Animal food, including raw materials, other ingredients, or rework is accurately identified;

(3) Animal food-packaging materials are safe and suitable;

(4) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(5) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;

(6) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;

(7) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(8) All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.

(b) Raw materials and other ingredients:

(1) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize contamination; and

(iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, *e.g.*, appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and

(3) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(c) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:

(1) Animal food must be maintained under conditions, *e.g.*, appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(2) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (*e.g.*, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a_w) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;

(6) Animal food that relies principally on the control of water activity

(a_w) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe a_w level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

§ 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and

(2) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.

(b) The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.

(d) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(e) Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.34(b);

(3) The written supply-chain program as required by subpart E of this part;

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

(2) The hazard analysis must be written regardless of its outcome.

(b) The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and other ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.34 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed,

or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart E of this part;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls. These include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of animal food could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented; and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard (except as provided in paragraph (c) of this section);

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements;

(4) You rely on your customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that your customer:

(A) Will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is ''not processed to control [identified hazard]''; and

(B) Will only sell to another entity that agrees, in writing, it will:

(*1*) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part), except as provided in paragraph (d) of this section, or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part); or

(*2*) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 507.37, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food you distribute and you document the implementation of that system.

(b) You must document any circumstance specified in paragraph (a) of this section that applies to you, including:

(1) A determination in accordance with paragraph (a) of this section that the type of animal food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the animal food you distribute.

(c) For the written assurance required by paragraph (a)(2)(ii) of this section, if your customer has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, your customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance of procedures established and followed that will significantly minimize or prevent the identified hazard.

(d) For the written assurance required by paragraph (a)(4)(ii)(B) of this section, if the entity in the distribution chain subsequent to your customer is subject to subpart C of this part and has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance that the identified hazard will be significantly minimized or prevented.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4).

A facility that provides a written assurance under § 507.36(a)(2), (3), or (4)

must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 507.38 Recall plan.

(a) For animal food with a hazard requiring a preventive control you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;

(3) Conduct effectiveness checks to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food, *e.g.*, through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier nonconformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.40 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system you must:

(a) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(b) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c)(1) You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i);

(2)(i) Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

§ 507.42 Corrective actions and corrections.

(a) As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented,

including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 507.34 are

adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan; or

(B) When necessary to demonstrate the control measures can be implemented as designed:

(*1*) Within 90 calendar days after production of the applicable animal food first begins; or

(*2*) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so.

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.

(c) You do not need to validate:

(1) The sanitation controls in § 507.34(c)(2);

(2) The recall plan in § 507.38;

(3) The supply-chain program in subpart E of this part; and

(4) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring and verification instruments (or checking them for accuracy);

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

(ii) Records of calibration, testing (*e.g.*, product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1)(ii).

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the animal food;

(3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable animal food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

(a) If a facility that is solely engaged in the storage of unexposed packaged animal food stores any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged animal food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]

§ 507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;

(4) Determination that validation is not required (§ 507.47(c)(4));

(5) Review of records (§ 507.49(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;

(7) Reanalysis of the food safety plan (§ 507.50(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds

the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of a Qualified Facility Exemption

§ 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 507.62 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and E of this part on the date that is 120 calendar days after the date of receipt of the order or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85;

(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(i) The name and the title of the FDA representative who approved the order.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]

§ 507.67 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

(a) If you receive an order under § 507.65 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the requirements in § 507.7.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), you may include a written request for an informal hearing as provided in § 507.71.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3718, Jan. 22, 2016]

§ 507.71 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing

participant under paragraph (c)(4) of this section are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3), and (a)(5), of this chapter, and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Residing officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA District Director.

[82 FR 14147, Mar. 17, 2017]

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 507.85 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for

Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 507.60(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

Subpart E—Supply-Chain Program

§ 507.105 Requirement to establish and implement a supply-chain program.

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to animal food that is supplied for research or evaluation use, provided that such animal food:

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement ''Animal food for research or evaluation use'';

(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of; and

(iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.*, when a non-supplier applies controls to certain produce (*i.e.*, produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

EFFECTIVE DATE NOTE: At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (a)(2) in § 507.105, which is not yet effective.

§ 507.110 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 507.120;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125;

(3) Conducting supplier verification activities as required by §§ 507.130 and 507.135;

(4) Documenting supplier verification activities as required by § 507.175; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 507.175, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 507.175.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of animal food and other FDA compliance actions related to animal food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 507.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier

is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

§ 507.115 Responsibilities of the receiving facility.

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 507.110(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135.

§ 507.120 Using approved suppliers.

(a) The receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b)(1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

§ 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d).

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.

(a) Except as provided by paragraphs (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 507.110(b), as determined under § 507.110(d), must be

conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals:

(i) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(c) If a supplier is a qualified facility as defined by § 507.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 507.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign counties.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or,

when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interest that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity.

§ 507.135 Onsite audit.

(a) An onsite audit of a supplier must be performed by a qualified auditor.

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (*e.g.*, Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

EFFECTIVE DATE NOTE: At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (d) in § 507.135, which is not yet effective.

§ 507.175 Records documenting the supply-chain program.

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 507.49(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

EFFECTIVE DATE NOTE: At 80 FR 56337, Sept. 17, 2015, part 507 was added, effective Nov. 16, 2015, with the exception of paragraph (c)(2) in § 507.175, which is not yet effective.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 507.200 Records subject to the requirements of this subpart.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart.

(b) Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

(d) The requirements of § 507.206 apply only to the written food safety plan.

(e) The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to the records required by § 507.7.

§ 507.202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) Information adequate to identify the plant or facility (*e.g.*, the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(c) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6)

of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 507.206 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification.

§ 507.208 Requirements for record retention.

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.*, because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the written food safety plan (§ 507.45(b))).

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 507.212 Use of existing records.

(a) Existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 507.215 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) The applicable assurance under:

(i) § 507.36(a)(2);

(ii) § 507.36(a)(3);

(iii) § 507.36(a)(4);

(iv) § 507.130(c)(2);

(v) § 507.130(d)(2); or

(vi) § 507.130(e)(2).

(b) A written assurance required under § 507.36(a)(2), (3) or (4) must include:

(1) Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

Sec.
509.3 Definitions and interpretations.
509.4 Establishment of tolerances, regulatory limits, and action levels.
509.5 Petitions.
509.6 Added poisonous or deleterious substances.
509.7 Unavoidability.
509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

AUTHORITY: 21 U.S.C. 336, 342, 346, 346a, 348, 371.

SOURCE: 42 FR 52821, Sept. 30, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A *naturally occurring poisonous or deleterious substance* is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An *added poisonous or deleterious substance* is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) *Food* includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of § 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of § 509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of § 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Division of Dockets Management before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These

regulations do not constitute a complete list of such foods.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

§ 509.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.30 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

[42 FR 52821, Sept. 30, 1977, as amended at 54 FR 18280, Apr. 28, 1989]

§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be

withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

(e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

§ 509.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances, regulatory limits, and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances, regulatory limits, or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term *polychlorinated biphenyls (PCB's)* is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any

components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled ''Analytical Methodology for Polychlorinated Biphenyls, February 1973'' for determining compliance with the tolerances established in this section is available from the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 510—NEW ANIMAL DRUGS

Subpart A—General Provisions

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510.4 Biologics; products subject to license control.
510.7 Consignees of new animal drugs for use in the manufacture of animal feed.
510.95 [Reserved]

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510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.
510.110 Antibiotics used in food-producing animals.
510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

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Subpart D—Records and Reports

510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.
510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Subpart E—Requirements for Specific New Animal Drugs

510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.
510.440 Injectable iron preparations.
510.455 Requirements for free-choice medicated feeds.

Subpart F [Reserved]

Subpart G—Sponsors of Approved Applications

510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 321–392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) *Person* means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed,

recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research* and *laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) *Sponsor* means the person requesting designation for a minor-use or minor-species drug as defined in part 516 of this chapter, who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the person responsible for an investigation of a new animal drug. In this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs. Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts, the sponsor is responsible for compliance with applicable provisions of the act and regulations.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989; 64 FR 69190, Dec. 10, 1999; 72 FR 41017, July 26, 2007]

§510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Holds a license issued under § 515.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 515.10 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

[40 FR 13807, Mar. 27, 1975, as amended at 64 FR 63203, Nov. 19, 1999]

§ 510.95 [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 526 of this chapter provides for new animal drugs intended for intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(c)(ii) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the following statement: ''Warning: Milk that has been taken from animals during treatment and for ____ hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry violative residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

[40 FR 13807, Mar. 27, 1975, as amended at 63 FR 32980, June 17, 1998; 64 FR 51241, Sept. 22, 1999]

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement ''Warning: Not for use in animals producing milk, since this use will result in contamination of the milk'' or the statement ''Warning: Milk that has been taken from animals during treatment and for ____hours after the latest treatment must not be used for food'', the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt

the drug from bearing either of the above warning statements.

[63 FR 32980, June 17, 1998]

§510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, §510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the date of publication of §510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Pub. L. 85–929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those products for which there are inadequate residue data, actions will be initiated to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations, including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 64 FR 403, Jan. 5, 1999]

§510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Nonmedical Uses of Antibiotics, was

formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been accumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations the data shall be submitted within 60 days of such publication. Data demonstrating the absence in milk of residues of intramammary infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 46 FR 8460, Jan. 27, 1981; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

Subpart C [Reserved]

Subpart D—Records and Reports

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) or index listing(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application or request for determination of eligibility for indexing.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from

the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or in support of the index listing or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or in support of the index listing or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 72 FR 69121, Dec. 6, 2007]

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved or index listed labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

[64 FR 63203, Nov. 19, 1999, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart E—Requirements for Specific New Animal Drugs

§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed?* For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements (''lick tank'' supplements) containing one or more new animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations in part 225 of this chapter for medicated feeds.

(b) *What is required for new animal drugs intended for use in free-choice feed?* Any new animal drug intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)) or listed in the index under section 572 of the act (21 U.S.C. 360ccc–1). Such approvals under section 512 of the act must be:

(1) An original new animal drug application (NADA),

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(c) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in free-choice feed?* An approval under section 512 of the act for a Type A medicated article intended for use in free-choice feed must contain the following information:

(1) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(2) Data, or reference to data in an MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted?* The data must be submitted as follows:

(1) Directly in the NADA, by a sponsor; and/or

(2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed?* The approval of a new animal drug intended for use in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication, or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-choice medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All free-choice medicated feeds that contain a Category II drug, and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

[69 FR 30197, May 27, 2004, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart F [Reserved]

Subpart G—Sponsors of Approved Applications

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527	057699
Accord Healthcare, Inc., 1009 Slater Rd., suite 210–B, Durham, NC 27703	016729
ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115	012286
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045	059399
Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712	064146
Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510	069334
American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140	065531
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043	086073
AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754	086053
Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211	086026
Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218	076175
Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009	051072
Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France	086009
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756	067188
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	000859
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	062250
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002	000010
Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767	068330
Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France	013744
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
Cooperative Research Farms, Box 69, Charlotteville, NY 12036	051267
Cronus Pharma LLC, 2 Tower Center Blvd., suite 1101, East Brunswick, NJ 08816	069043
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	043264
ECO LLC, 344 Nassau St., Princeton, NJ 08540	066916
Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	058198
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928	017135
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	058829
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463
G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201	010515
GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702	042976
Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661	012164
Happy Jack, Inc., Snow Hill, NC 28580	023851
Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964	063075
Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525	063604
Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118	059115
HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652	042791
Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	016592
IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409	065274
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	000061
Ivaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155	086064
JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069	051233
Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia	049480
Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509	051031
LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702	086047
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	061690
Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967	010797
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861	054925
Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258	099207
Merial, Inc., 3239 Satellite Blvd., bldg. 500, Duluth, GA 30096–4640	050604
Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186	015914
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103	063286
Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120	049968
Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511	059051
Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	055529
Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden	052818
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
OXIS International, Inc., 6040 N. Cutter Circle, suite 317, Portland, OR 97217–3935	024991
Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia	068504
Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	055246
Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970	050057
Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069	042552

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

Firm name and address	Drug labeler code
Pharmaq AS, Skogmo Industriomrade, N–7863 Overhalla, Norway	015331
Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	066104
Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017	066794
Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, India	065085
Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil	060728
Purina Animal Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126–2910	017800
Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	026637
Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349	076475
Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	068287
Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500	067949
RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620	058670
Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138	021091
Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	058005
Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151	017153
Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503	054628
Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752	037990
Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062	027053
Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248	050378
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532	051672
Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503	052923
Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204	051330
VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524	086072
Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5	059320
Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	017030
Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	051311
Walco International, Inc., 15 West Putnam, Porterville, CA 93257	049185
Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.	000402
Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550	053923
Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	054771

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
000010	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.
000061	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
000402	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
000859	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.
010515	G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201.
010797	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.
012164	Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661.
012286	ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115.
012578	Janssen Pharmaceutica NV, Turnhoutseweg 30, B–2340 Beerse, Belgium.
013744	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.
015331	Pharmaq AS, Skogmo Industriomrade, N–7863 Overhalla, Norway.
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
015914	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186.
016592	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.
016729	Accord Healthcare, Inc., 1009 Slater Rd., suite 210–B, Durham, NC 27703.
017030	Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.
017135	Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928.
017153	Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151.
017762	Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112.
017800	Purina Animal Nutrition, 1080 County Road F West, Shoreview, MN 55126–2910.
021091	Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138.
023851	Happy Jack, Inc., Snow Hill, NC 28580.
024991	OXIS International, Inc., 6040 N. Cutter Circle, suite 317 Portland, OR 97217–3935.
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747.
026637	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101.
027053	Superior Equine Pharmaceuticals, Inc., Pleasant Grove, UT 84062.
037990	Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.
042552	Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069.
042791	HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652.
042976	GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702.
043264	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.
049185	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.

(2) NUMERICAL LISTING OF SPONSORS—Continued

Drug labeler code	Firm name and address
049480	Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia.
049968	Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120.
050057	Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970.
050378	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248.
050604	Merial, Inc., 3239 Satellite Blvd., bldg. 500, Duluth, GA 30096–4640.
051031	Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509.
051072	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009.
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.
051233	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069.
051267	Cooperative Research Farms, Box 69, Charlotteville, NY 12036.
051311	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137.
051330	Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204.
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland.
052818	Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden.
052923	Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503.
053923	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550.
054628	Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503.
054771	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
054925	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.
055246	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.
055529	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503.
057699	A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527.
058005	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.
058198	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.
058670	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.
058829	First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123.
059051	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511.
059115	Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118.
059320	Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5.
059399	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045.
060728	Planalquimica Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Alto, Brazil.
060865	Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801.
061623	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.
061651	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.
061690	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.
062250	Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777.
062794	Mylan Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478.
063075	Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964.
063286	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
063604	Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.
064146	Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712.
065085	Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013, India.
065274	IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409.
065531	American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140.
066104	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.
066794	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017.
066916	ECO LLC, 344 Nassau St., Princeton, NJ 08540.
067188	B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.
067949	Ridley U.S. Holdings, Inc., 424 N. Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500.
068287	Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500.
068330	Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767.
068504	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.
069043	Cronus Pharma LLC, 2 Tower Center Blvd., suite 1101, East Brunswick, NJ 08816.
069254	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.
069334	Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510.
076175	Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218.
076475	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349.
086009	Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France.
086026	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.
086047	LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702.
086053	AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754.
086064	Ivaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155.
086072	VetDC, Inc., 320 E Vine Dr., suite 218, Fort Collins, CO 80524.
086073	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.
099207	Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258.

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

2. At 77 FR 46613, Aug. 6, 2012, §510.600 was amended by removing the entry for ''012758'' in the table in paragraph (c)(2); however, the amendment could not be incorporated because ''012758'' didn't exist.

EFFECTIVE DATE NOTE: At 83 FR 13635, Mar. 30, 2018, §510.600 was amended in the table in paragraph (c)(1), by removing the entry for ''Watson Laboratories, Inc.''; and in the table in paragraph (c)(2), by removing the entry for ''000402'', effective Apr. 9, 2018.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

Sec.

511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.
511.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

§511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new animal drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new animal drug or drugs, which discs are intended for use in determining susceptibility of microorganisms to the new animal drug or drugs.

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt from section 512(a) and (m) of the act if all the following conditions are met:

(1) The label shall bear the statements:

Caution. Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the caution statements required by paragraph (a) or (b) of this section, the statements may be included on the carton label and other labeling on or within the package from which the new animal drug is to be dispensed.

(2) The person or firm distributing or causing the distribution of the new animal drug or animal feed containing a

new animal drug shall use due diligence to assure that the new animal drug or animal feed containing a new animal drug will actually be used for tests in animals and is not used in humans.

(3) The person who introduced such shipment or who delivered the new animal drug or animal feed containing a new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the investigator to whom the new animal drug or animal feed containing a new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, such records shall be made available for inspection and copying.

(4) Prior to shipment of the new animal drug for clinical tests in animals, the sponsor of the investigation shall submit in triplicate to FDA a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' including a signed statement containing the following information:

(i) The identity of the new animal drug.

(ii) All labeling and other pertinent information to be supplied to the investigators. When such pertinent information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(iii) The name and address of each clinical investigator.

(iv) The approximate number of animals to be treated (or if not available, the amount of new animal drug to be shipped).

(v) If the new animal drug is given to food-producing animals, the statement shall contain the following additional information:

(*a*) A commitment that the edible products from such animals shall not be used for food without prior authorization in accordance with the provisions prescribed in this section.

(*b*) Approximate dates of the beginning and end of the experiment or series of experiments.

(*c*) The maximum daily dose(s) to be administered to a given species, the size of animal, maximum duration of administration, method(s) of administration, and proposed withdrawal time, if any.

(vi) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(5) Authorization for use of edible products derived from a treated food-producing animal may be granted under the provisions of this section and when the following specified conditions are met, except that in the case of an animal administered any unlicensed experimental veterinary biological product regulated under the viruses, serums, toxins statute (21 U.S.C., chapter V, sec. 151 *et seq.*) the product shall be exempt from the requirements of this section when U.S. Department of Agriculture approval has been obtained as provided in 9 CFR 103.2. Conditional authorization may be granted in advance of identification of the name(s) and address(es) of the clinical investigator(s) as required by paragraph (b)(4)(iii) of this section. Information required for authorization shall include, in addition to all other requirements of this section, the following:

(i) Data to show that consumption of food derived from animals treated at the maximum levels with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(4)(v)(*c*) of this section, will not be inconsistent with the public health; or

(ii) Data to show that food derived from animals treated at the maximum

levels and with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(4)(v)(*c*) of this section, does not contain drug residues or metabolites.

(iii) The name and location of the packing plant where the animals will be processed, except that this requirement may be waived, on request, by the terms of the authorization.

Authorizations granted under this paragraph do not exempt investigational animals and their products from compliance with other applicable inspection requirements. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before FDA pursuant to part 16 of this chapter.

(6) On written request of FDA, the sponsor shall submit any additional information reported to or otherwise received by him with respect to the investigation deemed necessary to facilitate a determination whether there are grounds in the interest of public health for terminating the exemption.

(7) The sponsor shall assure himself that the new animal drug is shipped only to investigators who:

(i) Are qualified by scientific training and/experience to evaluate the safety and/or effectiveness of the new animal drug.

(ii) Shall maintain complete records of the investigations, including complete records of the receipt and disposition of each shipment or delivery of the new animal drug under investigation. Copies of all records of the investigation shall be retained by the investigator for 2 years after the termination of the investigation or approval of a new animal drug application.

(iii) Shall furnish adequate and timely reports of the investigation to the sponsor.

(8) The sponsor:

(i) Shall retain all reports received from investigators for 2 years after the termination of the investigation or approval of a new animal drug application and make such reports available to a duly authorized employee of the Department for inspection at all reasonable times.

(ii) Shall provide for current monitoring of the investigation by a person qualified by scientific training and experience to evaluate information obtained from the investigation, and shall promptly investigate and report to FDA and to all investigators any findings associated with use of the new animal drug that may suggest significant hazards pertinent to the safety of the new animal drug.

(iii) Shall not unduly prolong distribution of the new animal drug for investigational use.

(iv) Shall not, nor shall any person acting for or on behalf of the sponsor, represent that the new animal drug is safe or effective for the purposes for which it is under investigation. This requirement is not intended to restrict the full exchange of scientific information.

(v) Shall not commercially distribute nor test-market the new animal drug until a new animal drug application is approved pursuant to section 512(c) of the act.

(9) If the shipment or other delivery of the new animal drug is imported or offered for importation into the United States for clinical investigational use in animals, it shall also meet the following conditions:

(i) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has, prior to such shipments and deliveries, informed FDA of his intention to import the new animal drug as sponsor in compliance with the conditions prescribed in this subdivision; or

(ii) The new animal drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct laboratory or clinical investigations and is intended solely for use in such institutions and which institution has submitted a statement as sponsor of the investigation.

(10) The sponsor shall submit either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

(c) *Disqualification of a clinical investigator.* (1) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with

the conditions of these exempting regulations or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Center for Veterinary Medicine, the Center will discontinue the disqualification proceeding. If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

(2) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this subchapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator and the sponsor of any investigation in which the investigator has been named as a participant that the investigator is not eligible to receive test articles under this part. The notification to the investigator and sponsor will provide a statement of the basis for such determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

(3) Each application or submission to FDA under the provisions of this chapter containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles is subject to examination to determine whether the investigator has submitted unreliable data that are essential to the continuation of an investigation or essential to the approval of a marketing application, or essential to the continued marketing of an FDA-regulated product.

(4) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor, who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the exemption immediately and notify the sponsor of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 on the question of whether the exemption should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

(5) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(6) An investigator who has been determined to be ineligible under paragraph (c)(2) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug, solely in compliance with the applicable provisions of this chapter.

(d) *Termination of exemption.* If the Commissioner finds that:

(1) The sponsor of the investigation has failed to comply with any of the conditions for the exemption established under this section, or

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is being or has been used for purposes other than bona fide scientific investigation, he shall first notify the sponsor and invite his immediate correction. If the conditions of the exemption are not immediately met, the sponsor shall have an opportunity for a regulatory hearing before FDA pursuant of part 16 of this chapter on whether the exemption should be terminated. If the exemption is terminated the sponsor shall recall or have destroyed the unused supplies of the new animal drug.

(e) *Statements and requests.* ''Notice(s) of Claimed Investigational Exemption for a New Animal Drug'' and requests for authorization to use investigational animals and their products for food should be addressed to the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(f) *Contract research organizations.* (1) For purposes of this part and part 514, *contract research organization* means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to FDA.

(2) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be in writing and, if not all obligations are transferred, shall describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(3) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to *sponsor* in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

(g) *Index of legally marketed unapproved new animal drugs for minor species.* All provisions of part 511 apply to new animal drugs for investigational use in support of indexing, as described in section 572 of the act, subject to the provisions of § 516.125 of this chapter.

[40 FR 13823, Mar. 27, 1975, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8847, Mar. 19, 1987; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992; 62 FR 40599, July 29, 1997; 72 FR 69121, Dec. 6, 2007; 77 FR 25359, Apr. 30, 2012; 82 FR 61446, Dec. 28, 2017]

§ 511.3 Definitions.

As used in this part:

Contract research organization means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. ''Subinvestigator'' includes any other individual member of that team.

Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-Investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

[77 FR 25359, Apr. 30, 2012]

PART 514—NEW ANIMAL DRUG APPLICATIONS

Subpart A—General Provisions

Sec.

514.1 Applications.
514.3 Definitions.
514.4 Substantial evidence.
514.5 Presubmission conferences.
514.6 Amended applications.
514.7 Withdrawal of applications without prejudice.
514.8 Supplements and other changes to an approved application.
514.11 Confidentiality of data and information in a new animal drug application file.
514.12 Confidentiality of data and information in an investigational new animal drug notice.
514.15 Untrue statements in applications.

Subpart B—Administrative Actions on Applications

514.80 Records and reports concerning experience with approved new animal drugs.
514.87 Annual reports for antimicrobial animal drug sales and distribution.
514.100 Evaluation and comment on applications.
514.105 Approval of applications.
514.106 Approval of supplemental applications.
514.110 Reasons for refusing to file applications.
514.111 Refusal to approve an application.
514.115 Withdrawal of approval of applications.
514.116 Notice of withdrawal of approval of application.
514.117 Adequate and well-controlled studies.
514.120 Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.
514.121 Service of notices and orders.

Subpart C—Hearing Procedures

514.200 Notice of opportunity for hearing; notice of participation and requests for hearing; grant or denial of hearing.
514.201 Procedures for hearings.

Subparts D–E [Reserved]

Subpart F—Judicial Review

514.235 Judicial review.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

SOURCE: 40 FR 13825, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 514.1 Applications.

(a) Applications to be filed under section 512(b) of the act shall be submitted in the form and contain the information described in paragraph (b) of this section, as appropriate to support the particular submission. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of literature printed in a foreign language shall be accompanied by copies of the original publication. The application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a

place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States. Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of § 511.1 of this chapter, in the files of the Food and Drug Administration; however, the reference must be specific in identifying the information. Any reference to information furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it.

(b) Applications for new animal drugs shall be submitted in triplicate and assembled in the manner prescribed by paragraph (b)(15) of this section, and shall include the following information, as appropriate to support the particular submission:

(1) *Identification.* Whether the submission is an original or supplemental application; the name and the address of the applicant; the date of the application; the trade name(s) (if one has been proposed) and chemical name(s) of the new animal drug. Upon receipt, the application will be assigned a number NADA ____, which shall be used for all correspondence with respect to the application.

(2) *Table of contents and summary.* The application shall be organized in a cohesive fashion, shall contain a table of contents which identifies the data and other material submitted, and shall contain a well-organized summary and evaluation of the data in the following form:

(i) Chemistry:

(*a*) Chemical structural formula or description for any new animal drug substance.

(*b*) Relationship to other chemically or pharmacologically related drugs.

(*c*) Description of dosage form and quantitative composition.

(ii) Scientific rationale and purpose the new animal drug is to serve:

(*a*) Clinical purpose.

(*b*) Highlights of laboratory studies: The reasons why certain types of studies were done or omitted as related to the proposed conditions of use and to information already known about this class of compounds. Emphasize any unusual or particularly significant pharmacological effects or toxicological findings.

(*c*) Highlights of clinical studies: The rationale of the clinical study plan showing why types of studies were done, amended, or omitted as related to laboratory studies and prior clinical experience.

(*d*) Conclusions: A short statement of conclusions combining the major points of effectiveness and safety as they relate to the use of the new animal drug.

(3) *Labeling.* Three copies of each piece of all labeling to be used for the article (total of 9).

(i) All labeling should be identified to show its position on, or the manner in which it is to accompany the market package.

(ii) Labeling for nonprescription new animal drugs should include adequate directions for use by the layman under all conditions of use for which the new animal drug is intended, recommended, or suggested in any of the labeling or advertising sponsored by the applicant.

(iii) Labeling for prescription veterinary drugs should bear adequate information for use under which veterinarians can use the new animal drug safely and for the purposes for which it is intended, including those purposes for which it is to be advertised or represented, in accord with § 201.105 of this chapter.

(iv) All labeling for prescription or nonprescription new animal drugs shall be submitted with any necessary use restrictions prominently and conspicuously displayed.

(v) Labeling for new animal drugs intended for use in the manufacture of medicated feeds shall include:

(*a*) Specimens of labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested

in any of the labeling, including advertising, sponsored by the applicant. Ingredient labeling may utilize collective names as provided in §501.110 of this chapter.

(*b*) Representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.

(vi) Draft labeling may be submitted for preliminary consideration of an application. Final printed labeling will ordinarily be required prior to approval of an application. Proposed advertising for veterinary prescription drugs may be submitted for comment or approval.

(4) *Components and composition.* A complete list of all articles used for production of the new animal drug including a full list of the composition of each article:

(i) A full list of the articles used as components of the new animal drug. This list should include all substances used in the synthesis, extraction, or other method of preparation of any new animal drug and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each component should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary name is used, it should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed component may be specified.

(ii) A full statement of the composition of the new animal drug. The statement shall set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the new animal drug in the form in which it is to be distributed (for example, amount per tablet or milliliter) and a batch formula representative of that to be employed for the manufacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variation may be specified.

(iii) If it is a new animal drug produced by fermentation:

(*a*) Source and type of microorganism used to produce the new animal drug.

(*b*) Composition of media used to produce the new animal drug.

(*c*) Type of precursor used, if any, to guide or enhance production of the antibiotic during fermentation.

(*d*) Name and composition of preservative, if any, used in the broth.

(*e*) A complete description of the extraction and purification processes including the names and compositions of the solvents, precipitants, ion exchange resins, emulsifiers, and all other agents used.

(*f*) If the new animal drug is produced by a catalytic hydrogenation process (such as tetracycline from chlortetracycline), a complete description of each chemical reaction with graphic formulas used to produce the new animal drug, including the names of the catalyst used, how it is removed, and how the new animal drug is extracted and purified.

(5) *Manufacturing methods, facilities, and controls.* A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug. This description should include full information with respect to any new animal drug in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing, and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the new animal drug, and the following:

(i) If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new animal drug, he shall: Identify each person who will perform any part of such operations and designate the part; and provide a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls he will use in his part of the operation. The statement shall include a commitment that no changes will be made without prior approval by the Food and Drug Administration, unless permitted under §514.8.

(ii) A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the new animal drug has the identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

(iii) A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

(iv) The methods used in the synthesis, extraction, isolation, or purification of any new animal drug. When the specifications and controls applied to such new animal drugs are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperature, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the new animal drug may be specified. A flow sheet and indicated equations should be submitted when needed to explain the process.

(v) Precautions to insure proper identity, strength, quality, and purity of the raw materials, whether active or not, including:

(*a*) The specifications for acceptance and methods of testing for each lot of raw material.

(*b*) A statement as to whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

(vi) The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new animal drug, including:

(*a*) The method of preparation of the master formula records and individual batch records and the manner in which these records are used.

(*b*) The number of individuals checking weight or volume of each individual ingredient entering into each batch of the new animal drug.

(*c*) A statement as to whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and, if so, at what stage and by whom it is done.

(*d*) The precautions used in checking the actual package yield produced from a batch of the new animal drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteria used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

(*e*) The precautions used to assure that each lot of the new animal drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

(*f*) Any special precautions used in the operations.

(vii) The analytical controls used during the various stages of the manufacturing, processing, packaging, and labeling of the new animal drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components.

(*a*) A description of practicable methods of analysis of adequate sensitivity to determine the amount of the new animal drug in the final dosage form should be included. The dosage form may be a finished pharmaceutical product, a Type A medicated article, a Type B or a Type C medicated feed, or a product for use in animal drinking water. Where two or more active ingredients are included, methods should be quantitative and specific for each active ingredient.

(*b*) If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

(viii) An explanation of the exact significance of any batch control numbers used in the manufacturing, processing, packaging, and labeling of the new animal drug, including such control numbers that may appear on the label of

the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

(ix) Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

(x) A complete description of, and data derived from, studies of the stability of the new animal drug in the final dosage form, including information showing the suitability of the analytical methods used. A description of any additional stability studies underway or planned. Stability data for the finished dosage form of the new animal drug in the container in which it is to be marketed, including any proposed multiple dose container, and, if it is to be put into solution at the time of dispensing, for the solution prepared as directed. If the new animal drug is intended for use in the manufacture of Type C medicated feed as defined in §558.3 of this chapter, stability data derived from studies in which representative formulations of the medicated feed articles are used. Similar data may be required for Type B medicated feeds as determined by the Food and Drug Administration on a case-by-case basis. Expiration dates shall be proposed for finished pharmaceutical dosage forms and Type A medicated articles. If the data indicate that an expiration date is needed for Type B or Type C medicated feeds, the applicant shall propose such expiration date. If no expiration date is proposed for Type B or Type C medicated feeds, the applicant shall justify its absence with data.

(xi) Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product. An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the new animal drug are adequate to preserve its identity, strength, quality, and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.

(6) *Samples.* Samples of the new animal drug and articles used as components and information concerning them may be requested by the Center for Veterinary Medicine as follows:

(i) Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics, to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new animal drug application to which it relates. Included are:

(*a*) A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new animal drug and other assayed components of the finished new animal drug.

(*b*) A representative sample or samples of each strength of the finished dosage form proposed in the application and employed in the clinical investigations and a representative sample or samples of each new animal drug from the batch(es) employed in the production of such dosage form.

(*c*) A representative sample or samples of finished market packages of each strength of the dosage form of the new animal drug prepared for initial marketing and, if any such sample is not from a representative commercial-scale production batch, such a sample from a representative commercial-scale production batch, and a representative sample or samples of each new animal drug from the batch(es) employed in the production of such dosage form, provided that in the case of new animal drugs marketed in large packages the sample should contain only three times a sufficient quantity of the new animal drug to allow for performing the control tests for drug identity and assays.

(ii) The following information shall be included for the samples when requested:

(*a*) For each sample submitted, full information regarding its identity and the origin of any new animal drug contained therein (including a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays.

(*b*) For any reference standard submitted, a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reporting results.

(7) *Analytical methods for residues.* Applications shall include a description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions to ensure that the proposed use of this drug will be safe. When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required.

(i) The kind of information required by this subdivision may include: Complete experimental protocols for determining drug residue levels in the edible products, and the length of time required for residues to be eliminated from such products following the drug's use; residue studies conducted under appropriate (consistent with the proposed usage) conditions of dosage, time, and route of administration to show levels, if any, of the drug and/or its metabolites in test animals during and upon cessation of treatment and at intervals thereafter in order to establish a disappearance curve; if the drug is to be used in combination with other drugs, possible effects of interaction demonstrated by the appropriate disappearance curve or depletion patterns after drug withdrawal under appropriate (consistent with the proposed usage) conditions of dosage, time, and route of administration; if the drug is given in the feed or water, appropriate consumption records of the medicated feed or water and appropriate performance data in the treated animal; if the drug is to be used in more than one species, drug residue studies or appropriate metabolic studies conducted for each species that is food-producing. To provide these data, a sufficient number of birds or animals should be used at each sample interval. Appropriate use of labeled compounds (e.g. radioactive tracers), may be utilized to establish metabolism and depletion curves. Drug residue levels ordinarily should be determined in muscle, liver, kidney, and fat and where applicable, in skin, milk, and eggs (yolk and egg white). As a part of the metabolic studies, levels of the drug or metabolite should be determined in blood where feasible. Samples may be combined where necessary. Where residues are suspected or known to be present in litter from treated animals, it may be necessary to include data with respect to such residues becoming components of other agricultural commodities because of use of litter from treated animals.

(ii) A new animal drug that has the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

(8) *Evidence to establish safety and effectiveness.* (i) An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the new animal drug is safe and effective for use as suggested in the proposed labeling.

(ii) An application may be refused unless it includes substantial evidence of the effectiveness of the new animal drug as defined in § 514.4.

(iii) An application may be refused unless it contains detailed reports of the investigations, including studies made on laboratory animals, in which the purpose, methods, and results obtained are clearly set forth of acute, subacute, and chronic toxicity, and unless it contains appropriate clinical laboratory results related to safety and

efficacy. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted, and where the raw data are available in the application.

(iv) All information pertinent to an evaluation of the safety and effectiveness of the new animal drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commercial marketing (for example, outside the United States), or reports in the scientific literature, both favorable and unfavorable, involving the new animal drug that is the subject of the application and related new animal drugs shall be submitted. An adequate summary may be acceptable in lieu of a reprint of a published report that only supports other data submitted. Include any evaluation of the safety or effectiveness of the new animal drug that has been made by the applicant's veterinary or medical department, expert committee, or consultants.

(v) If the new animal drug is a combination of active ingredients or animal drugs, an application may be refused unless it includes substantial evidence of the effectiveness of the combination new animal drug as required in §514.4.

(vi) An application shall include a complete list of the names and post office addresses of all investigators who received the new animal drug. This may be incorporated in whole or in part by reference to information submitted under the provisions of §511.1 of this chapter.

(vii) Explain any omission of reports from any investigator to whom the investigational new animal drug has been made available. The unexplained omission of any reports of investigations made with the new animal drug by the applicant or submitted to him by an investigator or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other sources that would bias an evaluation of the safety of the new animal drug or its effectiveness in use, constitutes grounds for the refusal or withdrawal of the approval of an application.

(viii) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, the application is required to include a statement containing the name and address of the contract research organization, identifying the clinical study, and listing the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(ix) If original subject records were audited or reviewed by the sponsor in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the sponsor, a list identifying each clinical study so audited or reviewed.

(9) *Veterinary feed directive.* Three copies of a veterinary feed directive (VFD) must be submitted in a form that accounts for the information described under §§558.6(b)(3) and 558.6(b)(4) of this chapter.

(10) *Supplemental applications.* If it is a supplemental application, full information shall be submitted on each proposed change concerning any statement made in the approved application.

(11) *Applicant's commitment.* It is understood that the labeling and advertising for the new animal drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application and if the article is a prescription new animal drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the new animal drug will also contain, in the same language and emphasis, information for its use including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications, side effects, and precautions contained in the labeling which is part of this application. It is understood that all representations in this application apply to the drug produced until changes are made in conformity with §514.8.

(12) *Additional commitments.* (i) New animal drugs as defined in § 510.3 of this chapter, intended for use in the manufacture of animal feeds in any State will be shipped only to persons who may receive such drugs in accordance with § 510.7 of this chapter.

(ii) The methods, facilities, and controls described under item 5 of this application conform to the current good manufacturing practice regulations in subchapter C of this chapter.

(iii) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(13) [Reserved]

(14) *Environmental assessment.* The applicant is required to submit either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

(15) *Assembling and binding the application.* Assemble and bind an original and two copies of the application as follows:

(i) Bind the original or ribbon copy of the application as copy No. 1.

(ii) Bind two identical copies as copy No. 2 and copy No. 3.

(iii) Identify each front cover with the name of the applicant, new animal drug, and the copy number.

(iv) Number each page of the application sequentially in the upper right hand corner or in another location so that the page numbers remain legible after the application has been bound, and organize the application consistent with paragraphs (b) (1) through (14) of this section. Each copy should bear the same page numbering, whether sequential in each volume or continuous and sequential throughout the application.

(v) Include complete labeling in each of the copies. It is suggested that labeling be identified by date of printing or date of preparation.

(vi) Submit separate applications for each different dosage form of the drug proposed. Repeating basic information pertinent to all dosage forms in each application is unnecessary if reference is made to the application containing such information. Include in each application information applicable to the specific dosage form, such as labeling, composition, stability data, and method of manufacture.

(vii) Submit in folders amendments, supplements, and other correspondence sent after submission of an original application. The front cover of these submissions should be identified with the name of the applicant, new animal drug, copy number, and the new animal drug application number, if known.

(c) When a new animal drug application is submitted for a new animal drug which has a stimulant, depressant, or hallucinogenic effect on the central nervous system, if it appears that the drug has a potential for abuse, the Commissioner shall forward that information to the Attorney General of the United States.

[40 FR 13825, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 514.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 514.3 Definitions.

The definition and interpretation of terms contained in this section apply to those terms as used throughout subchapter E.

Adverse drug experience is any adverse event associated with the use of a new animal drug, whether or not considered to be drug related, and whether or not the new animal drug was used in accordance with the approved labeling (i.e., used according to label directions or used in an extralabel manner, including but not limited to different route of administration, different species, different indications, or other than labeled dosage). Adverse drug experience includes, but is not limited to:

(1) An adverse event occurring in animals in the course of the use of an animal drug product by a veterinarian or by a livestock producer or other animal owner or caretaker.

(2) Failure of a new animal drug to produce its expected pharmacological or clinical effect (lack of expected effectiveness).

(3) An adverse event occurring in humans from exposure during manufacture, testing, handling, or use of a new animal drug.

ANADA is an abbreviated new animal drug application including all amendments and supplements.

Applicant is a person or entity who owns or holds on behalf of the owner the approval for an NADA or an ANADA, and is responsible for compliance with applicable provisions of the act and regulations.

Increased frequency of adverse drug experience is an increased rate of occurrence of a particular serious adverse drug event, expected or unexpected, after appropriate adjustment for drug exposure.

NADA is a new animal drug application including all amendments and supplements.

Nonapplicant is any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product.

Potential applicant means any person:

(1) Intending to investigate a new animal drug under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act),

(2) Investigating a new animal drug under section 512(j) of the act,

(3) Intending to file a new animal drug application (NADA) or supplemental NADA under section 512(b)(1) of the act, or

(4) Intending to file an abbreviated new animal drug application (ANADA) under section 512(b)(2) of the act.

Presubmission conference means one or more conferences between a potential applicant and FDA to reach a binding agreement establishing a submission or investigational requirement.

Presubmission conference agreement means that section of the memorandum of conference headed ''Presubmission Conference Agreement'' that records any agreement on the submission or investigational requirement reached by a potential applicant and FDA during the presubmission conference.

Product defect/manufacturing defect is the deviation of a distributed product from the standards specified in the approved application, or any significant chemical, physical, or other change, or deterioration in the distributed drug product, including any microbial or chemical contamination. A manufacturing defect is a product defect caused or aggravated by a manufacturing or related process. A manufacturing defect may occur from a single event or from deficiencies inherent to the manufacturing process. These defects are generally associated with product contamination, product deterioration, manufacturing error, defective packaging, damage from disaster, or labeling error. For example, a labeling error may include any incident that causes a distributed product to be mistaken for, or its labeling applied to, another product.

Serious adverse drug experience is an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement.

Unexpected adverse drug experience is an adverse event that is not listed in the current labeling for the new animal drug and includes any event that may be symptomatically and pathophysiologically related to an event listed on the labeling, but differs from the event because of greater severity or specificity. For example, under this definition hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.

[68 FR 15365, Mar. 31, 2003, as amended at 69 FR 51170, Aug. 18, 2004]

§514.4 Substantial evidence.

(a) *Definition of substantial evidence.* Substantial evidence means evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by experts qualified by scientific training and experience to evaluate the effectiveness of the new animal drug involved that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling

or proposed labeling thereof. Substantial evidence shall include such adequate and well-controlled studies that are, as a matter of sound scientific judgment, necessary to establish that a new animal drug will have its intended effect.

(b) *Characteristics of substantial evidence*—(1) *Qualifications of experts.* Any study that is intended to be part of substantial evidence of the effectiveness of a new animal drug shall be conducted by experts qualified by scientific training and experience.

(2) *Intended uses and conditions of use.* Substantial evidence of effectiveness of a new animal drug shall demonstrate that the new animal drug is effective for each intended use and associated conditions of use for and under which approval is sought.

(i) *Dose range labeling.* Sponsors should, to the extent possible, provide for a dose range because it increases the utility of the new animal drug by providing the user flexibility in the selection of a safe and effective dose. In general, substantial evidence to support dose range labeling for a new animal drug intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease must consist of at least one adequate and well-controlled study on the basis of which qualified experts could fairly and reasonably conclude that the new animal drug will be effective for the intended use at the lowest dose of the dose range suggested in the proposed labeling for that intended use. Substantial evidence to support dose range labeling for a new animal drug intended to affect the structure or function of the body of an animal generally must consist of at least one adequate and well-controlled study on the basis of which qualified experts could fairly and reasonably conclude that the new animal drug will be effective for the intended use at all doses within the range suggested in the proposed labeling for the intended use.

(ii) [Reserved]

(3) *Studies*—(i) *Number.* Substantial evidence of the effectiveness of a new animal drug for each intended use and associated conditions of use shall consist of a sufficient number of current adequate and well-controlled studies of sufficient quality and persuasiveness to permit qualified experts:

(A) To determine that the parameters selected for measurement and the measured responses reliably reflect the effectiveness of the new animal drug;

(B) To determine that the results obtained are likely to be repeatable, and that valid inferences can be drawn to the target animal population; and

(C) To conclude that the new animal drug is effective for the intended use at the dose or dose range and associated conditions of use prescribed, recommended, or suggested in the proposed labeling.

(ii) *Types.* Adequate and well-controlled studies that are intended to provide substantial evidence of the effectiveness of a new animal drug may include, but are not limited to, published studies, foreign studies, studies using models, and studies conducted by or on behalf of the sponsor. Studies using models shall be validated to establish an adequate relationship of parameters measured and effects observed in the model with one or more significant effects of treatment.

(c) *Substantial evidence for combination new animal drugs*—(1) *Definitions.* The following definitions of terms apply to this section:

(i) *Combination new animal drug* means a new animal drug that contains more than one active ingredient or animal drug that is applied or administered simultaneously in a single dosage form or simultaneously in or on animal feed or drinking water.

(ii) *Dosage form combination new animal drug* means a combination new animal drug intended for use other than in animal feed or drinking water.

(iii) *Antibacterial* with respect to a particular target animal species means an active ingredient or animal drug: That is approved in that species for the diagnosis, cure, mitigation, treatment, or prevention of bacterial disease; or that is approved for use in that species for any other use that is attributable to its antibacterial properties. But, antibacterial does not include ionophores or arsenicals intended for use in combination in animal feed or drinking water.

(iv) *Appropriate concurrent use* exists when there is credible evidence that

the conditions for which the combination new animal drug is intended can occur simultaneously.

(2) *Combination new animal drugs that contain only active ingredients or animal drugs that have previously been separately approved.* (i) For dosage form combination new animal drugs, except for those that contain a nontopical antibacterial, that contain only active ingredients or animal drugs that have previously been separately approved for the particular uses and conditions of use for which they are intended in combination, a sponsor shall demonstrate:

(A) By substantial evidence, as defined in this section, that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the effectiveness of the combination new animal drug;

(B) That each active ingredient or animal drug intended for at least one use that is different from all the other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target animal population; and

(C) That the active ingredients or animal drugs are physically compatible and do not have disparate dosing regimens if FDA, based on scientific information, has reason to believe the active ingredients or animal drugs are physically incompatible or have disparate dosing regimens.

(ii) For combination new animal drugs intended for use in animal feed or drinking water that contain only active ingredients or animal drugs that have previously been separately approved for the particular uses and conditions of use for which they are intended in combination, the sponsor shall demonstrate:

(A) By substantial evidence, as defined in this section, that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the effectiveness of the combination new animal drug;

(B) For such combination new animal drugs that contain more than one antibacterial ingredient or animal drug, by substantial evidence, as defined in this section, that each antibacterial makes a contribution to labeled effectiveness;

(C) That each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target animal population; and

(D) That the active ingredients or animal drugs intended for use in drinking water are physically compatible if FDA, based on scientific information, has reason to believe the active ingredients or animal drugs are physically incompatible.

(3) *Other combination new animal drugs.* For all other combination new animal drugs, the sponsor shall demonstrate by substantial evidence, as defined in this section, that the combination new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling and that each active ingredient or animal drug contributes to the effectiveness of the combination new animal drug.

[64 FR 40756, July 28, 1999]

§514.5 Presubmission conferences.

(a) *General principle underlying the conduct of a presubmission conference.* The general principle underlying the conduct of any presubmission conference is that there should be candid, full, and open communication.

(b) *Requesting a presubmission conference.* A potential applicant is entitled to one or more conferences prior to the submission of an NADA, supplemental NADA, or an ANADA to reach an agreement establishing part or all of a submission or investigational requirement. A potential applicant's request for a presubmission conference must be submitted to FDA in a signed letter. The letter must include a proposed agenda that clearly outlines the scope, purpose, and objectives of the presubmission conference and must list the names and positions of the representatives who are expected to attend the presubmission conference on behalf of the applicant.

(c) *Timing.* A potential applicant may request one or more presubmission conferences at any time prior to the filing of a NADA, supplemental NADA, or an ANADA. A request for a presubmission conference must be received by FDA at least 30 calendar days in advance of the requested conference date. FDA will schedule the presubmission conference at a time agreeable to both FDA and the potential applicant.

(d) *Advance information.* The potential applicant must provide to FDA, at least 30 calendar days before a scheduled presubmission conference, a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and copies of materials evaluated or referenced relative to issues listed in the agenda for the conference. If the materials are not provided or are not sufficient to provide the basis for meaningful discussion, FDA may elect to postpone part or all of the meeting until sufficient materials are provided to FDA.

(e) *Conduct of a presubmission conference.* The potential applicant and FDA may each bring consultants to the presubmission conference. The presubmission conference(s) will be directed primarily at establishing agreement between FDA and the potential applicant regarding a submission or investigational requirement. The submission or investigational requirement may include, among other things, the number, types, and general design of studies that are necessary to demonstrate the safety and effectiveness of a new animal drug for the intended uses and conditions of use prescribed, recommended, or suggested in the proposed labeling for the new animal drug.

(f) *Documentation of a presubmission conference*—(1) *Memorandum of conference*—(i) *Preparation.* FDA will prepare a memorandum for each presubmission conference that will include, among other things, any background pertinent to the request for meeting; a summary of the key points of discussion; agreements; and action items and assignments of responsibility. That portion of the memorandum of conference that documents any agreements reached regarding all or part of a submission or investigational requirement will be included under the heading ''Presubmission Conference Agreement.'' If the presubmission conference agreement section of the memorandum is silent on an issue, including one that was discussed in the conference or addressed by materials provided for the conference, such silence does not constitute agreement between FDA and the potential applicant on the issue.

(ii) *Sending a copy to the potential applicant.* FDA will send a copy of the memorandum to the potential applicant for review no later than 45 calendar days after the date of the conference

(iii) *Requests for changes or clarification.* If a potential applicant requests changes to, or clarification of, the substance of the memorandum, the request must be sent to FDA within 30 calendar days from the date a copy of the memorandum is sent to the applicant. If the potential applicant requests changes or clarification, FDA will send the potential applicant a response to their request no later than 45 calendar days after the date of receipt of the request.

(iv) *Administrative record.* A copy of FDA's original memorandum of conference and, as appropriate, a copy of an amended memorandum to correct or clarify the content of the original memorandum will be made part of the administrative file.

(2) *Field studies.* If FDA requires more than one field study to establish by substantial evidence that the new animal drug is effective for its intended uses under the conditions of use prescribed, recommended, or suggested in the proposed labeling, FDA will provide written scientific justification for requiring more than one field study. Such justification must be provided no later than 25 calendar days after the date of the conference at which the requirement for more than one field study is established. If FDA does not believe more than one field study is required but the potential applicant voluntarily proposes to conduct more than one field study, FDA will not provide such written justification. If FDA

requires one field study to be conducted at multiple locations, FDA will provide justification for requiring multiple locations verbally during the presubmission conference and in writing as part of the memorandum of conference.

(g) *Modification of presubmission conference agreements.* An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

(h) *When the terms of a presubmission conference agreement are not valid* (1) A presubmission conference agreement will no longer be valid if:

(i) The potential applicant makes to FDA, before, during, or after the presubmission conference, any untrue statement of material fact; or

(ii) The potential applicant fails to follow any material term of the agreement; and

(2) A presubmission conference may no longer be valid if the potential applicant submits false or misleading data relating to a new animal drug to FDA.

(i) *Dispute resolution.* FDA is committed to resolving differences between a potential applicant and FDA reviewing divisions with respect to requirements for the investigation of new animal drugs and for NADAs, supplemental NADAs, and ANADAs as quickly and amicably as possible through a cooperative exchange of information and views. When administrative or procedural disputes arise, a potential applicant should first attempt to resolve the matter within the appropriate review division beginning with the individual(s) most directly assigned to the review of the application or investigational exemption. If the dispute cannot be resolved after such attempts, the dispute shall be evaluated and administered in accordance with applicable regulations (21 CFR 10.75). Dispute resolution procedures may be further explained by guidance available from the Center for Veterinary Medicine.

[69 FR 51170, Aug. 18, 2004]

§ 514.6 Amended applications.

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§ 514.7 Withdrawal of applications without prejudice.

The sponsor may withdraw his pending application from consideration as a new animal drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The original application will be retained by the Food and Drug Administration although it is considered withdrawn. The applicant shall be furnished a copy at cost on request.

§ 514.8 Supplements and other changes to an approved application.

(a) *Definitions.* (1) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to those terms when used in this part.

(2) The following definitions of terms apply to this part:

(i) *Assess the effects of the change* means to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency

of a drug as these factors may relate to the safety or effectiveness of the drug.

(ii) *Drug substance* means an active ingredient as defined under § 210.3(b)(7) of this chapter.

(iii) *Minor changes and stability report (MCSR)* means an annual report that is submitted to the application once each year within 60 days before or after the anniversary date of the application's original approval or on a mutually agreed upon date. The report must include minor manufacturing and control changes made according to § 514.8(b)(4) or state that no changes were made; and stability data generated on commercial or production batches according to an approved stability protocol or commitment.

(iv) *Specification* means the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved application to confirm the quality of drugs including, for example, drug substances, Type A medicated articles, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug. For the purpose of this definition, the term ''acceptance criteria'' means numerical limits, ranges, or other criteria for the tests described.

(b) *Manufacturing changes to an approved application*—(1) *General provisions.* (i) The applicant must notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant must notify FDA about it in a supplement under paragraph (b)(2) or (b)(3) of this section or by inclusion of the information in the annual report to the application under paragraph (b)(4) of this section.

(ii) The holder of an approved application under section 512 of the act must assess the effects of the change before distributing a drug made with a manufacturing change.

(iii) Notwithstanding the requirements of paragraphs (b)(2) and (b)(3) of this section, an applicant must make a change provided for in those paragraphs in accordance with a regulation or guidance that provides for a less burdensome notification of the change (for example, by submission of a supplement that does not require approval prior to distribution of the drug, or by notification in the next annual report described in paragraph (b)(4) of this section).

(iv) In each supplement and amendment to a supplement providing for a change under paragraph (b)(2) or (b)(3) of this section, the applicant must include a statement certifying that a field copy has been provided to the appropriate FDA district office. No field copy is required for a supplement providing for a change made to a drug manufactured outside of the United States.

(v) A supplement or annual report described in paragraph (b)(4) of this section must include a list of all changes contained in the supplement or annual report. For supplements, this list must be provided in the cover letter.

(2) *Changes requiring submission and approval of a supplement prior to distribution of the drug made using the change (major changes).* (i) A supplement must be submitted for any change in the drug, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug.

(ii) These changes include, but are not limited to:

(A) Except those described in paragraphs (b)(3) and (b)(4) of this section, changes in the qualitative or quantitative formulation of the drug, including inactive ingredients, or in the specifications provided in the approved application;

(B) Changes requiring completion of appropriate clinical studies to demonstrate the equivalence of the drug to the drug as manufactured without the change;

(C) Changes that may affect drug substance or drug product sterility assurance, such as changes in drug substance, drug product or component sterilization method(s) or an addition, deletion, or substitution of steps in an aseptic processing operation;

(D) Changes in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance;

(E) Changes in a drug product container closure system that controls the drug delivered to the animal or changes in the type or composition of a packaging component that may affect the impurity profile of the drug product;

(F) Changes solely affecting a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody for the following:

(*1*) Changes in the virus or adventitious agent removal or inactivation method(s),

(*2*) Changes in the source material or cell line, and

(*3*) Establishment of a new master cell bank or seed;

(G) Changes to a drug under an application that is subject to a validity assessment because of significant questions regarding the integrity of the data supporting that application.

(iii) The applicant must obtain approval of a supplement from FDA prior to distribution of a drug made using a change under paragraph (b)(2) of this section. The supplement must be labeled ''Prior Approval Supplement.'' Except for submissions under paragraph (b)(2)(v) of this section, the following information must be contained in the supplement:

(A) A completed Form FDA 356V;

(B) A detailed description of the proposed change;

(C) The drug(s) involved;

(D) The manufacturing site(s) or area(s) affected;

(E) A description of the methods used and studies performed to assess the effects of the change;

(F) The data derived from such studies;

(G) Appropriate documentation (for example, updated master batch records, specification sheets) including previously approved documentation (with the changes highlighted) or references to previously approved documentation;

(H) For a natural product, a recombinant DNA-derived protein/polypeptide, or a complex or conjugate of a drug substance with a monoclonal antibody, relevant validation protocols and standard operating procedures must be provided in addition to the requirements in paragraphs (b)(2)(iii)(E) and (b)(2)(iii)(F) of this section;

(I) For sterilization process and test methodologies related to sterilization process validation, relevant validation protocols and a list of relevant standard operating procedures must be provided in addition to the requirements in paragraphs (b)(2)(iii)(E) and (b)(2)(iii)(F) of this section; and

(J) Any other information as directed by FDA.

(iv) An applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover must be plainly marked: ''Prior Approval Supplement-Expedited Review Requested.''

(v) *Comparability Protocols.* An applicant may submit one or more protocols describing the specific tests and studies and acceptance criteria to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug. Any such protocols, if not included in the approved application, or changes to an approved protocol, must be submitted as a supplement requiring approval from FDA prior to distribution of the drug produced with the manufacturing change. The supplement, if approved, may subsequently justify a reduced reporting category for the particular change because the use of the protocol for that type of change reduces the potential risk of an adverse effect. A comparability protocol supplement must be labeled ''Prior Approval Supplement—Comparability Protocol.''

(3) *Changes requiring submission of a supplement at least 30 days prior to distribution of the drug made using the change (moderate changes).* (i) A supplement must be submitted for any change in the drug, production process,

quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug.

(ii) These changes include, but are not limited to:

(A) A change in the container closure system that does not affect the quality of the drug except as otherwise described in paragraphs (b)(2) and (b)(4) of this section;

(B) Changes solely affecting a natural protein, a recombinant DNA-derived protein/polypeptide or a complex or conjugate of a drug substance with a monoclonal antibody, including:

(*1*) An increase or decrease in production scale during finishing steps that involves different equipment, and

(*2*) Replacement of equipment with that of a different design that does not affect the process methodology or process operating parameters.

(C) Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements.

(iii) A supplement submitted under paragraph (b)(3)(i) or (b)(3)(vi) of this section is required to give a full explanation of the basis for the change and identify the date on which the change is made. The supplement submitted under paragraph (b)(3)(i) must be labeled ''Supplement-Changes Being Effected in 30 Days.''

(iv) Pending approval of the supplement by FDA and except as provided in paragraph (b)(3)(vi) of this section, distribution of the drug made using the change may begin not less than 30 days after receipt of the supplement by FDA. The information listed in paragraphs (b)(2)(iii)(A) through (b)(2)(iii)(J) of this section must be contained in the supplement.

(v) The applicant must not distribute the drug made using the change if within 30 days following FDA's receipt of the supplement, FDA informs the applicant that either:

(A) The change requires approval prior to distribution of the drug in accordance with paragraph (b)(2) of this section; or

(B) Any of the information required under paragraph (b)(3)(iv) of this section is missing. In this case, the applicant must not distribute the drug made using the change until the supplement has been amended to provide the missing information.

(vi) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug involved upon receipt by the agency of a supplement for the change. The information listed in paragraphs (b)(2)(iii)(A) through (b)(2)(iii)(J) of this section must be contained in the supplement. The supplement must be labeled ''Supplement-Changes Being Effected.'' These changes include, but are not limited to:

(A) Addition to a specification or changes in the methods or controls to provide increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess; and

(B) A change in the size and/or shape of a container for a nonsterile drug product, except for solid dosage forms, without a change in the labeled amount of drug product or from one container closure system to another.

(vii) If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug(s) made with the manufacturing change.

(4) *Changes and updated stability data to be described and submitted in an annual report (minor changes).* (i) Changes in the drug, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug must be documented by the applicant in an annual report to the application as described under paragraph (a)(2)(iii) of this section. The report must be labeled ''Minor Changes and Stability Report.''

(ii) These changes include but are not limited to:

(A) Any change made to comply with a change to an official compendium,

except a change in paragraph (b)(3)(ii)(C) of this section, that is consistent with FDA statutory and regulatory requirements;

(B) The deletion or reduction of an ingredient intended to affect only the color of the drug product;

(C) Replacement of equipment with that of the same design and operating principles except for those equipment changes described in paragraph (b)(3)(ii)(B)(2) of this section;

(D) A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form drug product, without a change from one container closure system to another;

(E) A change within the container closure system for a nonsterile drug product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium;

(F) An extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the application;

(G) The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the drug being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure; and

(H) The addition by embossing, debossing, or engraving of a code imprint to a solid oral dosage form drug product other than a modified release dosage form, or a minor change in an existing code imprint.

(iii) For changes under this category, the applicant is required to submit in the annual report:

(A) A completed Form FDA 356V;

(B) A statement by the holder of the approved application that the effects of the change have been assessed;

(C) A detailed description of the change(s);

(D) The manufacturing site(s) or area(s) involved;

(E) The date each change was implemented;

(F) Data from studies and tests performed to assess the effects of the change;

(G) For a natural product, recombinant DNA-derived protein/polypeptide, complex or conjugate of a drug substance with a monoclonal antibody, sterilization process or test methodology related to sterilization process validation, relevant validation protocols and/or standard operating procedures;

(H) Appropriate documentation (for example, updated master batch records, specification sheets, etc.) including previously approved documentation (with the changes highlighted) or references to previously approved documentation;

(I) Updated stability data generated on commercial or production batches according to an approved stability protocol or commitment; and

(J) Any other information as directed by FDA.

(c) *Labeling and other changes to an approved application*—(1) *General provisions.* The applicant must notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully.

(2) *Labeling changes requiring the submission and approval of a supplement prior to distribution of the drug made using the change (major changes).* (i) Addition of intended uses and changes to package labeling require a supplement. These changes include, but are not limited to:

(A) Revision in labeling, such as updating information pertaining to effects, dosages, adverse reactions, contraindications, which includes information headed ''adverse reactions,'' ''warnings,'' ''precautions,'' and ''contraindications,'' except ones described in (c)(3) of this section;

(B) Addition of an intended use;

(C) If it is a prescription drug, any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application, unless:

(*1*) The parts of the labeling furnishing directions, warnings, and information for use of the drug are the same

in language and emphasis as labeling approved or permitted; and

(*2*) Any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(*3*) Prescription drug labeling not requiring an approved supplemental application is submitted in accordance with § 514.80(b)(5)(ii).

(D) Any other changes in labeling, except ones described in paragraph (c)(3) of this section.

(ii) The applicant must obtain approval of the supplement from FDA prior to distribution of the drug. The supplement must contain the following:

(A) A completed Form FDA 356V;

(B) A detailed description of the proposed change;

(C) The drug(s) involved;

(D) The data derived from studies in support of the change; and

(E) Any other information as directed by FDA.

(3) *Labeling changes to be placed into effect prior to receipt of a written notice of approval of a supplemental application.* (i) Labeling changes of the following kinds that increase the assurance of drug safety proposed in supplemental applications must be placed into effect immediately:

(A) The addition to package labeling, promotional labeling, or prescription drug advertising of additional warning, contraindication, adverse reaction, and precaution information;

(B) The deletion from package labeling, promotional labeling, or drug advertising of false, misleading, or unsupported intended uses or claims for effectiveness; and

(C) Any other changes as directed by FDA.

(ii) Labeling changes (for example, design and style) that do not decrease safety of drug use proposed in supplemental applications may be placed into effect prior to written notice of approval from FDA of a supplemental application.

(iii) A supplement submitted under paragraph (c)(3) of this section must include the following information:

(A) A full explanation of the basis for the changes, the date on which such changes are being effected, and plainly marked on the mailing cover and on the supplement, ''Supplement—Labeling Changes Being Effected'';

(B) Two sets of printed copies of any revised labeling to be placed in use, identified with the new animal drug application number; and

(C) A statement by the applicant that all promotional labeling and all drug advertising will promptly be revised consistent with the changes made in the labeling on or within the new animal drug package no later than upon approval of the supplemental application.

(iv) If the supplemental application is not approved and the drug is being distributed with the proposed labeling, FDA may initiate an enforcement action because the drug is misbranded under section 502 of the act and/or adulterated under section 501 of the act. In addition, under section 512(e) of the act, FDA may, after due notice and opportunity for a hearing, issue an order withdrawing approval of the application.

(4) *Changes providing for additional distributors to be reported under Records and reports concerning experience with approved new animal drugs (§ 514.80).* Supplemental applications as described under paragraph (c)(2) of this section will not be required for an additional distributor to distribute a drug that is the subject of an approved new animal drug application or abbreviated new animal drug application if the conditions described under § 514.80(b)(5)(iii) are met.

(d) *Patent information.* The applicant must comply with the patent information requirements under section 512(c)(3) of the act.

(e) *Claimed exclusivity.* If an applicant claims exclusivity under section 512(c)(2)(F) of the act upon approval of a supplemental application for a change in its previously approved drug, the applicant must include such a statement.

(f) *Good laboratory practice for nonclinical laboratory studies.* A supplemental application that contains nonclinical laboratory studies must include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this

chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

[71 FR 74782, Dec. 13, 2006]

§ 514.11 Confidentiality of data and information in a new animal drug application file.

(a) For purposes of this section the *NADA file* includes all data and information submitted with or incorporated by reference in the NADA, INAD's incorporated into the NADA, supplemental NADA's, reports under §§ 514.80 and 510.301 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NADA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

(c) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure.

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 20.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file. Such summaries do not constitute the full reports of investigations under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(i) For an NADA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of:

(*a*) Names and any information that would identify the investigators.

(*b*) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NADA approved after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

(*a*) The Center for Veterinary Medicine may at an appropriate time prior to approval of the NADA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Center.

(*b*) The Center for Veterinary Medicine may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is

shown to fall within the exemption established in § 20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of part 20 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time any one of the following events occurs unless extraordinary circumstances are known:

(1) The NADA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

[40 FR 13825, Mar. 27, 1975, as amended at 42 FR 3109, Jan. 14, 1977; 42 FR 15675, Mar. 22, 1977; 54 FR 18280, Apr. 28, 1989; 68 FR 15365, Mar. 31, 2003; 79 FR 14611, Mar. 17, 2014]

§ 514.12 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.11.

§ 514.15 Untrue statements in applications.

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and § 514.80 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief statement of the reason for the noncompliance.

[40 FR 13825, Mar. 27, 1975, as amended at 49 FR 7226, Feb. 28, 1984; 50 FR 7517, Feb. 22, 1985; 68 FR 15365, Mar. 31, 2003]

Subpart B—Administrative Actions on Applications

§ 514.80 Records and reports concerning experience with approved new animal drugs.

The following table outlines the purpose for each paragraph of this section:

Purpose	21 CFR Paragraph and Title
What information must be reported concerning approved NADAs or ANADAs?	514.80(a) Applicability.
What authority does FDA have for requesting records and reports? Who is required to establish, maintain, and report required information relating to experiences with a new animal drug? Is information from foreign sources required?	514.80(a)(1).
What records must be established and maintained and what reports filed with FDA?	514.80(a)(2).
What is FDA's purpose for requiring reports?	514.80(a)(3).
Do applicants of Type A medicated articles have to establish, maintain, and report information required under § 514.80?	514.80(a)(4).
How do the requirements under § 514.80 relate to current good manufacturing practices?	514.80(a)(5).
	514.80(b) Reporting requirements.
What are the requirements for reporting product/manufacturing defects?	514.80(b)(1) Three-day NADA/ANADA field alert report.
	514.80(b)(2) Fifteen-day NADA/ANADA alert report.
What are the requirements for reporting serious and unexpected adverse drug experiences?	514.80(b)(2)(i) Initial report.
What are the requirements for followup reporting of serious and unexpected adverse drug experiences?	514.80(b)(2)(ii) Followup report.
What are the requirements for nonapplicants for reporting adverse drug experiences?	514.80(b)(3) Nonapplicant report.
What are the general requirements for submission of periodic drug experience reports, e.g., forms to be submitted, submission date and frequency, when is it to be submitted, how many copies? How do I petition to change the date of submission or frequency of submissions?	514.80(b)(4) Periodic drug experience report.
What must be submitted in the periodic drug experience reports?	514.80(b)(4)(i) through (b)(4)(iv).
What distribution data must be submitted? How should the distribution data be submitted?	514.80(b)(4)(i) Distribution data.
What labeling materials should be submitted? How do I report changes to the labeling materials since the last report?	514.80(b)(4)(ii) Labeling.

Purpose	21 CFR Paragraph and Title
	514.80(b)(4)(iii) Nonclinical laboratory studies and clinical data not previously reported.
What are the requirements for submission of nonclinical laboratory studies?	514.80(b)(4)(iii)(A).
What are the requirements for submission of clinical laboratory data?	514.80(b)(4)(iii)(B).
When must results of clinical trials conducted by or for the applicant be reported?	514.80(b)(4)(iii)(C).
	514.80(b)(4)(iv) Adverse drug experiences.
How do I report product/manufacturing defects and adverse drug experiences not previously reported to FDA?	514.80(b)(4)(iv)(A).
What are the requirements for submitting adverse drug experiences cited in literature?	514.80(b)(4)(iv)(B).
What are the requirements for submitting adverse drug experiences in postapproval studies and clinical trials?	514.80(b)(4)(iv)(C).
What are the requirements for reporting increases in the frequency of serious, expected, and unexpected adverse drug experiences?	514.80(b)(4)(v) Summary report of increased frequency of adverse drug experience.
	514.80(b)(5) Other reporting.
Can FDA request that an applicant submit information at different times than stated specifically in this regulation?	514.80(b)(5)(i) Special drug experience report.
What are the requirements for submission of advertisement and promotional labeling to FDA?	514.80(b)(5)(ii) Advertisements and promotional labeling.
What are the requirements for adding a new distributor to the approved application?	514.80(b)(5)(iii) Distributor's statement.
What labels and how many labels need to be submitted for review?	514.80(b)(5)(iii)(A).
What changes are required and allowed to distributor labeling?	514.80(b)(5)(iii)(A)(*1*).
What are the requirements for making other changes to the distributor labeling?	514.80(b)(5)(iii)(A)(*2*).
What information should be included in each new distributor's signed statement?	514.80(b)(5)(iii)(B)(*1*) through (b)(5)(iii)(B)(*5*).
What are the conditions for submitting information that is common to more than one application? (i.e., can I submit common information to one application?)	514.80(c) Multiple applications.
What information has to be submitted to the common application and related application?	514.80(c)(1) through (c)(4).
What forms do I need? What are Forms FDA 1932 and 2301? How can I get them? Can I use computer-generated equivalents?	514.80(d) Reporting forms.
How long must I maintain Form FDA 1932 and records and reports of other required information, i.e., how long do I need to maintain this information?	514.80(e) Records to be maintained.
What are the requirements for allowing access to these records and reports, and copying by authorized FDA officer or employee?	514.80(f) Access to records and reports.
How do I obtain Forms FDA 1932 and 2301? Where do I mail FDA's required forms, records, and reports?	514.80(g) Mailing addresses.
What happens if the applicant fails to establish, maintain, or make the required reports? What happens if the applicant refuses to allow FDA access to, and/or copying and/or verify records and reports?	514.80(h) Withdrawal of approval.

Purpose	21 CFR Paragraph and Title
Does an adverse drug experience reflect a conclusion that the report or information constitutes an admission that the drug caused an adverse effect?	514.80(i) Disclaimer.

(a) *Applicability*. (1) Each applicant must establish and maintain indexed and complete files containing full records of all information pertinent to safety or effectiveness of a new animal drug that has not been previously submitted as part of the NADA or ANADA. Such records must include information from domestic as well as foreign sources. Each nonapplicant must establish and maintain indexed and complete files containing full records of all information pertinent to safety or effectiveness of a new animal drug that is received or otherwise obtained by the nonapplicant. Such records must include information from domestic as well as foreign sources.

(2) Each applicant must submit reports of data, studies, and other information concerning experience with new animal drugs to the Food and Drug Administration (FDA) for each approved NADA and ANADA, as required in this section. A nonapplicant must submit data, studies, and other information concerning experience with new animal drugs to the appropriate applicant, as required in this section. The applicant, in turn, must report the nonapplicant's data, studies, and other information to FDA. Applicants and nonapplicants must submit data, studies, and other information described in this section from domestic, as well as foreign sources.

(3) FDA reviews the records and reports required in this section to facilitate a determination under section 512(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA.

(4) The requirements of this section also apply to any approved Type A medicated article. In addition, the requirements contained in § 514.80(b)(1), (b)(2), (b)(4)(iv), and (b)(4)(v) apply to any approved Type A medicated article incorporated in animal feeds.

(5) The records and reports referred to in this section are in addition to those required by the current good manufacturing practice regulations in parts 211, 225, and 226 of this chapter.

(b) *Reporting requirements*—(1) *Three-day NADA/ANADA field alert report*. This report provides information pertaining to product and manufacturing defects that may result in serious adverse drug events. The applicant (or nonapplicant through the applicant) must submit the report to the appropriate FDA District Office or local FDA resident post within 3 working days of first becoming aware that a defect may exist. The information initially may be provided by telephone or other telecommunication means, with prompt written followup using Form FDA 1932 ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' The mailing cover for these reports must be plainly marked ''3-Day NADA/ANADA Field Alert Report.''

(2) *Fifteen-day NADA/ANADA alert report*—(i) *Initial report*. This report provides information on each serious, unexpected adverse drug event, regardless of the source of the information. The applicant (or nonapplicant through the applicant) must submit the report to FDA within 15 working days of first receiving the information. The report must be submitted on Form FDA 1932, and its mailing cover must be plainly marked ''15-Day NADA/ANADA Alert Report.''

(ii) *Followup report*. The applicant must promptly investigate all adverse drug events that are the subject of 15-day NADA/ANADA alert reports. If this investigation reveals significant new information, a followup report must be submitted within 15 working days of receiving such information. A followup report must be submitted on Form FDA 1932, and its mailing cover must be plainly marked ''15-Day NADA/ANADA Alert Report Followup.'' The followup report must state the date of the initial report and provide the additional information. If additional information is sought but not obtained

within 3 months of the initial report, a followup report is required describing the steps taken and why additional information was not obtained.

(3) *Nonapplicant report.* Nonapplicants must forward reports of adverse drug experiences to the applicant within 3 working days of first receiving the information. The applicant must then submit the report(s) to FDA as required in this section. The nonapplicant must maintain records of all nonapplicant reports, including the date the nonapplicant received the information concerning adverse drug experiences, the name and address of the applicant, and a copy of the adverse drug experience report including the date such report was submitted to the applicant. If the nonapplicant elects to also report directly to FDA, the nonapplicant should submit the report on Form FDA 1932 within 15 working days of first receiving the information.

(4) *Periodic drug experience report.* This report must be accompanied by a completed Form FDA 2301 ''Transmittal of Periodic Reports and Promotional Materials for New Animal Drugs.'' It must be submitted every 6 months for the first 2 years following approval of an NADA or ANADA and yearly thereafter. Reports required by this section must contain data and information for the full reporting period. The 6-month periodic drug experience reports must be submitted within 30 days following the end of the 6-month reporting period. The yearly periodic drug experience reports must be submitted within 90 days of the anniversary date of the approval of the NADA or ANADA. Any previously submitted information contained in the report must be identified as such. For yearly (annual) periodic drug experience reports, the applicant may petition FDA to change the date of submission or frequency of reporting, and after approval of such petition, file such reports on the new filing date or at the new reporting frequency. Also, FDA may require a report at different times or more frequently. The periodic drug experience report must contain the following:

(i) *Distribution data.* (A) Information about the distribution of each new animal drug product, including information on any distributor-labeled product. This information must include the total number of distributed units of each size, strength, or potency (*e.g.*, 100,000 bottles of 100 5-milligram tablets; 50,000 10-milliliter vials of 5-percent solution). This information must be presented in two categories: Quantities distributed domestically and quantities exported.

(B) Applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under § 514.87 have the option not to report distribution data under paragraph (b)(4)(i)(A) of this section for the approved applications that include these same products, but only provided each of the following conditions are met:

(*1*) Applicants must have submitted complete periodic drug experience reports under this section for such applications for at least 2 full years after the date of their initial approval.

(*2*) Applicants must ensure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. For applications that currently have a reporting period that begins on a date other than January 1, applicants must request a change in reporting submission date such that the reporting period begins on January 1 and ends on December 31, as described in paragraph (b)(4) of this section.

(*3*) Applicants that change their reporting submission date must also submit a special drug experience report, as described in paragraph (b)(5)(i) of this section, that addresses any gaps in distribution data caused by the change in date of submission.

(*4*) Applicants who choose not to report under paragraph (b)(4)(i)(A) of this section must ensure that full sales and distribution data for each product approved under such applications are alternatively reported under § 514.87, including products that are labeled for use only in nonfood-producing animals.

(ii) *Labeling.* Applicant and distributor current package labeling, including package inserts (if any). For large-size package labeling or large shipping cartons, a representative copy must be submitted (e.g., a photocopy of pertinent areas of large feed bags). A summary of any changes in labeling

made since the last report (listed by date of implementation) must be included with the labeling or if there have been no changes, a statement of such fact must be included with the labeling.

(iii) Nonclinical laboratory studies and clinical data not previously reported.

(A) Copies of in vitro studies (e.g., mutagenicity) and other nonclinical laboratory studies conducted by or otherwise obtained by the applicant.

(B) Copies of published clinical trials of the new animal drug (or abstracts of them) including clinical trials on safety and effectiveness, clinical trials on new uses, and reports of clinical experience pertinent to safety conducted by or otherwise obtained by the applicant. Review articles, papers, and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data are not required to be reported.

(C) Descriptions of completed clinical trials conducted by or for the applicant must be submitted no later than 1 year after completion of research. Supporting information is not to be reported.

(iv) *Adverse drug experiences.* (A) Product/manufacturing defects and adverse drug experiences not previously reported under § 514.80(b)(1) and (b)(2) must be reported individually on Form FDA 1932.

(B) Reports of adverse drug experiences in the literature must be noted in the periodic drug experience report. A bibliography of pertinent references must be included with the report. Upon FDA's request, the applicant must provide a full text copy of these publications.

(C) Reports of previously not reported adverse drug experiences that occur in postapproval studies must be reported separately from other experiences in the periodic drug experience report and clearly marked or highlighted.

(v) *Summary report of increased frequency of adverse drug experience.* The applicant must periodically review the incidence of reports of adverse drug experiences to determine if there has been an increased frequency of serious (expected and unexpected) adverse drug events. The applicant must evaluate the increased frequency of serious (expected or unexpected) adverse drug events at least as often as reporting of periodic drug experience reports. The applicant must report the increased frequency of serious (expected and unexpected) adverse drug events in the periodic drug experience report. Summaries of reports of increased frequency of adverse drug events must be submitted in narrative form. The summaries must state the time period on which the increased frequency is based, time period comparisons in determining increased frequency, references to any previously submitted Form FDA 1932, the method of analysis, and the interpretation of the results. The summaries must be submitted in a separate section within the periodic drug experience report.

(5) *Other reporting*—(i) *Special drug experience report.* Upon written request, FDA may require that the applicant submit a report required under § 514.80 at different times or more frequently than the timeframes stated in § 514.80.

(ii) *Advertisements and promotional labeling.* The applicant must submit at the time of initial dissemination one set of specimens of mailing pieces and other labeling for prescription and over-the-counter new animal drugs. For prescription new animal drugs, the applicant must also submit one set of specimens of any advertisement at the time of initial publication or broadcast. Mailing pieces and labeling designed to contain product samples must be complete except that product samples may be omitted. Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

(iii) *Distributor's statement.* At the time of initial distribution of a new animal drug product by a distributor, the applicant must submit a special drug experience report accompanied by a completed Form FDA 2301 containing the following:

(A) The distributor's current product labeling.

(*1*) The distributor's labeling must be identical to that in the approved NADA/ANADA except for a different and suitable proprietary name (if used)

and the name and address of the distributor. The name and address of the distributor must be preceded by an appropriate qualifying phrase as permitted by the regulations such as ''manufactured for'' or ''distributed by.''

(*2*) Other labeling changes must be the subject of a supplemental NADA or ANADA as described under § 514.8.

(B) A signed statement by the distributor stating:

(*1*) The category of the distributor's operations (e.g., wholesale or retail),

(*2*) That the distributor will distribute the new animal drug only under the approved labeling,

(*3*) That the distributor will promote the product only for use under the conditions stated in the approved labeling,

(*4*) That the distributor will adhere to the records and reports requirements of this section, and

(*5*) That the distributor is regularly and lawfully engaged in the distribution or dispensing of prescription products if the product is a prescription new animal drug.

(c) *Multiple applications.* Whenever an applicant is required to submit a periodic drug experience report under the provisions of § 514.80(b)(4) with respect to more than one approved NADA or ANADA for preparations containing the same new animal drug so that the same information is required to be reported for more than one application, the applicant may elect to submit as a part of the report for one such application (the primary application) all the information common to such applications in lieu of reporting separately and repetitively on each. If the applicant elects to do this, the applicant must do the following:

(1) State when a report applies to multiple applications and identify all related applications for which the report is submitted by NADA or ANADA number.

(2) Ensure that the primary application contains a list of the NADA or ANADA numbers of all related applications.

(3) Submit a completed Form FDA 2301 to the primary application and each related application with reference to the primary application by NADA/ANADA number and submission date for the complete report of the common information.

(4) All other information specific to a particular NADA/ANADA must be included in the report for that particular NADA/ANADA.

(d) *Reporting forms.* Applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301 ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs,'' in accordance with directions provided on the forms. Computer-generated equivalents of Form FDA 1932 or Form FDA 2301, approved by FDA before use, may be used. Form FDA 1932 and Form FDA 2301 may be obtained on the Internet at *http://www.fda.gov/cvm/forms/forms.html*, by telephoning the Division of Surveillance (HFV–210), or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance (HFV–210), 7500 Standish Pl., Rockville, MD 20855–2764.

(e) *Records to be maintained.* The applicants and nonapplicants must maintain records and reports of all information required by this section for a period of 5 years after the date of submission.

(f) *Access to records and reports.* The applicant and nonapplicant must, upon request from any authorized FDA officer or employee, at all reasonable times, permit such officer or employee to have access to copy and to verify all such required records and reports.

(g) *Mailing addresses.* Completed 15-day alert reports, periodic drug experience reports, and special drug experience reports must be submitted to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855–2764. Three-day alert reports must be submitted to the appropriate FDA district office or local FDA resident post. Addresses for district offices and resident posts may be obtained from the Internet at *http://www.fda.gov*

(click on ''Contact FDA,'' then ''FDA Field Offices'').

(h) *Withdrawal of approval.* If FDA finds that the applicant has failed to establish the required records, or has failed to maintain those records, or failed to make the required reports, or has refused access to an authorized FDA officer or employee to copy or to verify such records or reports, FDA may withdraw approval of the application to which such records or reports relate. If FDA determines that withdrawal of the approval is necessary, the agency shall give the applicant notice and opportunity for hearing, as provided in § 514.200, on the question of whether to withdraw approval of the application.

(i) *Disclaimer.* Any report or information submitted under this section and any release of that report or information by FDA will be without prejudice and does not necessarily reflect a conclusion that the report or information constitutes an admission that the drug caused or contributed to an adverse event. A person need not admit, and may deny, that the report or information constitutes an admission that a drug caused or contributed to an adverse event.

[68 FR 15365, Mar. 31, 2003, as amended at 81 FR 29141, May 11, 2016]

§ 514.87 Annual reports for antimicrobial animal drug sales and distribution.

(a) The applicant for each new animal drug product approved under section 512 of the Federal Food, Drug, and Cosmetic Act, or conditionally approved under section 571 of the Federal Food, Drug, and Cosmetic Act, and containing an antimicrobial active ingredient, must submit an annual report to FDA on the amount of each such antimicrobial active ingredient in the drug that is sold or distributed in the reporting year for use in food-producing animal species, including information on any distributor-labeled product.

(b) This report must identify the approved or conditionally approved application and must include the following information for each new animal drug product described in paragraph (a) of this section:

(1) A listing of each antimicrobial active ingredient contained in the product;

(2) A description of each product sold or distributed by unit, including the container size, strength, and dosage form of such product units;

(3) For each such product, a listing of the target animal species, indications, and production classes that are specified on the approved label;

(4) For each such product, the number of units sold or distributed in the United States (*i.e.*, domestic sales) for each month of the reporting year; and

(5) For each such product, the number of units sold or distributed outside the United States (*i.e.*, quantities exported) for each month of the reporting year.

(c) Each report must also provide a species-specific estimate of the percentage of each product described in paragraph (b)(2) of this section that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of ''other species/unknown'' must also be reported.

(d) Each report must:

(1) Be submitted not later than March 31 each year;

(2) Cover the period of the preceding calendar year; and

(3) Be submitted using Form FDA 3744, ''Antimicrobial Animal Drug Distribution Report.''

(e) Sales and distribution data and information reported under this section will be considered to fall within the exemption for confidential commercial information established in § 20.61 of this chapter and will not be publicly disclosed, except that summary reports of such information aggregated in such a way that does not reveal information that is not available for public disclosure under this provision will be prepared by FDA and made available to the public as provided in paragraph (f) of this section.

(f) FDA will publish an annual summary report of the data and information it receives under this section for each calendar year by December 31 of the following year. Such annual reports must include a summary of sales and distribution data and information by antimicrobial drug class and may include additional summary data and information as determined by FDA. In order to protect confidential commercial information, each individual datum appearing in the summary report must:

(1) Reflect combined product sales and distribution data and information obtained from three or more distinct sponsors of approved products that were actively sold or distributed that reporting year, and

(2) Be reported in a manner consistent with protecting both national security and confidential commercial information.

[81 FR 29141, May 11, 2016]

§ 514.100 Evaluation and comment on applications.

(a) After the filed application has been evaluated, the applicant will be furnished written comment on any apparent deficiencies in the application.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the new animal drug solely from consideration of this description, the applicant may be notified that an establishment inspection is required to verify their adequacy.

(c) A request for samples of a new animal drug or any edible tissues and byproducts of animals treated with such a drug, shall specify the quantity deemed adequate to permit tests of analytical methods to determine their adequacy for regulatory purposes. The request should be made as early in the 180-day period as possible to assure timely completion. The date used for computing the 180-day limit for the purposes of section 512(c) of the act shall be moved forward 1 day for each day after the mailing date of the request until all of the requested samples are received. If the samples are not received within 90 days after the request, the application will be considered withdrawn without prejudice.

(d) The information contained in an application may be insufficient to determine whether a new animal drug is safe or effective in use if it fails to include (among other things) a statement showing whether such drug is to be limited to prescription sale and exempt under section 502(f) of the act from the requirement that its labeling bear adequate directions for lay use. If such drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for professional use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer such drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 201.105 of this chapter, and information concerning hazards, contraindications, side effects, and precautions relevant with respect to any uses for which such drug is to be prescribed.

(2) The application fails to show that the labeling and advertising of such drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for professional use of such drug will contain, in the same language and emphasis, the information for use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application in accordance with § 201.105 of this chapter.

(e) The information contained in an application will be considered insufficient to determine whether a new animal drug is safe and effective for use when there is a refusal or failure upon

written notice to furnish inspectors authorized by the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and records pertinent to the application.

(f) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

(g) When an application has been found incomplete on the basis of a need for the kind of information described in § 514.6, such application shall be considered withdrawn without prejudice to future filing on the date of issuance of the letter citing the inadequacies contained in the application, unless within 30 days the sponsor chooses to avail himself of the opportunity for hearing as prescribed by § 514.111.

§ 514.105 Approval of applications.

(a) The Commissioner shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which the new animal drug may be used, including the name and address of the applicant; the conditions and indications for use covered by the application; any tolerance, withdrawal period, or other use restrictions; any tolerance required for the new animal drug substance or its metabolites in edible products of food-producing animals; and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed; and such other information the Commissioner deems necessary to assure safe and effective use.

(b) He shall notify the applicant by sending him a copy of the proposed publication as described in paragraph (a)(1) of this section.

[40 FR 13825, Mar. 27, 1975, as amended at 51 FR 7392, Mar. 3, 1986; 64 FR 63203, Nov. 19, 1999]

§ 514.106 Approval of supplemental applications.

(a) Within 180 days after a supplement to an approved application is filed pursuant to § 514.8, the Commissioner shall approve the supplemental application in accordance with procedures set forth in § 514.105(a)(1) and (2) if he/she determines that the application satisfies the requirements of applicable statutory provisions and regulations.

(b) The Commissioner will assign a supplemental application to its proper category to ensure processing of the application.

(1) *Category I.* Supplements that ordinarily do not require a reevaluation of any of the safety or effectiveness data in the parent application. Category I supplements include the following:

(i) A corporate change that alters the identity or address of the sponsor of the new animal drug application (NADA).

(ii) The sale, purchase, or construction of manufacturing facilities.

(iii) The sale or purchase of an NADA.

(iv) A change in container, container style, shape, size, or components.

(v) A change in approved labeling (color, style, format, addition, deletion, or revision of certain statements, e.g., trade name, storage, expiration dates, etc).

(vi) A change in promotional material for a prescription new animal drug not exempted by § 514.8(c)(2)(i)(C)(*1*) through (c)(2)(i)(C)(*3*).

(vii) Changes in manufacturing processes that do not alter the method of manufacture or change the final dosage form.

(viii) A change in bulk drug shipments.

(ix) A change in an analytical method or control procedures that do not alter the approved standards.

(x) A change in an expiration date.

(xi) Addition of an alternate manufacturer, repackager, or relabeler of the drug product.

(xii) Addition of an alternate supplier of the new drug substance.

(xiii) A change permitted in advance of approval as described under § 514.8(b)(3).

(2) *Category II.* Supplements that may require a reevaluation of certain safety or effectiveness data in the parent application. Category II supplements include the following:

(i) A change in the active ingredient concentration or composition of the final product.

(ii) A change in quality, purity, strength, and identity specifications of the active or inactive ingredients.

(iii) A change in dose (amount of drug administered per dose).

(iv) A change in the treatment regimen (schedule of dosing).

(v) Addition of a new therapeutic claim to the approved uses of the product.

(vi) Addition of a new or revised animal production claim.

(vii) Addition of a new species.

(viii) A change in the prescription or over-the-counter status of a drug product.

(ix) A change in statements regarding side effects, warnings, precautions, and contraindications, except the addition of approved statements to container, package, and promotional labeling, and prescription drug advertising.

(x) A change in the drug withdrawal period prior to slaughter or in the milk discard time.

(xi) A change in the tolerance for drug residues.

(xii) A change in analytical methods for drug residues.

(xiii) A revised method of synthesis or fermentation of the new drug substance.

(xiv) Updating or changes in the manufacturing process of the new drug substance and/or final dosage form (other than a change in equipment that does not alter the method of manufacture of a new animal drug, or a change from one commercial batch size to another without any change in manufacturing procedure), or changes in the methods, facilities, or controls used for the manufacture, processing, packaging, or holding of the new animal drug (other than use of an establishment not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

[55 FR 46052, Nov. 1, 1990; 55 FR 49973, Dec. 3, 1990; 56 FR 12422, Mar. 25, 1991; 71 FR 74785, Dec. 13, 2006]

§ 514.110 Reasons for refusing to file applications.

(a) The date of receipt of an application for a new animal drug shall be the date on which the application shall be deemed to be filed.

(b) An application for a new animal drug shall not be considered acceptable for filing for any of the following reasons:

(1) It does not contain complete and accurate English translations of any pertinent part in a foreign language.

(2) Fewer than three copies are submitted.

(3) It is incomplete on its face in that it is not properly organized and indexed.

(4) On its face the information concerning required matter is so inadequate that the application is clearly not approvable.

(5) The new animal drug is to be manufactured, prepared, propagated, compounded, or processed in whole or in part in any State in an establishment that has not been registered or exempted from registration under the provisions of section 510 of the act.

(6) The sponsor does not reside or maintain a place of business within the United States and the application has not been countersigned by an attorney, agent, or other representative of the applicant, which representative resides in the United States and has been duly authorized to act on behalf of the applicant and to receive communications on all matters pertaining to the application.

(7) The new animal drug is a drug subject to licensing under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*). Such applications will be referred to the U.S. Department of Agriculture for action.

(8) It fails to include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reasons for the noncompliance.

(9) [Reserved]

(10) The applicant fails to submit a complete environmental assessment under §25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under §25.30 or §25.33 of this chapter.

(c) If an application is determined not to be acceptable for filing, the applicant shall be notified within 30 days of receipt of the application and shall be given the reasons therefore.

(d) If the applicant disputes the findings that his application is not acceptable for filing, he may make written request that the application be filed over protest, in which case it will be filed as of the day originally received.

[40 FR 13825, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 62 FR 40600, July 29, 1997]

§514.111 Refusal to approve an application.

(a) The Commissioner shall, within 180 days after the filing of the application, inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to a new animal drug, that:

(1) The reports of investigations required to be submitted pursuant to section 512(b) of the act do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substance formed in or on food because of the use of such drug;

(ii) The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substances;

(iii) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data; and

(iv) Whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice; or

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence as defined in §514.4.

(6) Failure to include an appropriate proposed tolerance for residues in edible products derived from animals or a withdrawal period or other restrictions for use of such drug if any tolerance or withdrawal period or other restrictions for use are required in order to assure that the edible products derived from animals treated with such drug will be safe.

(7) Based on a fair evaluation of all material facts, the labeling is false or misleading in any particular; or

(8) Such drug induces cancer when ingested by man or animal or, after appropriate tests for evaluation of the safety of such drug, induces cancer in man or animal, except that this subparagraph shall not apply with respect to such drug if the Commissioner finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice:

(i) Such drug will not adversely affect the animal for which it is intended; and

(ii) No residue of such drug will be found (by methods of examination prescribed or approved by the Commissioner by regulations) in any edible portion of such animal after slaughter or in any food yielded by, or derived from the living animals.

(9) The applicant fails to submit an adequate environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter.

(10) The drug fails to satisfy the requirements of subpart E of part 500 of this chapter.

(11) Any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(12) The drug will be produced in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the Federal Food, Drug, and Cosmetic Act and part 207 of this chapter.

(b) The Commissioner, as provided in § 514.200 of this chapter, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

[40 FR 13825, Mar. 27, 1975, as amended at 43 FR 22675, May 26, 1978; 44 FR 16007, Mar. 16, 1979; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 49588, Dec. 31, 1987; 54 FR 18280, Apr. 28, 1989; 62 FR 40600, July 29, 1997; 63 FR 10770, Mar. 5, 1998; 64 FR 40757, July 28, 1999; 64 FR 63204, Nov. 19, 1999; 81 FR 60221, Aug. 31, 2016]

§ 514.115 Withdrawal of approval of applications.

(a) The Secretary may suspend approval of an application approved pursuant to section 512(c) of the act and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such new animal drug or animal feed is intended.

(b) The Commissioner shall notify in writing the person holding an application approved pursuant to section 512(c) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application, or such changes are those for which written authorization or approval is not required as provided for in § 514.8. The supplemental application shall be treated in the same manner as the original application.

(3) That in the case of an application for use of a new animal drug approved or deemed approved pursuant to section 512(c) of the act:

(i) Experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(ii) New evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods,

or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that section 512(d)(1)(H) of the act applies to such drug; or

(iii) On the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

(4) That any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(c) The Commissioner may notify in writing the person holding an application approved pursuant to section 512(c) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under section 512(l)(1) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by section 512(l)(2) of the act; or

(2) That on the basis of new information before him evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug or animal feed are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(d) Approval of an application pursuant to section 512(c) of the act will be withdrawn on the basis of a request for its withdrawal submitted in writing by a person holding an approved new animal drug application on the grounds that the drug subject to such application is no longer being marketed and information is included in support of this finding, provided none of the conditions cited in paragraphs (a), (b), and (c) of this section pertain to the subject drug. A written request for such withdrawal shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Withdrawal of approval of an application under the provisions of this paragraph shall be without prejudice.

(e) On the basis of the withdrawal of approval of an application for a new animal drug approved pursuant to section 512(c) of the act, the regulation published pursuant to section 512(i) of the act covering the conditions of use of such drug as provided for in the application shall be revoked.

[40 FR 13825, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 64 FR 63204, Nov. 19, 1999]

§514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§ 514.117 Adequate and well-controlled studies.

(a) *Purpose.* The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well controlled, as used in the phrase adequate and well controlled, emphasizes an important aspect of adequacy. The Food and Drug Administration (FDA) considers these characteristics in determining whether a study is adequate and well controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Adequate and well-controlled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be relied upon to support target animal safety. The report of an adequate and well-controlled study should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) *Characteristics.* An adequate and well-controlled study has the following characteristics:

(1) The protocol for the study (protocol) and the report of the study results (study report) must include a clear statement of the study objective(s).

(2) The study is conducted in accordance with an appropriate standard of conduct that addresses, among other issues, study conduct, study personnel, study facilities, and study documentation. The protocol contains a statement acknowledging the applicability of, and intention to follow, a standard of conduct acceptable to FDA. The study report contains a statement describing adherence to the standard.

(3) The study is conducted with a new animal drug that is produced in accordance with appropriate manufacturing practices, which include, but are not necessarily limited to, the manufacture, processing, packaging, holding, and labeling of the new animal drug such that the critical characteristics of identity, strength, quality, purity, and physical form of the new animal drug are known, recorded, and reproducible, to permit meaningful evaluations of and comparisons with other studies conducted with the new animal drug. The physical form of a new animal drug includes the formulation and physical characterization (including delivery systems thereof, if any) of the new animal drug as presented to the animal. The protocol and study report must include an identification number which can be correlated with the specific formulation and production process used to manufacture the new animal drug used in the study.

(4) The study uses a design that permits a valid comparison with one or more controls to provide a quantitative evaluation of drug effects. The protocol and the study report must describe the precise nature of the study design, e.g., duration of treatment periods, whether treatments are parallel, sequential, or crossover, and the determination of sample size. Within the broad range of studies conducted to support a determination of the effectiveness of a new animal drug, certain of the controls listed below would be appropriate and preferred depending on the study conducted:

(i) *Placebo concurrent control.* The new animal drug is compared with an inactive preparation designed to resemble the new animal drug as far as possible.

(ii) *Untreated concurrent control.* The new animal drug is compared with the absence of any treatment. The use of this control may be appropriate when objective measurements of effectiveness, not subject to observer bias, are available.

(iii) *Active treatment concurrent control.* The new animal drug is compared with known effective therapy. The use of this control is appropriate when the use of a placebo control or of an untreated concurrent control would unreasonably compromise the welfare of

the animals. Similarity of the new animal drug and the active control drug can mean either that both drugs were effective or that neither was effective. The study report should assess the ability of the study to have detected a difference between treatments. The evaluation of the study should explain why the new animal drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control.

(iv) *Historical control.* The results of treatment with the new animal drug are quantitatively compared with experience historically derived from the adequately documented natural history of the disease or condition, or with a regimen (therapeutic, diagnostic, prophylactic) whose effectiveness is established, in comparable animals. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies in which the effect of the new animal drug is self-evident or studies of diseases with high and predictable mortality, or signs and symptoms of predictable duration or severity, or, in the case of prophylaxis, predictable morbidity.

(5) The study uses a method of selecting animals that provides adequate assurances that the animals are suitable for the purposes of the study. For example, the animals can reasonably be expected to have animal production characteristics typical of the class(es) of animals for which the new animal drug is intended, there is adequate assurance that the animals have the disease or condition being studied, or, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired has been provided. The protocol and the study report describe the method of selecting animals for the study.

(6) The study uses a method to assign a treatment or a control to each experimental unit of animals that is random and minimizes bias. Experimental units of animals are groups of animals that are comparable with respect to pertinent variables such as age, sex, class of animal, severity of disease, duration of disease, dietary regimen, level of animal production, and use of drugs or therapy other than the new animal drug. The protocol and the study report describe the method of assignment of animals to an experimental unit to account for pertinent variables and method of assignment of a treatment or a control to the experimental units. When the effect of such variables is accounted for by an appropriate design, and when, within the same animal, effects due to the test drug can be obtained free of the effects of such variables, the same animal may be used for both the test drug and the control using the controls set forth in paragraph (b)(4) of this section.

(7) The study uses methods to minimize bias on the part of observers and analysts of the data that are adequate to prevent undue influences on the results and interpretation of the study data. The protocol and study report explain the methods of observation and recording of the animal response variables and document the methods, such as ''blinding'' or ''masking,'' used in the study for excluding or minimizing bias in the observations.

(8) The study uses methods to assess animal response that are well defined and reliable. The protocol and study report describe the methods for conducting the study, including any appropriate analytical and statistical methods, used to collect and analyze the data resulting from the conduct of the study, describe the criteria used to assess response, and, when appropriate, justify the selection of the methods to assess animal response.

(9) There is an analysis and evaluation of the results of the study in accord with the protocol adequate to assess the effects of the new animal drug. The study report evaluates the methods used to conduct, and presents and evaluates the results of, the study as to their adequacy to assess the effects of the new animal drug. This evaluation of the results of the study assesses, among other items, the comparability of treatment and control groups with respect to pertinent variables and the effects of any interim analyses performed.

(c) *Field studies.* (1) Field conditions as used in this section refers to conditions which closely approximate the conditions under which the new animal drug, if approved, is intended to be applied or administered.

(2) Studies of a new animal drug conducted under field conditions shall, consistent with generally recognized scientific principles and procedures, use an appropriate control that permits comparison, employ procedures to minimize bias, and have the characteristics generally described in paragraph (b) of this section. However, because field studies are conducted under field conditions, it is recognized that the level of control over some study conditions need not or should not be the same as the level of control in laboratory studies. While not all conditions relating to a field study need to be or should be controlled, observations of the conditions under which the new animal drug is tested shall be recorded in sufficient detail to permit evaluation of the study. Adequate and well-controlled field studies shall balance the need to control study conditions with the need to observe the true effect of the new animal drug under closely approximated actual use conditions.

(d) *Waiver.* The Director of the Center for Veterinary Medicine (the Director) may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular study, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the studies so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(e) *Uncontrolled studies.* Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness or target animal safety. Such studies, carefully conducted and documented, may provide corroborative support of adequate and well-controlled studies regarding effectiveness and may yield valuable data regarding safety of the new animal drug. Such studies will be considered on their merits in light of the characteristics listed here. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

[63 FR 10770, Mar. 5, 1998]

§ 514.120 Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.

The Commissioner, upon his own initiative or upon request of an applicant stating reasonable grounds therefor and if he finds that the facts so require, may issue an order approving an application that previously has had its approval refused, suspended, or withdrawn.

§ 514.121 Service of notices and orders.

All notices and orders under this subchapter E and section 512 of the act pertaining to new animal drug applications shall be served:

(a) In person by any officer or employee of the Department designated by the Commissioner; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at his last known address in the records of the Food and Drug Administration.

Subpart C—Hearing Procedures

§ 514.200 Notice of opportunity for hearing; notice of participation and requests for hearing; grant or denial of hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner to refuse to approve an application or to withdraw the approval of an application will be published in the FEDERAL REGISTER together with an explanation of the grounds for the proposed action. The notice will describe how to request a hearing. An applicant has 30 days after publication of the notice to request a hearing.

(b) If the applicant fails to request a hearing within the 30-day timeframe, the Commissioner, without further notice, will publish a final order denying or withdrawing approval of the application.

(c) If the applicant desires to request a hearing:

(1) Within 30 days after publication of the notice of opportunity for hearing, the applicant must submit to the Division of Dockets Management written objections and a request for a hearing in accordance with §§ 12.20 and 12.22. This request for a hearing must include each specific objection to the proposal on which a hearing is requested, together with a detailed description and analysis of the factual information (including all relevant clinical and other investigational data) the applicant will present in support of that objection. A request for a hearing may not rest upon mere allegations or denials or general descriptions of positions or contentions, but must set forth specific reliable evidence showing there is a genuine and substantial issue of fact that requires a hearing.

(2) If the Commissioner determines upon review of the data and information submitted in the objections and request for a hearing that a hearing is not justified because no genuine and substantial issue of fact precludes the refusal to approve the application or the withdrawal of approval of the application (for example, the applicant has not identified any adequate and well-controlled clinical investigations to support the claims of effectiveness), the Commissioner will enter an order denying the hearing and stating the final findings and conclusions.

(3) If the Commissioner determines upon review of the data and information submitted in the objections and request for a hearing that a hearing is justified, the Commissioner will publish a notice setting forth the following:

(i) The regulation or order that is the subject of the hearing;

(ii) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion;

(iii) The parties to the hearing;

(iv) The specific issues of fact for resolution at the hearing;

(v) The presiding officer, or a statement that the presiding officer will be designated in a later notice; and

(vi) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. However, in the case of a denial of approval, the hearing must not occur more than 90 days after expiration of the 30-day time period in which to request a hearing, unless the presiding officer and the applicant otherwise agree; and in the case of withdrawal of approval, the hearing will occur as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the request for a hearing.

[81 FR 52997, Aug. 11, 2016]

§ 514.201 Procedures for hearings.

Hearings relating to new animal drugs under section 512(d) and (e) of the act shall be governed by part 12 of this chapter.

[64 FR 63204, Nov. 19, 1999]

Subparts D–E [Reserved]

Subpart F—Judicial Review

§ 514.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a

United States court of appeals pursuant to section 505(h) of the act.

[42 FR 4717, Jan. 25, 1977]

PART 515—MEDICATED FEED MILL LICENSE

Subpart A—Applications

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AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 64 FR 63204, Nov. 19, 1999, unless otherwise noted.

Subpart A—Applications

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Forms FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

(b) A completed medicated feed mill license must contain the following information:

(1) The full business name and address of the facility at which the manufacturing is to take place.

(2) The facility's FDA registration number as required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act).

(3) The name, title, and signature of the responsible individual or individuals for that facility.

(4) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published under section 512(i) of the act or in accordance with the index listing published under section 572(e)(2) of the act.

(5) A certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds conform to current good manufacturing practice as described in section 501(a)(2)(B) of the act and in part 225 of this chapter.

(6) A certification that the facility will establish and maintain all records required by regulation or order issued under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, and will permit access to, or copying or verification of such records.

(7) A commitment that current approved or index listed Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.

(8) A commitment to renew registration every year with FDA as required in part 207 of this chapter.

(c) Applications must be completed, signed, and submitted to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(d) Applications that are facially deficient will be returned to the applicant. All reasons for the return of the application will be made known to the applicant.

(e) Upon approval, the original copy of the application will be signed by an authorized employee of FDA designated by the Commissioner of Food and Drugs, and a copy will be returned to the applicant.

[64 FR 63204, Nov. 19, 1999, as amended at 72 FR 69121, Dec. 6, 2007; 81 FR 60221, Aug. 31, 2016]

§ 515.11 Supplemental medicated feed mill license applications.

(a) After approval of a medicated feed mill license application to manufacture animal feed, a supplemental application shall be submitted for a change in ownership and/or a change in mailing address of the facility site.

(b) Each supplemental application should be accompanied by a fully completed Form FDA 3448 and include an explanation of the change.

(c) Within 30 working days after a supplemental application has been filed, if the Commissioner of Food and Drugs determines that the application provides adequate information respecting the change in ownership and/or postal address of the facility site, then an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448. Supplemental applications that do not provide adequate information shall be returned to the applicant and all reasons for the return of the application shall be made known to the applicant.

Subpart B—Administrative Actions on Licenses

§ 515.20 Approval of medicated feed mill license applications.

Within 90 days after an application has been filed under § 515.10, if the Commissioner of Food and Drugs (the Commissioner) determines that none of the grounds for denying approval specified in section 512(m)(3) of the Federal Food, Drug, and Cosmetic Act (the act) applies, an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448.

§ 515.21 Refusal to approve a medicated feed mill license application.

(a) The Commissioner of Food and Drugs (the Commissioner) shall within 90 days, or such additional period as may be agreed upon by the Commissioner and the applicant, after the filing of an application under § 515.10, inform the applicant in writing of his/her intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, on the basis of a preapproval inspection, or upon the basis of any other information before him that:

(1) The application is incomplete, false, or misleading in any particular; or

(2) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(3) The facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published under section 512(i) or 572(e)(2) of the act.

(b) The Commissioner, as provided in § 515.30, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

[64 FR 63204, Nov. 19, 1999, as amended at 72 FR 69121, Dec. 6, 2007]

§ 515.22 Suspension and/or revocation of approval of a medicated feed mill license.

(a) The Secretary of Health and Human Services may suspend a medicated feed mill license approved under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) and give the person holding the medicated feed mill license application prompt notice of this action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended.

(b) The Commissioner of Food and Drugs (the Commissioner) shall notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing a supplemental application under § 515.11.

(c) The Commissioner may notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by sections 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

§ 515.23 Voluntary revocation of medicated feed mill license.

A license issued under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under § 558.4(b) of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

§ 515.24 Notice of revocation of a medicated feed mill license.

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) is revoked by the Commissioner of Food and Drugs (the Commissioner), the Commissioner will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

The Commissioner of Food and Drugs (the Commissioner), upon his/her own initiative or upon request of an applicant stating reasonable grounds therefor and if the Commissioner finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

§ 515.26 Services of notices and orders.

All notices and orders under this part 515 and section 512 of the Federal Food, Drug, and Cosmetic Act (the act) pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at the applicant or respondent's last known address in the records of the Food and Drug Administration.

Subpart C—Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the FEDERAL REGISTER and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of

approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

§ 515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

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516.171 Confidentiality of data and information in an index file.

Subpart D [Reserved]

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

516.1684 Paclitaxel.
516.2065 Rabacfosadine.

AUTHORITY: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

SOURCE: 72 FR 41017, July 26, 2007, unless otherwise noted.

Subpart A—General Provisions

§ 516.1 Scope.

(a) This part implements section 573 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc–2) and contains the following subparts:

(1) Subpart A—General Provisions.

(2) Subpart B—Designation of a Minor Use or Minor Species New Animal Drug.

(3) Subpart C [Reserved]

(4) Subpart D [Reserved]

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 516.2 Purpose.

This part establishes standards and procedures for implementing section 573 of the act, including designation of minor use or minor species new animal drugs and associated exclusive marketing rights.

§ 516.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to those terms when used in this part.

(b) The following definitions of terms apply to all subparts of part 516:

Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the pharmacological action of the drug substance.

Functionally superior means that a drug has been shown to provide a significant therapeutic or physiologic advantage over that provided by a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in one or more of the following ways:

(i) The drug has been shown to be more effective, as assessed by effect on a clinically meaningful endpoint in adequate and well-controlled clinical trials, than a conditionally approved or approved MUMS drug, that is otherwise the same drug. Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials will be necessary; or

(ii) The drug has been shown to be safer than a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in a substantial portion of the target population, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary.

Infrequently, as used in the minor use definition, means a disease or condition that is uncommon or that occurs only sporadically on an annualized basis.

Limited geographical areas, as used in the minor use definition, means regions of the United States distinguished by physical, chemical, or biological factors that limit the distribution of a disease or condition.

Major species means cattle, horses, swine, chickens, turkeys, dogs, and cats.

Minor species means animals, other than humans, that are not major species.

Minor use means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

MUMS drug means a new animal drug, as defined in section 201 of the act, intended for a minor use or for use in a minor species.

Same dosage form means the same as one of the dosage form categories specified in the following parts of this chapter:

(i) Part 520: Oral dosage form new animal drugs (excluding use in animal feeds as specified in part 558 of this chapter).

(ii) Part 522: Implantation or injectable dosage form new animal drugs.

(iii) Part 524: Ophthalmic and topical dosage form new animal drugs.

(iv) Part 526: Intramammary dosage forms.

(v) Part 529: Certain other dosage form new animal drugs.

(vi) Part 558: New animal drugs for use in animal feeds.

Same drug means a MUMS drug for which designation, indexing, or conditional approval is sought that meets the following criteria:

(i) If it is a MUMS drug composed of small molecules and contains the same active moiety as a prior designated, conditionally-approved, or approved MUMS drug, even if the particular ester or salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative such as a complex, chelate or clathrate is not the same, it is considered the same drug; except that, if the prior MUMS drug is conditionally approved or approved and the second MUMS drug is shown to be functionally superior to the conditionally approved or approved MUMS drug for the same intended use, it is not considered the same drug.

(ii) If it is a MUMS drug composed of large molecules (macromolecules) and contains the same principal molecular structural features (but not necessarily all of the same structural features) as a prior designated, conditionally approved, or approved MUMS drug, it is considered the same drug; except that, if the prior MUMS drug is conditionally approved or approved and the second MUMS drug is shown to be functionally superior to the conditionally approved or approved MUMS drug for the same intended use, it is not considered the same drug. This criterion will be applied as follows to different kinds of macromolecules:

(A) Two protein drugs would be considered the same if the only differences in structure between them were due to post-translational events or infidelity of translation or transcription or were minor differences in amino acid sequence; other potentially important differences, such as different glycosylation patterns or different tertiary structures, would not cause the drugs to be considered different unless the subsequent drug is shown to be functionally superior.

(B) Two polysaccharide drugs would be considered the same if they had identical saccharide repeating units, even if the number of units were to vary and even if there were postpolymerization modifications, unless the subsequent drug is shown to be functionally superior.

(C) Two polynucleotide drugs consisting of two or more distinct nucleotides would be considered the same if they had an identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars), unless the subsequent drug is shown to be functionally superior.

(D) Closely related, complex partly definable drugs with similar pharmacologic intent would be considered the same unless the subsequent drug is shown to be functionally superior.

Same intended use means an intended use of a MUMS drug, for which designation, indexing, or conditional approval is sought, that is determined to be the same as (or not different from) a previously designated, conditionally approved, or approved intended use of a MUMS drug. Same intended use is established by comparing two intended uses and not by simply comparing the specific language by means of which the intent is established in labeling in accordance with the following criteria:

(i) Two intended uses are considered the same if one of the intended uses falls completely within the scope of the other.

(ii) For intended uses associated with diseases or conditions with multiple causative organisms, two intended uses are not considered the same when they involve different causative organisms or different subsets of causative organisms of that disease or condition when the causative organisms involved can

reliably be shown to be clinically significant causes of the disease or condition.

(iii) Two intended uses of a drug are not considered the same if they involve different intended species or different definable subpopulations (including ''production classes'') of a species.

Small number of animals means equal to or less than 50,000 horses; 70,000 dogs; 120,000 cats; 310,000 cattle; 1,450,000 pigs; 14,000,000 turkeys; and 72,000,000 chickens.

Sponsor means the person requesting designation for a MUMS drug who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the person responsible for an investigation of a new animal drug (in this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs). Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts, the sponsor is responsible for compliance with applicable provisions of the act and regulations.

[72 FR 41017, July 26, 2007, as amended at 74 FR 43050, Aug. 25, 2009; 75 FR 69588, Nov. 15, 2010]

Subpart B—Designation of a Minor Use or Minor Species New Animal Drug

§ 516.11 Scope of this subpart.

This subpart implements section 573 of the act. Specifically, this subpart sets forth the procedures and requirements for submissions to FDA of requests for designation of a new animal drug for a minor use or a minor species.

§ 516.12 Purpose.

This subpart establishes standards and procedures for determining eligibility for designation and the associated incentives and benefits described in section 573 of the act, including a 7-year period of exclusive marketing rights.

§ 516.13 Definitions.

The following definitions of terms apply only in the context of subpart B of this part:

Director means the Director of the Office of Minor Use and Minor Species Animal Drug Development of the FDA Center for Veterinary Medicine.

Intended use means the intended treatment, control or prevention of a disease or condition, or the intention to affect the structure or function of the body of animals within an identified species, subpopulation of a species, or collection of species.

MUMS-designated drug means a new animal drug, as defined in section 201 of the act, intended for a minor use or for use in a minor species that has been designated under section 573 of the act.

MUMS-drug exclusive marketing rights or *exclusive marketing rights* means that, effective on the date of FDA conditional approval or approval as stated in the approval letter of an application for a MUMS-designated drug, no conditional approval or approval will be given to a subsequent application for the same drug, in the same dosage form, for the same intended use for 7 years, except as otherwise provided by law or in this subpart.

§ 516.14 Submission of requests for designation.

All correspondence relating to a request for designation of a MUMS drug must be addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development. Submissions not including all elements specified in § 516.20 will be returned to the sponsor without review.

§ 516.16 Eligibility to request designation.

The person requesting designation must be the sponsor and the real party in interest of the development and the intended or actual production and sales of the drug or the permanent-resident U.S. agent for such a sponsor.

§ 516.20 Content and format of a request for MUMS-drug designation.

(a) A sponsor that submits a request for designation of a new animal drug intended for a minor use or minor species must submit each request in the form and containing the information required in paragraph (b) of this section. While a request for designation may involve multiple intended uses, each request for designation must constitute a separate submission. A sponsor may request MUMS-drug designation of a previously unapproved drug, or a new intended use or dosage form for an already conditionally approved or approved drug. Only one sponsor may receive MUMS-drug designation of the same drug, in the same dosage form, for the same intended use.

(b) A sponsor must submit two copies of a completed, dated, and signed request for designation that contains the following information:

(1) A request for designation of a new animal drug for a minor use or use in a minor species, which must be specific.

(2) The name and address of the sponsor; the name of the sponsor's primary contact person and/or permanent-resident U.S. agent including title, address, and telephone number; the established name (and proprietary name, if any) of the active pharmaceutical ingredient of the drug; and the name and address of the source of the active pharmaceutical ingredient of the drug.

(3) A description of the proposed intended use for which the drug is being or will be investigated.

(4) A description of the drug and dosage form.

(5) A discussion of the scientific rationale for the intended use of the drug; specific reference, including date(s) of submission, to all data from nonclinical laboratory studies, clinical investigations, copies of pertinent unpublished and published papers, and other relevant data that are available to the sponsor, whether positive, negative, or inconclusive.

(6) A specific description of the product development plan for the drug, its dosage form, and its intended use.

(7) If the drug is intended for a minor use in a major species, documentation in accordance with § 516.21, with appended authoritative references, to demonstrate that such use is a minor use.

(8) A statement that the sponsor submitting the request is the real party in interest of the development and the intended or actual production and sales of the product.

(9) A statement that the sponsor acknowledges that, upon granting a request for MUMS designation, FDA will make information regarding the designation publicly available as specified in § 516.28.

[72 FR 41017, July 26, 2007, as amended at 75 FR 69588, Nov. 15, 2010; 77 FR 18685, Mar. 28, 2012]

§ 516.21 Documentation of minor use status.

So that FDA can determine whether a drug qualifies for MUMS-drug designation as a minor use in a major species under section 573 of the act, the sponsor shall include in its request to FDA for MUMS-drug designation under § 516.20 documentation demonstrating that the use is limited to a small number of animals (annualized). This documentation must include the following information:

(a) The estimated total number of animals to which the drug could potentially be administered on an annual basis for the treatment, control, or prevention of the disease or condition for which the drug is being developed, including animals administered the drug as part of herd or flock treatment, together with a list of the sources (including dates of information provided and literature citations) for the estimate.

(b) The estimated total number of animals referred to in paragraph (a) of this section may be further reduced to only a subset of the estimated total number of animals if administration of the drug is only medically justified for this subset. To establish this, requestors must demonstrate that administration of the drug to animals subject to the disease or condition for which the drug is being developed other than the subset is not medically justified. The sponsor must also include a list of

the sources (including dates of information provided and literature citations) for the justification that administration of the drug to animals other than the targeted subset is medically inappropriate.

[72 FR 41017, July 26, 2007, as amended at 74 FR 43050, Aug. 25, 2009]

§ 516.22 Permanent-resident U.S. agent for foreign sponsor.

Every foreign sponsor that seeks MUMS-drug designation shall name a permanent resident of the United States as the sponsor's agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the sponsor. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent-resident U.S. agent may be an individual, firm, or domestic corporation and may represent any number of sponsors. The name and address of the permanent-resident U.S. agent shall be provided to the Director of the Office of Minor Use and Minor Species Animal Drug Development.

§ 516.23 Timing of requests for MUMS-drug designation.

A sponsor may request MUMS-drug designation at any time in the drug development process prior to the submission of an application for either conditional approval or approval of the MUMS drug for which designation is being requested.

§ 516.24 Granting MUMS-drug designation.

(a) FDA may grant the request for MUMS-drug designation if none of the reasons described in § 516.25 for refusal to grant such a request apply.

(b) When a request for MUMS-drug designation is granted, FDA will notify the sponsor in writing and will give public notice of the MUMS-drug designation in accordance with § 516.28.

§ 516.25 Refusal to grant MUMS-drug designation.

(a) FDA will refuse to grant a request for MUMS-drug designation if any of the following reasons apply:

(1) The drug is not intended for use in a minor species or FDA determines that there is insufficient evidence to demonstrate that the drug is intended for a minor use in a major species.

(2) The drug is the same drug in the same dosage form for the same intended use as one that already has a MUMS-drug designation but has not yet been conditionally approved or approved.

(3) The drug is the same drug in the same dosage form for the same intended use as one that is already conditionally approved or approved. A drug that FDA has found to be functionally superior is not considered the same drug as an already conditionally approved or approved drug even if it is otherwise the same drug in the same dosage form for the same intended use.

(4) The sponsor has failed to provide:

(i) A credible scientific rationale in support of the intended use,

(ii) Sufficient information about the product development plan for the drug, its dosage form, and its intended use to establish that adherence to the plan can lead to successful drug development in a timely manner, and

(iii) Any other information required under § 516.20.

(b) FDA may refuse to grant a request for MUMS-drug designation if the request for designation contains an untrue statement of material fact or omits material information.

§ 516.26 Amendment to MUMS-drug designation.

(a) At any time prior to conditional approval or approval of an application for a MUMS-designated drug, the sponsor may apply for an amendment to the designated intended use if the proposed change is due to new and unexpected findings in research on the drug, information arising from FDA recommendations, or other unforeseen developments.

(b) FDA will grant the amendment if it finds:

(1) That the initial designation request was made in good faith;

(2) That the amendment is intended to make the MUMS-drug designated intended use conform to the results of new and unexpected findings in research on the drug, information arising from FDA recommendations, or other unforeseen developments; and

(3) In the case of a minor use, that as of the date of the submission of the amendment request, the amendment would not result in the intended use of the drug no longer being considered a minor use.

§ 516.27 Change in sponsorship.

(a) A sponsor may transfer sponsorship of a MUMS-designated drug to another person. A change of sponsorship will also transfer the designation status of the drug which will remain in effect for the new sponsor subject to the same conditions applicable to the former sponsor provided that at the time of a potential transfer, the new and former sponsors submit the following information in writing and obtain permission from FDA:

(1) The former sponsor shall submit a letter to FDA that documents the transfer of sponsorship of the MUMS-designated drug. This letter shall specify the date of the transfer. The former sponsor shall also certify in writing to FDA that a complete copy of the request for MUMS-drug designation, including any amendments to the request, and correspondence relevant to the MUMS-drug designation, has been provided to the new sponsor.

(2) The new sponsor shall submit a letter or other document containing the following information:

(i) A statement accepting the MUMS-drug designated file or application;

(ii) The date that the change in sponsorship is intended to be effective;

(iii) A statement that the new sponsor has a complete copy of the request for MUMS-drug designation, including any amendments to the request and any correspondence relevant to the MUMS-drug designation;

(iv) A statement that the new sponsor understands and accepts the responsibilities of a sponsor of a MUMS-designated drug established elsewhere in this subpart;

(v) The name and address of a new primary contact person or permanent resident U.S. agent; and

(vi) Evidence that the new sponsor is capable of actively pursuing approval with due diligence.

(b) No sponsor may relieve itself of responsibilities under the act or under this subpart by assigning rights to another person without:

(1) Assuring that the new sponsor will carry out such responsibilities; and

(2) Obtaining prior permission from FDA.

§ 516.28 Publication of MUMS-drug designations.

FDA will periodically update a publicly available list of MUMS-designated drugs. This list will be placed on file at the FDA Division of Dockets Management, and will contain the following information for each MUMS-designated drug:

(a) The name and address of the sponsor;

(b) The established name and trade name, if any, of the drug;

(c) The dosage form of the drug;

(d) The species and the proposed intended use for which MUMS-drug designation was granted; and

(e) The date designation was granted.

§ 516.29 Termination of MUMS-drug designation.

(a) The sponsor of a MUMS-designated drug must notify FDA of any decision to discontinue active pursuit of conditional approval or approval of such MUMS drug. FDA must terminate the designation upon such notification.

(b) A conditionally-approved or approved MUMS-designated drug sponsor must notify FDA at least 1 year before it intends to discontinue the manufacture of such MUMS drug. FDA must terminate designation upon such notification.

(c) MUMS designation shall terminate upon the expiration of any applicable period of exclusive marketing rights under this subpart.

(d) FDA may terminate designation if it independently determines that the sponsor is not actively pursuing conditional approval or approval with due

diligence. At a minimum, due diligence must be demonstrated by:

(1) Submission of annual progress reports in a timely manner in accordance with § 516.30 that demonstrate that the sponsor is progressing in accordance with the drug development plan submitted to the agency under § 516.20 and

(2) Compliance with all applicable requirements of part 511 of this chapter.

(e) Designation of a conditionally approved or approved MUMS-designated drug and the associated exclusive marketing rights may be terminated if the sponsor is unable to provide sufficient quantities of the drug to meet the needs for which it is designated.

(f) FDA may also terminate MUMS-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this subpart; or

(3) FDA subsequently finds that the drug in fact had not been eligible for MUMS-drug designation at the time of submission of the request;

(4) The same drug, in the same dosage form, for the same intended use becomes conditionally approved or approved for another sponsor; or

(5) FDA withdraws the conditional approval or approval of the application for the new animal drug.

(g) For a conditionally approved or approved drug, termination of MUMS-drug designation also terminates the sponsor's exclusive marketing rights for the drug but does not withdraw the conditional approval or approval of the drug's application.

(h) Where a drug has been MUMS-designated for a minor use in a major species, its designation will not be terminated on the grounds that the number of animals to which the drug could potentially be administered on an annual basis for the treatment, control, or prevention of the disease or condition for which the drug is being developed, including animals administered the drug as part of herd or flock treatment, subsequently increases.

(i) When a MUMS-drug designation is terminated, FDA will notify the sponsor in writing and will give public notice of the termination of the MUMS-drug designation.

§ 516.30 Annual reports for a MUMS-designated drug.

Within 14 months after the date on which a MUMS drug is granted designation and annually thereafter until approval, the sponsor of a MUMS-designated drug shall submit a brief progress report on the drug to the investigational new animal drug file addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development that includes the following information:

(a) A short account of the progress of drug development including a description of studies initiated, ongoing, and completed, and a short summary of the status or results of such studies;

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the MUMS-designated drug status of the product. For example, situations in which testing data demonstrate that the proposed intended use is inappropriate due to unexpected issues of safety or effectiveness.

§ 516.31 Scope of MUMS-drug exclusive marketing rights.

(a) After conditional approval or approval of an application for a MUMS-designated drug in the dosage form and for the intended use for which MUMS-drug designation has been granted, FDA will not conditionally approve or approve another application or abbreviated application for the same drug in the same dosage form for the same intended use before the expiration of 7 years after the date of conditional approval or approval as stated in the approval letter from FDA, except that such an application can be conditionally approved or approved sooner if, and at such time as, any of the following occurs:

(1) FDA terminates the MUMS-drug designation and associated exclusive marketing rights under § 516.29; or

(2) FDA withdraws the conditional approval or approval of the application for the drug for any reason; or

(3) The sponsor with exclusive marketing rights provides written consent to FDA to conditionally approve or approve another application before the expiration of 7 years; or

(4) The sponsor fails to assure a sufficient quantity of the drug in accordance with section 573 of the act and § 516.36.

(b) If an application for a MUMS drug cannot be approved until the expiration of the period of exclusive marketing of a MUMS-designated drug, FDA will so notify the sponsor in writing.

§ 516.34 FDA recognition of exclusive marketing rights.

(a) FDA will send the sponsor (or the permanent-resident U.S. agent, if applicable) timely written notice recognizing exclusive marketing rights when an application for a MUMS-designated drug has been conditionally approved or approved. The written notice will inform the sponsor of the requirements for maintaining MUMS-designated drug exclusive marketing rights for the full 7-year term. This notice will generally be contained in the letter conditionally approving or approving the application.

(b) When an application is conditionally approved or approved for a MUMS-designated drug that qualifies for exclusive marketing rights, FDA will publish this information in the FEDERAL REGISTER at the time of the conditional approval or approval. This notice will generally be contained in the notice of conditional approval or approval of the application.

§ 516.36 Insufficient quantities of MUMS-designated drugs.

(a) Under section 573 of the act, whenever FDA has reason to believe that sufficient quantities of a conditionally-approved or approved, MUMS-designated drug to meet the needs for which the drug was designated cannot be assured by the sponsor, FDA will so notify the sponsor of this possible insufficiency and will offer the sponsor the following options, one of which must be exercised by a time that FDA specifies:

(1) Provide FDA information and data regarding how the sponsor can assure the availability of sufficient quantities of the MUMS-designated drug within a reasonable time to meet the needs for which the drug was designated; or

(2) Provide FDA in writing the sponsor's consent for the conditional approval or approval of other applications for the same drug before the expiration of the 7-year period of exclusive marketing rights.

(b) If, within the time that FDA specifies, the sponsor fails to consent to the conditional approval or approval of other applications and if FDA finds that the sponsor has not shown that it can assure the availability of sufficient quantities of the MUMS-designated drug to meet the needs for which the drug was designated, FDA will issue a written order terminating designation of the MUMS drug and the associated exclusive marketing rights. This order will state FDA's findings and conclusions and will constitute final agency action. An order terminating designation and associated exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Such an order will not withdraw the conditional approval or approval of an application. Once terminated under this section, neither designation, nor exclusive marketing rights may be reinstated.

§ 516.52 Availability for public disclosure of data and information in requests.

(a) FDA will not publicly disclose the existence of a request for MUMS-drug designation under section 573 of the act prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Except as provided in paragraph (d) of this section, upon final FDA action on a request for designation, the public availability of data and information in the request will be determined

in accordance with part 20 of this chapter and other applicable statutes and regulations.

(d) In accordance with §516.28, FDA will make a cumulative list of all MUMS-drug designations available to the public and update such list periodically. In accordance with §516.29, FDA will give public notice of the termination of all MUMS-drug designations.

Subpart C—Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

SOURCE: 72 FR 69121, Dec. 6, 2007, unless otherwise noted.

§516.111 Scope of this subpart.

This subpart implements section 572 of the act and provides standards and procedures to establish an index of legally marketed unapproved new animal drugs. This subpart applies only to minor species and not to minor use in major species. This index is only available for new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, nonfood life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the act (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance). The index shall not include a new animal drug that is contained in, or a product of, a transgenic animal. Among its topics, this subpart sets forth the standards and procedures for:

(a) Investigational exemptions for indexing purposes;

(b) Submissions to FDA of requests for determination of eligibility of a new animal drug for indexing;

(c) Establishment and operation of expert panels;

(d) Submissions to FDA of requests for addition of a new animal drug to the index;

(e) Modifications to index listings;

(f) Publication of the index; and

(g) Records and reports.

§516.115 Definitions.

(a) The following definitions of terms apply only in the context of subpart C of this part:

Director OMUMS means the Director of the Office of Minor Use and Minor Species Animal Drug Development of the FDA Center for Veterinary Medicine.

Holder means the requestor of an index listing after the request is granted and the new animal drug is added to the index.

Index means FDA's list of legally marketed unapproved new animal drugs for minor species.

Intended use has the same meaning as that given in §516.13 of this chapter.

Qualified expert panel means a panel that is composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of a new animal drug under consideration for indexing.

Requestor means the person making a request for determination of eligibility for indexing or a request for addition to the index.

Transgenic animal means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal, provided that the term 'transgenic animal' does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

(b) The definitions of the following terms are given in §514.3 of this chapter:

Adverse drug experience.

Product defect/manufacturing defect.

Serious adverse drug experience.

Unexpected adverse drug experience.

(c) The definitions of the following terms are given in §516.3 of this chapter:

Same dosage form.

Same drug.

Same intended use.

§516.117 Submission of correspondence under this subpart.

Unless directed otherwise by FDA, all correspondence relating to any aspect of the new animal drug indexing process described in this subpart must

be addressed to the Director, OMUMS. The initial correspondence for a particular index listing should include the name and address of the authorized contact person. Notifications of changes in such person or changes of address of such person should be provided in a timely manner.

§ 516.119 Permanent-resident U.S. agent for foreign requestors and holders.

Every foreign requestor and holder shall name a permanent resident of the United States as their agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the requestor or holder. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent resident U.S. agent may be an individual, firm, or domestic corporation and may represent any number of requestors or holders. The name and address of the permanent-resident U.S. agent shall be submitted to the Director, OMUMS, and included in the index file.

§ 516.121 Meetings.

(a) A requestor or potential requestor is entitled to one or more meetings to discuss the requirements for indexing a new animal drug.

(b) Requests for such meetings should be in writing, be addressed to the Director, OMUMS, specify the participants attending on behalf of the requestor or potential requestor, and contain a proposed agenda for the meeting.

(c) Within 30 days of receiving a request for a meeting, FDA will attempt to schedule the meeting at a time agreeable to both FDA and the person making the request.

§ 516.123 Informal conferences regarding agency administrative actions.

(a) Should FDA make an initial decision denying a request for determination of eligibility for indexing, terminating an investigational exemption, determining that a qualified expert panel does not meet the selection criteria, denying a request for addition to the index, or removing a new animal drug from the index, FDA will give written notice that specifies the grounds for the initial decision and provides an opportunity for an informal conference for review of the decision.

(b) The written notice will include information for scheduling the informal conference and state that a written request for a conference must be made within 60 days of the date FDA sends its notice.

(c) Within 45 days of receiving a request for an informal conference, FDA will schedule and hold the informal conference at a time agreeable to both FDA and the person making the request.

(d) Such an informal conference will be conducted by a presiding officer who will be the Director of the Center for Veterinary Medicine or his or her designee, excluding the Director of the Office of Minor Use and Minor Species Animal Drug Development and other persons significantly involved in the initial decision.

(e) The person requesting an informal conference must provide a written response to FDA's initial decision at least 2 weeks prior to the date of the scheduled meeting. Generally, this written response would be attached to the request for an informal conference. At the option of the person requesting an informal conference, such written response to FDA's initial decision may act in lieu of a face-to-face meeting. In this case, the informal conference will consist of a review by the presiding officer of the submitted written response.

(f) The purpose of an informal conference is to discuss scientific and factual issues. It will involve a discussion of FDA's initial decision and any written response to that decision.

(g) Internal agency review of a decision must be based on the information in the administrative file. If the person requesting an informal conference presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

(h) Informal conferences under this part are not subject to the separation

of functions rules in § 10.55 of this chapter.

(i) The rules of evidence do not apply to informal conferences. No motions or objections relating to the admissibility of information and views will be made or considered, but any party to the conference may comment upon or rebut all such data, information and views.

(j) [Reserved]

(k) The presiding officer will prepare a written report regarding the subject of the informal conference that states and describes the basis for his or her findings. Whenever time permits, the parties to the informal conference will have 30 days to review and comment on the report.

(l) The administrative record of the informal conference will consist of:

(1) The notice providing an opportunity for an informal conference and the written response to the notice.

(2) All written information and views submitted to the presiding officer at the conference or, at the discretion of the presiding officer, thereafter.

(3) The presiding officer's written report.

(4) All correspondence and memoranda of any and all meetings between the participants and the presiding officer.

(m) The administrative record of the informal conference is closed to the submission of information at the close of the conference, unless the presiding officer specifically permits additional time for further submission.

(n) The administrative record of the informal conference specified herein constitutes the exclusive record for decision.

§ 516.125 Investigational use of minor species new animal drugs to support indexing.

(a) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species shall meet the requirements of part 511 of this chapter if the investigational use is for the purpose of:

(1) Demonstrating human food safety under section 572(a)(1)(B) of the act;

(2) Demonstrating safety with respect to individuals exposed to the new animal drug through its manufacture and use under section 572(c)(1)(F) of the act;

(3) Conducting an environmental assessment under section 572(c)(1)(E) of the act; or

(4) Obtaining approval of a new animal drug application or abbreviated new animal drug application under section 512(b) of the act.

(b) Correspondence and information associated with investigations described in paragraph (a) of this section shall not be sent to the Director, OMUMS, but shall be submitted to FDA in accordance with the provisions of part 511 of this chapter.

(c) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species, other than for an investigational use described in paragraph (a) of this section, shall meet the requirements of this section. For such investigations, all provisions of part 511 of this chapter apply with the following modifications:

(1) Under § 511.1(a)(1) of this chapter, the label statement is as follows:

''*Caution*. Contains a new animal drug for investigational use only in laboratory animals or for tests in vitro in support of index listing. Not for use in humans.''

(2) Under § 511.1(b)(1) of this chapter, the label statement is as follows:

''*Caution*. Contains a new animal drug for use only in investigational animals in clinical trials in support of index listing. Not for use in humans. Edible products of investigational animals are not to be used for food for humans or other animals unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.''

(3) Under § 511.1(b)(4) of this chapter, the notice is titled ''Notice of Claimed Investigational Exemption for a New Animal Drug for Index Listing'' and is submitted in duplicate to the Director, OMUMS.

(4) Under § 511.1(c)(3) of this chapter, if an investigator is determined to be ineligible to receive new animal drugs, each ''Notice of Claimed Investigational Exemption for a New Animal

Drug for Index Listing'' and each request for indexing shall be examined with respect to the reliability of information submitted by the investigator.

(5) Under § 511.1(c)(4) and (d)(2) of this chapter, with respect to termination of exemptions, the sponsor of an investigation shall not be granted an opportunity for a regulatory hearing before FDA pursuant to part 16 of this chapter. Instead, the sponsor shall have an opportunity for an informal conference as described in § 516.123.

(6) Under § 511.1(c)(5) of this chapter, if the Commissioner of Food and Drugs determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are such that a request for addition to the index would have been denied, FDA will remove the new animal drug from the index in accordance with § 516.167.

(d) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug subject to paragraph (c) of this section shall not be subject to the good laboratory practice requirements in part 58 of this chapter.

(e) Correspondence and information associated with investigations described in paragraph (c) of this section shall be sent to the Director, OMUMS, in accordance with the provisions of this section.

§ 516.129 Content and format of a request for determination of eligibility for indexing.

(a) Each request for determination of eligibility:

(1) May involve only one drug (or one combination of drugs) in one dosage form;

(2) May not involve a new animal drug that is contained in or a product of a transgenic animal;

(3) May not involve the same drug in the same dosage form for the same intended use as a drug that is already approved or conditionally approved; and

(4) Must be submitted separately.

(b) A request for determination of eligibility for indexing may involve multiple intended uses and/or multiple minor species. However, if a request for determination of eligibility for indexing that contains multiple intended uses and/or multiple minor species cannot be granted in any part, the entire request will be denied.

(c) A requestor must submit two copies of a dated request signed by the authorized contact person for determination of eligibility for indexing that contains the following:

(1) Identification of the minor species or groups of minor species for which the new animal drug is intended;

(2) Information regarding drug components and composition;

(3) A statement of the intended use(s) of the new animal drug in the identified minor species or groups of minor species;

(4) A statement of the proposed conditions of use associated with the stated intended use(s) of the new animal drug, including the proposed dosage, route of administration, contraindications, warnings, and any other significant limitations associated with the intended use(s) of the new animal drug;

(5) A brief discussion of the need for the new animal drug for the intended use(s);

(6) An estimate of the anticipated annual distribution of the new animal drug, in terms of the total quantity of active ingredient, after indexing;

(7) Information to establish that the new animal drug is intended for use:

(i) In a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; or

(ii) In a hatchery, tank, pond, or other similar contained man-made structure in (which includes on) an early, non-food life stage of a food-producing minor species, and information to demonstrate food safety in accordance with the standards of section 512(d) of the act and § 514.111 of this chapter (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance);

(8) A description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of the new animal drug sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture and control of the new animal drug and

that the requestor has an understanding of current good manufacturing practices;

(9) Either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter;

(10) Information sufficient to support the conclusion that the new animal drug is safe under section 512(d) of the act with respect to individuals exposed to the new animal drug through its manufacture and use; and

(11) The name and address of the contact person or permanent-resident U.S. agent.

§ 516.131 Refuse to file a request for determination of eligibility for indexing.

(a) If a request for determination of eligibility for indexing contains all of the information required by § 516.129, FDA shall file it, and the filing date shall be the date FDA receives the request.

(b) If a request for a determination of eligibility lacks any of the information required by § 516.129, FDA will not file it, but will inform the requestor in writing within 30 days of receiving the request as to what information is lacking.

§ 516.133 Denying a request for determination of eligibility for indexing.

(a) FDA will deny a request for determination of eligibility for indexing if it determines upon the basis of the request evaluated together with any other information before it with respect to the new animal drug that:

(1) The same drug in the same dosage form for the same intended use is already approved or conditionally approved;

(2) There is insufficient information to demonstrate that the new animal drug is intended for use:

(i) In a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals, or

(ii) In a hatchery, tank, pond, or other similar contained man-made structure in (which includes on) an early, non-food life stage of a food-producing minor species, and there is insufficient evidence to demonstrate safety for humans in accordance with the standard of section 512(d) of the act and § 514.111 of this chapter (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance);

(3) The new animal drug is contained in or is a product of a transgenic animal;

(4) There is insufficient information to demonstrate that the requestor has established appropriate specifications for the manufacture and control of the new animal drug and that the requestor has an understanding of current good manufacturing practices;

(5) The requester fails to submit an adequate environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter;

(6) There is insufficient information to determine that the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use; or

(7) The request for determination of eligibility for indexing fails to contain any other information required under the provisions of § 516.129.

(b) FDA may deny a request for determination of eligibility for indexing if it contains any untrue statement of a material fact or omits material information.

(c) When a request for determination of eligibility for indexing is denied, FDA will notify the requestor in accordance with § 516.137.

§ 516.135 Granting a request for determination of eligibility for indexing.

(a) FDA will grant the request for determination of eligibility for indexing if none of the reasons described in § 516.133 for denying such a request applies.

(b) When a request for determination of eligibility for indexing is granted, FDA will notify the requestor in accordance with § 516.137.

§ 516.137 Notification of decision regarding eligibility for indexing.

(a) Within 90 days after the filing of a request for a determination of eligibility for indexing based on § 516.129(c)(7)(i), or 180 days for a request based on § 516.129(c)(7)(ii), FDA shall grant or deny the request, and notify the requestor of FDA's decision in writing.

(b) If FDA denies the request, FDA shall provide due notice and an opportunity for an informal conference as described in § 516.123 regarding its decision. A decision of FDA to deny a request for determination of eligibility for indexing following an informal conference shall constitute final agency action subject to judicial review.

§ 516.141 Qualified expert panels.

(a) *Establishment of a qualified expert panel.* Establishing a qualified expert panel is the first step in the process of requesting the addition of a new animal drug to the index. A qualified expert panel may not be established until FDA has determined that the new animal drug is eligible for indexing. The requestor must choose members for the qualified expert panel in accordance with selection criteria listed in paragraph (b) of this section and submit information about these proposed members to FDA. FDA must determine whether the proposed qualified expert panel meets the selection criteria prior to the panel beginning its work. Qualified expert panels operate external to FDA and are not subject to the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

(b) *Criteria for the selection of a qualified expert panel.* (1) A qualified expert panel member must be an expert qualified by training and experience to evaluate a significant aspect of target animal safety or effectiveness of the new animal drug under consideration.

(2) A qualified expert panel member must certify that he or she has a working knowledge of section 572 of the act (the indexing provisions of the statute) and this subpart, and that he or she has also read and understood a clear written statement provided by the requestor stating his or her duties and responsibilities with respect to reviewing the new animal drug proposed for addition to the index.

(3) A qualified expert panel member may not be an FDA employee.

(4) A qualified expert panel must have at least three members.

(5) A qualified expert panel must have members with a range of expertise such that the panel, as a whole, is qualified by training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration.

(6) Unless FDA makes a determination to allow participation notwithstanding an otherwise disqualifying financial interest, a qualified expert panel member must not have a conflict of interest or the appearance of a conflict of interest, as described in paragraph (g) of this section.

(c) *Requestor responsibilities.* (1) The requestor must:

(i) Choose members for the qualified expert panel in accordance with selection criteria listed in paragraph (b) of this section.

(ii) Provide each potential expert panel member a copy of section 572 of the act (the indexing provisions of the statute) and this subpart and obtain certification that he or she has a working knowledge of the information.

(iii) Provide each potential expert panel member a written statement describing the purpose and scope of his or her participation on the qualified expert panel and obtain certification that he or she has read and understood the information. The written statement should describe the duties and responsibilities of qualified expert panels and their members established by paragraphs (e) and (f) of this section, including the need to prepare a written report under § 516.143.

(iv) Obtain information from each potential expert panel member demonstrating that he or she is qualified by training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration. This information can be obtained from a comprehensive curriculum vitae or similar document.

(v) Notify each potential expert panel member that he or she must submit information relating to potential conflict of interest directly to FDA in a timely

manner, as required in paragraph (e)(6) of this section.

(2) The requestor must submit, in writing, the names and addresses of the proposed qualified expert panel members and sufficient information about each proposed member for FDA to determine whether the panel meets the selection criteria listed in paragraphs (b)(1) through (b)(5) of this section.

(3) After FDA has determined that the qualified expert panel meets the selection criteria, the requestor must provide to the panel all information known by the requestor that is relevant to a determination of the target animal safety and the effectiveness of the new animal drug at issue. In addition, the requestor must notify FDA of the name of the qualified expert panel leader.

(4) The requestor must immediately notify FDA if it believes a qualified expert panel member no longer meets the selection criteria listed in paragraph (b) of this section or is otherwise not in compliance with the requirements of this section.

(5) If a qualified expert panel member cannot complete the review for which he or she was selected, the requestor must either choose a replacement or justify the continued work of the panel in the absence of the lost panelist. In either case, the requestor must submit sufficient information for FDA to determine whether the proposed revised qualified expert panel meets the selection criteria listed in paragraphs (b)(1) through (b)(5) of this section.

(6) The requestor must keep copies of all information provided to, or received from, qualified expert panel members, including the written report, for 2 years after the completion of the report, or the product is added to the index, whichever occurs later, and make them available to a duly authorized employee of the agency at all reasonable times.

(d) *FDA responsibilities.* (1) FDA will determine whether the requestor's proposed qualified expert panel meets the selection criteria listed in paragraph (b) of this section. FDA will expeditiously inform the requestor, in writing, of its determination. If FDA determines that the qualified expert panel does not meet the selection criteria, FDA will provide due notice and an opportunity for an informal conference as described in §516.123. A determination by FDA that a proposed qualified expert panel does not meet the selection criteria following an informal conference shall constitute final agency action subject to judicial review.

(2) If FDA determines that a qualified expert panel no longer meets the selection criteria listed in paragraph (b) of this section or that the panel or its members are not in compliance with the requirements of this section, the agency will expeditiously inform the requestor, in writing, of this determination and provide due notice and an opportunity for an informal conference as described in §516.123. A determination by FDA, following an informal conference, that a qualified expert panel no longer meets the selection criteria listed in paragraph (b) of this section or that the panel or its members are not in compliance with the requirements of this section shall constitute final agency action subject to judicial review.

(e) *Responsibilities of a qualified expert panel member.* A qualified expert panel member must do the following:

(1) Continue to meet all selection criteria described in paragraph (b) of this section.

(2) Act in accordance with generally accepted professional and ethical business practices.

(3) Review all information relevant to a determination of the target animal safety and effectiveness of the new animal drug provided by the requestor. The panel should also consider all relevant information otherwise known by the panel members, including anecdotal information.

(4) Participate in the preparation of the written report of the findings of the qualified expert panel, described in §516.143.

(5) Sign, or otherwise approve in writing, the written report. Such signature or other written approval will serve as certification that the written report meets the requirements of the written report in §516.143.

(6) Provide the information relating to potential conflict of interest described in paragraph (g) of this section

to FDA for its consideration. Such information should be submitted directly to the Director, OMUMS, when notified by the requestor.

(7) Immediately notify the requestor and FDA of any change in conflict of interest status.

(8) Certify at the time of submission of the written report that there has been no change in conflict of interest status, or identify and document to FDA any such change.

(f) *Additional responsibilities of a qualified expert panel leader.* (1) The qualified expert panel leader must ensure that the activities of the panel are performed efficiently and in accordance with generally accepted professional and ethical business practices.

(2) The qualified expert panel leader serves as the principal point of contact between representatives of the agency and the panel.

(3) The qualified expert panel leader is responsible for submitting the written report and all notes or minutes relating to panel deliberations to the requestor.

(4) The qualified expert panel leader must maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted. Such records must be made available to a duly authorized employee of the agency for inspection at all reasonable times.

(g) *Prevention of conflicts of interest.* (1) For the purposes of this subpart, FDA will consider a conflict of interest to be any financial or other interest that could impair a person's objectivity in serving on the qualified expert panel or could create an unfair competitive advantage for a person or organization.

(2) Factors relevant to whether there is a conflict of interest or the appearance of a conflict of interest include whether the qualified expert panel member, their spouse, their minor children, their general partners, or any organizations in which they serve as an officer, director, trustee, general partner or employee:

(i) Is currently receiving or seeking funding from the requestor through a contract or research grant (either directly or indirectly through another entity, such as a university).

(ii) Has any employment, contractual, or other financial arrangement with the requestor other than receiving a reasonable fee for serving as a member of the qualified expert panel.

(iii) Has any ownership or financial interest in any drug, drug manufacturer, or drug distributor which will benefit from either a favorable or unfavorable evaluation or opinion.

(iv) Has any ownership or financial interest in the new animal drug being reviewed by the qualified expert panel.

(v) Has participated in the design, manufacture, or distribution of any drug that will benefit from either a favorable or unfavorable opinion of the qualified expert panel.

(vi) Has provided within 1 year any consultative services regarding the new animal drug being reviewed by the qualified expert panel.

(vii) Has entered into an agreement in which fees charged or accepted are contingent upon the panel member making a favorable evaluation or opinion.

(viii) Receives payment for services related to preparing information the requestor presents to the qualified expert panel, other than for services related to the written report described in § 516.143.

(3) To permit FDA to make a decision regarding potential conflict of interest, a potential qualified expert panel member must submit to the Director, OMUMS, the following information relating to themselves, their spouse, their minor children, their general partners, or any organizations in which they serve as an officer, director, trustee, general partner or employee, regarding the following issues to the extent that they are, in any way, relevant to the subject of the review of the qualified expert panel:

(i) Investments (for example, stocks, bonds, retirement plans, trusts, partnerships, sector funds, etc.), including for each the following: Name of the firm, type of investment, owner (self, spouse, etc.), number of shares / current value.

(ii) Employment (full or part time, current or under negotiation), including for each the following: Name of the

firm, relationship (self, spouse, etc.), position in firm, date employment or negotiation began.

(iii) Consultant/advisor (current or under negotiation), including for each the following: Name of the firm, topic/issue, amount received, date initiated.

(iv) Contracts, grants, Cooperation Research and Development Agreement (CRADAs) (current or under negotiation), including for each the following: Type of agreement, product under study and indications, amount of remuneration (institution/self), time period, sponsor (government, firm, institution, individual), role of the person (site investigator, principal investigator, co-investigator, partner, no involvement, other), awardee.

(v) Patents/royalties/trademarks, including for each the following: Description, name of firm involved, income received.

(vi) Expert witness (last 12 months or under negotiation), including for each the following: For or against, name of firm, issue, amount received.

(vii) Speaking/writing (last 12 months or under negotiation), including for each the following: Firm, topic/issue, amount received (honorarium/travel), date.

(viii) Whether the potential qualified expert panel member, their spouse, their minor children, their general partners or any organizations in which they serve as an officer, director, trustee, general partner or employee, have had, at any time in the past, involvement of the kind noted in paragraph (g)(3)(i) through (g)(3)(vii) of this section with respect to the animal drug that is the subject of the qualified expert panel review.

(ix) Whether there are any other involvements (other kinds of relationships) that would give the appearance of a conflict of interest which have not been described in paragraph (g)(3)(i) through (g)(3)(viii) of this section.

(x) In all cases, a response of ''no,'' ''none,'' or ''not applicable'' is satisfactory when there is no relevant information to submit.

(xi) A certification statement signed by the potential qualified expert panel member to the effect that all information submitted is true and complete to the best of their knowledge, that they have read and understood their obligations as an expert panel member, and that they will notify FDA and the requestor of any change in their conflict of interest status.

(4) The fact that a qualified expert panel member receives a reasonable fee for services as a member of the qualified expert panel, provided that the fee is no more than commensurate with the value of the time that the member devotes to the review process, does not constitute a conflict of interest or the appearance of a conflict of interest.

§ 516.143 Written report.

The written report required in § 516.145(b)(3) shall:

(a) Be written in English by a qualified expert panel meeting the requirements of § 516.141;

(b) Describe the panel's evaluation of all available target animal safety and effectiveness information relevant to the proposed use of the new animal drug, including anecdotal information;

(c) For all information considered, including anecdotal information, include either a citation to published literature or a summary of the information;

(d) State the panel's opinion regarding whether the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question;

(e) Be signed, or otherwise approved in writing, by all panel members, in accordance with § 516.141; and

(f) If the panel unanimously concludes that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question, the written report shall:

(1) Provide draft labeling that includes all conditions of use and limitations of use of the new animal drug deemed necessary by the panel to assure that the benefits of use of the new

animal drug outweigh the risks, or provide narrative information from which such labeling can be written by the requestor; and

(2) Include a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian.

§ 516.145 Content and format of a request for addition to the index.

(a) A requestor may request addition of a new animal drug to the index only after the new animal drug has been granted eligibility for indexing.

(b) A requestor shall submit two copies of a dated request signed by the authorized contact for addition of a new animal drug to the index that contains the following:

(1) A copy of FDA's determination of eligibility issued under § 516.137;

(2) A copy of FDA's written determination that the proposed qualified expert panel meets the selection criteria provided for in § 516.141(b);

(3) A written report that meets the requirements of § 516.143;

(4) A proposed index entry that contains the information described in § 516.157;

(5) Proposed labeling, including representative labeling proposed to be used for Type B and Type C medicated feeds if the drug is intended for use in the manufacture of medicated feeds;

(6) Anticipated annual distribution of the new animal drug, in terms of the total quantity of active ingredient, after indexing;

(7) A written commitment to manufacture the new animal drug and animal feeds bearing or containing such new animal drug according to current good manufacturing practices;

(8) A written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(9) The name and address of the contact person or permanent-resident U.S. agent; and

(10) A draft Freedom of Information summary which includes the following information:

(i) A general information section that contains the name and address of the requestor and a description of the drug, route of administration, indications, and recommended dosage.

(ii) A list of the names and affiliations of the members of the qualified expert panel, not including their addresses or other contact information.

(iii) A summary of the findings of the qualified expert panel concerning the target animal safety and effectiveness of the drug.

(iv) Citations of all publicly-available literature considered by the qualified expert panel.

(v) For an early life stage of a food-producing minor species animal, a human food safety summary.

(c) Upon specific request by FDA, the requestor shall submit the information described in § 516.141 that it submitted to the qualified expert panel. Any such information not in English should be accompanied by an English translation.

§ 516.147 Refuse to file a request for addition to the index.

(a) If a request for addition to the index contains all of the information required by § 516.145(b), FDA shall file it, and the filing date shall be the date FDA receives the request.

(b) If a request for addition to the index lacks any of the information required by § 516.145, FDA will not file it, but will inform the requestor in writing within 30 days of receiving the request as to what information is lacking.

§ 516.149 Denying a request for addition to the index.

(a) FDA will deny a request for addition to the index if it finds the following:

(1) The same drug in the same dosage form for the same intended use is already approved or conditionally approved;

(2) On the basis of new information, the new animal drug no longer meets the conditions for eligibility for indexing;

(3) The request for indexing fails to contain information required under the provisions of § 516.145;

(4) The qualified expert panel fails to meet any of the selection criteria listed in § 516.141(b);

(5) The written report of the qualified expert panel and other information available to FDA is insufficient to permit FDA to determine that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question;

(6) On the basis of the report of the qualified expert panel and other information available to FDA, the benefits of using the new animal drug for the proposed use in a minor species do not outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question; or

(7) The request contains any untrue statement of a material fact or omits material information.

(b) When a request for addition to the index is denied, FDA will notify the requestor in accordance with §516.153.

§516.151 Granting a request for addition to the index.

(a) FDA will grant the request for addition of a new animal drug to the index if none of the reasons described in §516.149 for denying such a request applies.

(b) When a request for addition of a new animal drug to the index is granted, FDA will notify the requestor in accordance with §516.153.

§516.153 Notification of decision regarding index listing.

(a) Within 180 days after the filing of a request for addition of a new animal drug to the index, FDA shall grant or deny the request and notify the requestor of FDA's decision in writing.

(b) If FDA denies the request for addition of a new animal drug to the index, FDA shall provide due notice and an opportunity for an informal conference as described in §516.123. A decision of FDA to deny a request to index a new animal drug following an informal conference shall constitute final agency action subject to judicial review.

§516.155 Labeling of indexed drugs.

(a) The labeling of an indexed drug that is found to be eligible for indexing under §516.129(c)(7)(i) shall state, prominently and conspicuously: *''NOT APPROVED BY FDA.—Legally marketed as an FDA indexed product. Extra-label use is prohibited.'' ''This product is not to be used in animals intended for use as food for humans or other animals.''*

(b) The labeling of an indexed drug that was found to be eligible for indexing for use in an early, non-food life stage of a food-producing minor species animal, under §516.129(c)(7)(ii), shall state, prominently and conspicuously: *''NOT APPROVED BY FDA.—Legally marketed as an FDA indexed product. Extra-label use is prohibited.''*

(c) The labeling of an indexed drug shall contain such other information as may be prescribed in the index listing.

§516.157 Publication of the index and content of an index listing.

(a) FDA will make the list of indexed drugs available through the FDA Web site at *http://www.fda.gov*. A printed copy can be obtained by writing to the Freedom of Information Staff or by visiting FDA's Freedom of Information Staff's Public Reading Room at the address listed on the Agency's Web site at *http://www.fda.gov*.

(b) The list will contain the following information for each indexed drug:

(1) The name and address of the person who holds the index listing;

(2) The name of the drug and the intended use and conditions of use for which it is indexed;

(3) Product labeling; and

(4) Conditions and any limitations that FDA deems necessary regarding use of the drug.

[72 FR 69121, Dec. 6, 2007; 76 FR 31470, June 1, 2011, as amended at 79 FR 68115, Nov. 14, 2014]

§516.161 Modifications to indexed drugs.

(a) After a drug is listed in the index, certain modifications to the index listing may be requested. Any modification of an index listing may not cause an indexed drug to be a different drug (or different combination of drugs) or a different dosage form. If such modification is requested, FDA will notify the

holder that a new index listing is required for the new drug or dosage form.

(b) Modifications to the indexed drug will fall under one of three categories and must be submitted as follows:

(1) *Urgent changes.* (i) The following modifications to an indexed drug or its labeling should be made as soon as possible, and a request to modify the indexed drug should be concurrently submitted:

(A) The addition to package labeling, promotional labeling, or prescription drug advertising of additional warning, contraindication, side effect, or cautionary information.

(B) The deletion from package labeling, promotional labeling, and drug advertising of false, misleading, or unsupported indications for use or claims for effectiveness.

(C) Changes in manufacturing methods or controls required to correct product or manufacturing defects that may result in serious adverse drug events.

(ii) The modifications described in paragraph (b)(1)(i) of this section must be submitted to the Director, OMUMS, in the form of a request for modification of an indexed drug, and must contain sufficient information to permit FDA to determine the need for the modification and whether the modification appropriately addresses the need.

(iii) FDA will take no action against an indexed drug or index holder solely because modifications of the kinds described in paragraph (b)(1)(i) of this section are placed into effect by the holder prior to receipt of a written notice granting the request if all the following conditions are met:

(A) A request to modify the indexed drug providing a full explanation of the basis for the modifications has been submitted, plainly marked on the mailing cover and on the request as follows: ''Special indexing request— modifications being effected;''

(B) The holder specifically informs FDA of the date on which such modifications are to be effected and submits two printed copies of any revised labeling to be placed in use, and

(C) All promotional labeling and all drug advertising are promptly revised consistent with modifications made in the labeling on or within the indexed drug package.

(2) *Significant changes.* (i) The following modifications to an indexed drug or its labeling may be made only after a request has been submitted to and subsequently granted by FDA:

(A) Addition of an intended use.

(B) Addition of a species.

(C) Addition or alteration of an active ingredient.

(D) Alteration of the concentration of an active ingredient.

(E) Alteration of dose or dosage regimen.

(F) Alteration of prescription or over-the-counter status.

(ii) Each modification described in paragraph (b)(2)(i) of this section must go through the same review process as an original index listing and is subject to the same standards for review.

(iii) Each submission of a request for a modification described in paragraph (b)(2)(i) of this section should contain only one type of modification unless one modification is actually necessitated by another, such as a modification of dose necessitated by a modification of the concentration of an active ingredient. Submissions relating to addition of an intended use for an existing species or addition of a species should be submitted separately, but each such submission may include multiple additional intended uses and/or multiple additional species.

(3) *Minor changes.* All modifications other than those described in paragraphs (b)(1) and (b)(2) of this section including, but not limited to, formulation, labeling, and manufacturing methods and controls (at the same level of detail that these were described in the request for determination of eligibility for indexing) must be submitted as part of the annual indexed drug experience report or as otherwise required by § 516.165.

(c) When changes affect the index listing, it will be updated accordingly.

§ 516.163 Change in ownership of an index file.

(a) A holder may transfer ownership of a drug's index file to another person.

(1) The former owner shall submit in writing to FDA a statement that all

rights in the index file have been transferred, giving the name and address of the new owner and the date of the transfer. The former owner shall also certify that a complete copy of the following, to the extent that they exist at the time of the transfer of ownership, has been provided to the new owner:

(i) The request for determination of eligibility;

(ii) The request for addition to the index;

(iii) Any modifications to the index listing;

(iv) Any records and reports under § 516.165; and

(v) All correspondence with FDA relevant to the indexed drug and its index listing.

(2) The new owner shall submit the following information in writing to FDA:

(i) The date that the change in ownership is effective;

(ii) A statement that the new owner has a complete copy of all documents listed in paragraph (a)(1) of this section to the extent that they exist at the time of the transfer of ownership;

(iii) A statement that the new owner understands and accepts the responsibilities of a holder of an indexed drug;

(iv) The name and address of a new primary contact person or permanent-resident U.S. agent; and

(v) A list of labeling changes associated with the change of ownership (e.g., a new trade name) as draft labeling, with complete final printed labeling to be submitted in the indexed drug annual report in accordance with §§ 516.161 and 516.165.

(b) Upon receiving the necessary information to support a change of ownership of a drug's index file, FDA will update its publicly-available listing in accordance with § 516.157.

§ 516.165 Records and reports.

(a) *Scope and purpose.* (1) The recordkeeping and reporting requirements of this section apply to all holders of indexed drugs, including indexed drugs intended for use in medicated feeds.

(2) A holder is not required to report information under this section if the holder has reported the same information under § 514.80 of this chapter.

(3) The records and reports referred to in this section are in addition to those required by the current good manufacturing practice regulations in parts 211, 225, and 226 of this chapter.

(4) FDA will review the records and reports required in this section to determine, or facilitate a determination, whether there may be grounds for removing a drug from the index under section 572(f) of the act.

(b) *Recordkeeping requirements.* (1) Each holder of an indexed drug must establish and maintain complete files containing full records of all information pertinent to the safety or effectiveness of the indexed drug. Such records must include information from foreign and domestic sources.

(2) The holder must, upon request from any authorized FDA officer or employee, at all reasonable times, permit such officer or employee to have access to copy and to verify all such records.

(c) *Reporting requirements*—(1) *Three-day indexed drug field alert report.* The holder must inform the appropriate FDA District Office or local FDA resident post of any product or manufacturing defects that may result in serious adverse drug events within 3 working days of first becoming aware that such a defect may exist. The holder may initially provide this information by telephone or other electronic communication means, with prompt written followup. The mailing cover must be plainly marked ''3–Day Indexed Drug Field Alert Report.''

(2) *Fifteen-day indexed drug alert report.* The holder must submit a report on each serious, unexpected adverse drug event, regardless of the source of the information. The holder must submit the report within 15 working days of first receiving the information. The mailing cover must be plainly marked ''15–Day Indexed Drug Alert Report.''

(3) *Annual indexed drug experience report.* The holder must submit this report every year on the anniversary date of the letter granting the request for addition of the new animal drug to the index, or within 60 days thereafter. The report must contain data and information for the full reporting period. Any previously submitted information

contained in the report must be identified as such. The holder may ask FDA to change the date of submission and, after approval of such request, file such reports by the new filing date. The report must contain the following:

(i) The number of distributed units of each size, strength, or potency (e.g., 100,000 bottles of 100 5-milligram tablets; 50,000 10-milliliter vials of 5- percent solution) distributed during the reporting period. This information must be presented in two categories: Quantities distributed domestically and quantities exported. This information must include any distributor-labeled product.

(ii) If the labeling has changed since the last report, include a summary of those changes and the holder's and distributor's current package labeling, including any package inserts. For large-size package labeling or large shipping cartons, submit a representative copy (e.g., a photocopy of pertinent areas of large feed bags). If the labeling has not changed since the last report, include a statement of such fact.

(iii) A summary of any changes made during the reporting period in the methods used in, and facilities and controls used for, manufacture, processing, and packing. This information must be presented in the same level of detail that it was presented in the request for determination of eligibility for indexing. Do not include changes that have already been submitted under § 516.161.

(iv) Nonclinical laboratory studies and clinical data not previously reported under this section.

(v) Adverse drug experiences not previously reported under this section.

(vi) Any other information pertinent to safety or effectiveness of the indexed drug not previously reported under this section.

(4) *Distributor's statement.* At the time of initial distribution of an indexed drug by a distributor, the holder must submit a report containing the following:

(i) The distributor's current product labeling. This must be identical to that in the index listing except for a different and suitable proprietary name (if used) and the name and address of the distributor. The name and address of the distributor must be preceded by an appropriate qualifying phrase such as ''manufactured for'' or ''distributed by.''

(ii) A signed statement by the distributor stating:

(A) The category of the distributor's operations (e.g., wholesale or retail);

(B) That the distributor will distribute the drug only under the indexed drug labeling;

(C) That the distributor will promote the indexed drug only for use under the conditions stated in the index listing; and

(D) If the indexed drug is a prescription new animal drug, that the distributor is regularly and lawfully engaged in the distribution or dispensing of prescription products.

(5) *Other reporting.* FDA may by order require that a holder submit information in addition to that required by this section or that the holder submit the same information but at different times or reporting periods.

§ 516.167 Removal from the index.

(a) After due notice to the holder of the index listing and an opportunity for an informal conference as described in § 516.123, FDA shall remove a new animal drug from the index if FDA finds that:

(1) The same drug in the same dosage form for the same intended use has been approved or conditionally approved;

(2) The expert panel failed to meet the requirements in § 516.141;

(3) On the basis of new information before FDA, evaluated together with the evidence available to FDA when the new animal drug was listed in the index, the benefits of using the new animal drug for the indexed use do not outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question;

(4) Any of the conditions in § 516.133(a)(2), (5), or (6) are present;

(5) The manufacture of the new animal drug is not in accordance with current good manufacturing practices;

(6) The labeling, distribution, or promotion of the new animal drug is not in accordance with the index listing;

(7) The conditions and limitations of use associated with the index listing have not been followed; or

(8) Any information used to support the request for addition to the index contains any untrue statement of material fact.

(b) The agency may partially remove an indexing listing if, in the opinion of the agency, such partial removal would satisfactorily resolve a safety or effectiveness issue otherwise warranting removal of the listing under section 572(f)(1)(B) of the act.

(c) FDA may immediately suspend a new animal drug from the index if FDA determines that there is a reasonable probability that the use of the drug would present a risk to the health of humans or other animals. The agency will subsequently provide due notice and an opportunity for an informal conference as described in §516.123.

(d) A decision of FDA to remove a new animal drug from the index following an informal conference, if any, shall constitute final agency action subject to judicial review.

§516.171 Confidentiality of data and information in an index file.

(a) For purposes of this section, the index file includes all data and information submitted to or incorporated by reference into the index file, such as data and information related to investigational use exemptions under §516.125, requests for determination of eligibility for indexing, requests for addition to the index, modifications to indexed drugs, changes in ownership, reports submitted under §516.165, and master files. The availability for public disclosure of any record in the index file shall be handled in accordance with the provisions of this section.

(b) The existence of an index file will not be disclosed by FDA before an index listing has been made public by FDA, unless it has previously been publicly disclosed or acknowledged by the requestor.

(c) If the existence of an index file has not been publicly disclosed or acknowledged, no data or information in the index file are available for public disclosure.

(d) If the existence of an index file has been publicly disclosed or acknowledged before an index listing has been made public by FDA, no data or information contained in the file will be available for public disclosure before such index listing is made public, but the agency may, at its discretion, disclose a brief summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After FDA sends a written notice to the requestor granting a request for addition to the index, the following data and information in the index file are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in §20.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the index file. Such summaries do not constitute the full information described under section 572(c) and (d) of the act on which the safety or effectiveness of the drug may be determined. Such summaries will be based on the draft Freedom of Information summary submitted under §516.145, which will be reviewed and, where appropriate, revised by FDA.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in §20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of the following:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a veterinarian.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in §20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the index file, in accordance with the provisions of part 20 of this chapter.

(f) The following data and information in an index file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(g) Subject to the disclosure provisions of this section, the agency shall regard the contents of an index file as confidential information unless specifically notified in writing by the holder of the right to disclose, to reference, or otherwise utilize such information on behalf of another named person.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

(i) Safety and effectiveness data and information that have not been previously disclosed to the public are available for public disclosure at the time any of the following events occurs unless extraordinary circumstances are shown:

(1) No work is being or will be undertaken to have the drug indexed in accordance with the request.

(2) A final determination is made that the drug cannot be indexed and all legal appeals have been exhausted.

(3) The drug has been removed from the index and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

Subpart D [Reserved]

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

SOURCE: 72 FR 57200, Oct. 9, 2007, unless otherwise noted.

§ 516.1684 Paclitaxel.

(a) *Specifications.* Each vial of powder contains 60 milligrams (mg) paclitaxel. Each milliliter of constituted solution contains 1 mg paclitaxel.

(b) *Sponsor.* See No. 052818 in 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 150 mg per square meter of body surface area intravenously over 15 to 30 minutes, once every 3 weeks, for up to 4 doses.

(2) *Indications for use.* For the treatment of nonresectable stage III, IV, or V mammary carcinoma in dogs that have not received previous chemotherapy or radiotherapy. For the treatment of resectable and nonresectable squamous cell carcinoma in dogs that have not received previous chemotherapy or radiotherapy.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

[79 FR 18158, Apr. 1, 2014]

§ 516.2065 Rabacfosadine.

(a) *Specifications.* Each vial of powder contains 16.4 milligrams (mg) rabacfosadine. Each milliliter of constituted solution contains 8.2 mg rabacfosadine.

(b) *Sponsor.* See No. 086072 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer rabacfosadine at 1 mg/kilogram body weight as a 30-

minute intravenous infusion, once every 3 weeks, for up to 5 doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

[82 FR 12169, Mar. 1, 2017]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

520.23 Acepromazine.
520.28 Acetazolamide.
520.38 Albendazole oral dosage forms.
520.38a Albendazole suspension.
520.38b Albendazole paste.
520.43 Afoxolaner.
520.48 Altrenogest.
520.62 Aminopentamide.
520.82 Aminopropazine oral dosage forms.
520.82a Aminopropazine.
520.82b Aminopropazine and neomycin.
520.88 Amoxicillin oral dosage forms.
520.88a Amoxicillin trihydrate film-coated tablets.
520.88b Amoxicillin trihydrate for oral suspension.
520.88c Amoxicillin trihydrate oral suspension.
520.88d Amoxicillin trihydrate soluble powder.
520.88e Amoxicillin trihydrate boluses.
520.88f Amoxicillin trihydrate tablets.
520.88g Amoxicillin trihydrate and clavulanate potassium tablets.
520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.
520.90 Ampicillin oral dosage forms.
520.90a [Reserved]
520.90b Ampicillin tablets.
520.90c Ampicillin capsules.
520.90d Ampicillin for oral suspension.
520.90e Ampicillin for soluble powder.
520.90f Ampicillin boluses.
520.100 Amprolium.
520.110 Apramycin sulfate soluble powder.
520.154 Bacitracin oral dosage forms.
520.154a Bacitracin methylenedisalicylate.
520.154b Bacitracin methylenedisalicylate and streptomycin sulfate powder.
520.154c Bacitracin zinc soluble powder.
520.222 Bunamidine hydrochloride.
520.246 Butorphanol tablets.
520.260 n-Butyl chloride.
520.284 Cambendazole oral dosage forms.
520.284a Cambendazole suspension.
520.284b Cambendazole pellets.
520.284c Cambendazole paste.
520.292 Capromorelin.
520.301 Caramiphen ethanedisulfonate and ammonium chloride tablets.
520.302 Carnidazole tablets.
520.304 Carprofen.
520.314 Cefadroxil.
520.370 Cefpodoxime tablets.
520.376 Cephalexin.
520.390 Chloramphenicol oral dosage forms.
520.390a Chloramphenicol tablets.
520.390b Chloramphenicol capsules.
520.390c Chloramphenicol palmitate oral suspension.
520.420 Chlorothiazide tablets and boluses.
520.434 Chlorphenesin carbamate tablets.
520.441 Chlortetracycline powder.
520.443 Chlortetracycline tablets and boluses.
520.445 Chlortetracycline and sulfamethazine powder.
520.446 Clindamycin capsules and tablets.
520.447 Clindamycin solution.
520.452 Clenbuterol syrup.
520.455 Clomipramine tablets.
520.462 Clorsulon drench.
520.522 Cyclosporine.
520.530 Cythioate oral liquid.
520.531 Cythioate tablets.
520.534 Decoquinate.
520.538 Deracoxib.
520.540 Dexamethasone oral dosage forms.
520.540a Dexamethasone powder.
520.540b Dexamethasone tablets and boluses.
520.540c Dexamethasone chewable tablets.
520.563 Dexamethasone chewable tablets.
520.580 Dichlorophene and toluene.
520.581 Dichlorophene tablets.
520.600 Dichlorvos.
520.606 Diclazuril.
520.608 Dicloxacillin.
520.620 Diethylcarbamazine oral dosage forms.
520.622 Diethylcarbamazine citrate oral dosage forms.
520.622a Diethylcarbamazine citrate tablets.
520.622b Diethylcarbamazine citrate syrup.
520.622c Diethylcarbamazine citrate chewable tablets.
520.623 Diethylcarbamazine and oxibendazole chewable tablets.
520.645 Difloxacin.
520.666 Dirlotapide.
520.763 Dithiazanine oral dosage forms.
520.763a Dithiazanine tablets.
520.763b Dithiazanine powder.
520.763c Dithiazanine iodide and piperazine citrate suspension.
520.766 Domperidone.
520.784 Doxylamine.
520.804 Enalapril.
520.812 Enrofloxacin.
520.816 Epsiprantel.
520.823 Erythromycin.
520.852 Estriol.
520.863 Ethylisobutrazine.
520.870 Etodolac.

520.903 Febantel oral dosage forms.
520.903a Febantel paste.
520.903b Febantel suspension.
520.903c [Reserved]
520.903d Febantel and praziquantel paste.
520.903e Febantel tablets.
520.905 Fenbendazole oral dosage forms.
520.905a Fenbendazole suspension.
520.905b Fenbendazole granules.
520.905c Fenbendazole paste.
520.905d Fenbendazole powder.
520.905e Fenbendazole blocks.
520.928 Firocoxib tablets.
520.930 Firocoxib paste.
520.955 Florfenicol.
520.960 Flumethasone.
520.970 Flunixin.
520.980 Fluoxetine.
520.998 Fluralaner.
520.1010 Furosemide.
520.1044 Gentamicin sulfate oral dosage forms.
520.1044a Gentamicin sulfate oral solution.
520.1044b Gentamicin sulfate pig pump oral solution.
520.1044c Gentamicin sulfate powder.
520.1060 Glucose and glycine.
520.1084 Grapiprant.
520.1100 Griseofulvin.
520.1120 Haloxon oral dosage forms.
520.1120a Haloxon drench.
520.1120b Haloxon boluses.
520.1130 Hetacillin.
520.1156 Imidacloprid.
520.1157 Iodinated casein.
520.1158 Iodochlorhydroxyquin.
520.1182 Iron dextran suspension.
520.1189 Itraconazole.
520.1192 Ivermectin paste.
520.1193 Ivermectin tablets and chewables.
520.1194 Ivermectin meal.
520.1195 Ivermectin liquid.
520.1196 Ivermectin and pyrantel tablets.
520.1197 Ivermectin sustained-release bolus.
520.1198 Ivermectin and praziquantel paste.
520.1199 Ivermectin, pyrantel, and praziquantel tablets.
520.1200 Ivermectin, fenbendazole, and praziquantel tablets.
520.1204 Kanamycin, bismuth subcarbonate, activated *attapulgite*.
520.1242 Levamisole.
520.1242a Levamisole powder.
520.1242b Levamisole boluses or oblets.
520.1242c Levamisole and piperazine.
520.1242d Levamisole resinate.
520.1242e Levamisole hydrochloride effervescent tablets.
520.1242f Levamisole gel.
520.1242g Levamisole resinate and famphur paste.
520.1248 Levothyroxine.
520.1263 Lincomycin.
520.1263a Lincomycin tablets and syrup.
520.1263b [Reserved]
520.1263c Lincomycin powder.
520.1265 Lincomycin and spectinomycin powder.
520.1284 Liothyronine.
520.1288 Lufenuron tablets.
520.1289 Lufenuron suspension.
520.1310 Marbofloxacin.
520.1315 Maropitant.
520.1320 Mebendazole.
520.1326 Mebendazole and trichlorfon oral dosage forms.
520.1326a Mebendazole and trichlorfon powder.
520.1326b Mebendazole and trichlorfon paste.
520.1330 Meclofenamic acid granules.
520.1331 Meclofenamic acid tablets.
520.1341 Megestrol.
520.1367 Meloxicam.
520.1372 Methimazole.
520.1380 Methocarbamol.
520.1408 Methylprednisolone.
520.1409 Methylprednisolone and aspirin.
520.1422 Metoserpate hydrochloride.
520.1430 Mibolerone.
520.1441 Milbemycin oxime.
520.1443 Milbemycin oxime and lufenuron.
520.1445 Milbemycin oxime and praziquantel.
520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.
520.1450 Morantel tartrate oral dosage forms.
520.1450a Morantel tartrate bolus.
520.1450b Morantel tartrate cartridge.
520.1450c Morantel tartrate sustained-release trilaminate cylinder/sheet.
520.1451 Moxidectin tablets.
520.1452 Moxidectin gel.
520.1453 Moxidectin and praziquantel gel.
520.1454 Moxidectin solution.
520.1468 Naproxen.
520.1484 Neomycin.
520.1510 Nitenpyram.
520.1604 Oclacitinib.
520.1615 Omeprazole.
520.1616 Orbifloxacin tablets..
520.1618 Orbifloxacin suspension.
520.1628 Oxfendazole powder and pellets.
520.1629 Oxfendazole paste.
520.1630 Oxfendazole suspension.
520.1631 Oxfendazole and trichlorfon paste.
520.1638 Oxibendazole.
520.1660 Oxytetracycline.
520.1660a Oxytetracycline and carbomycin.
520.1660b Oxytetracycline hydrochloride capsules.
520.1660c Oxytetracycline hydrochloride tablets/boluses.
520.1660d Oxytetracycline powder.
520.1696 Penicillin.
520.1696a [Reserved]
520.1696b Penicillin G powder.
520.1696c Penicillin V powder.
520.1696d Penicillin V tablets.
520.1705 Pergolide.
520.1720 Phenylbutazone oral dosage forms.
520.1720a Phenylbutazone tablets and boluses.

520.1720b Phenylbutazone granules.
520.1720c Phenylbutazone paste.
520.1720d Phenylbutazone gel.
520.1720e Phenylbutazone powder.
520.1760 Phenylpropanolamine.
520.1780 Pimobendan.
520.1802 Piperazine-carbon disulfide complex oral dosage forms.
520.1802a Piperazine-carbon disulfide complex suspension.
520.1802b Piperazine-carbon disulfide complex boluses.
520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.
520.1803 Piperazine citrate capsules.
520.1804 Piperazine phosphate capsules.
520.1805 Piperazine phosphate with thenium closylate tablets.
520.1806 Piperazine suspension.
520.1807 Piperazine.
520.1840 Poloxalene.
520.1846 Polyoxyethylene (23) lauryl ether blocks.
520.1855 Ponazuril.
520.1860 Pradofloxacin.
520.1870 Praziquantel tablets.
520.1871 Praziquantel and pyrantel.
520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.
520.1880 Prednisolone.
520.1900 Primidone.
520.1920 Prochlorperazine and isopropamide.
520.1921 Prochlorperazine, isopropamide, and neomycin.
520.1962 Promazine.
520.2002 Propiopromazine.
520.2041 Pyrantel pamoate chewable tablets.
520.2042 Pyrantel pamoate tablets.
520.2043 Pyrantel pamoate suspension.
520.2044 Pyrantel pamoate paste.
520.2045 Pyrantel tartrate powder.
520.2046 Pyrantel tartrate pellets.
520.2075 Robenacoxib.
520.2086 Sarolaner.
520.2098 Selegiline.
520.2100 Selenium and vitamin E.
520.2123 Spectinomycin oral dosage forms.
520.2123a Spectinomycin tablets.
520.2123b Spectinomycin powder.
520.2123c Spectinomycin solution.
520.2130 Spinosad.
520.2134 Spinosad and milbemycin.
520.2150 Stanozolol.
520.2158 Streptomycin.
520.2170 Sulfabromomethazine.
520.2184 Sulfachloropyrazine.
520.2200 Sulfachlorpyridazine.
520.2215 Sulfadiazine/pyrimethamine suspension.
520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.
520.2220 Sulfadimethoxine oral dosage forms.
520.2220a Sulfadimethoxine oral solution and soluble powder.
520.2220b Sulfadimethoxine suspension.
520.2220c Sulfadimethoxine tablet.
520.2220d Sulfadimethoxine bolus.
520.2220e Sulfadimethoxine extended-release bolus.
520.2220f Sulfadimethoxine and ormetoprim tablet.
520.2240 Sulfaethoxypyridazine.
520.2240a Sulfaethoxypyridazine solution.
520.2240b Sulfaethoxypyridazine tablets.
520.2260 Sulfamethazine oral dosage forms.
520.2260a Sulfamethazine oblet, tablet, and bolus.
520.2260b Sulfamethazine sustained-release boluses.
520.2260c Sulfamethazine sustained-release tablets.
520.2261 Sulfamethazine sodium oral dosage forms.
520.2261a Sulfamethazine solution.
520.2261b Sulfamethazine powder.
520.2280 Sulfamethizole and methenamine.
520.2325 Sulfaquinoxaline oral dosage forms.
520.2325a Sulfaquinoxaline powder and solution.
520.2325b Sulfaquinoxaline drench.
520.2330 Sulfisoxazole tablets.
520.2340 Tepoxalin.
520.2345 Tetracycline.
520.2345a Tetracycline capsules.
520.2345b Tetracycline tablets.
520.2345c Tetracycline boluses.
520.2345d Tetracycline powder.
520.2345e Tetracycline solution.
520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.
520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.
520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.
520.2362 Thenium closylate.
520.2380 Thiabendazole oral dosage forms.
520.2380a Thiabendazole top dressing and mineral protein block.
520.2380b Thiabendazole drench or paste.
520.2380c Thiabendazole bolus.
520.2380d Thiabendazole and piperazine citrate.
520.2380e Thiabendazole and trichlorfon.
520.2380f Thiabendazole and piperazine phosphate.
520.2455 Tiamulin.
520.2471 Tilmicosin.
520.2473 Tioxidazole oral dosage forms.
520.2473a Tioxidazole granules.
520.2473b Tioxidazole paste.
520.2475 Toceranib.
520.2481 Triamcinolone acetonide tablets.
520.2482 Triamcinolone acetonide oral powder.
520.2483 Triamcinolone.
520.2520 Trichlorfon oral dosage forms.
520.2520a Trichlorfon and atropine.
520.2520b Trichlorofon boluses.
520.2520c Trichlorofon granules.
520.2520d Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.
520.2582 Triflupromazine.

520.2598 Trilostane.
520.2604 Trimeprazine and prednisolone tablets.
520.2605 Trimeprazine and prednisolone capsules.
520.2610 Trimethoprim and sulfadiazine tablets.
520.2611 Trimethoprim and sulfadiazine paste.
520.2612 Trimethoprim and sulfadiazine suspension.
520.2613 Trimethoprim and sulfadiazine powder.
520.2640 Tylosin.
520.2645 Tylvalosin.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine.

(a) *Specifications.* Each tablet contains 5, 10, or 25 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.25 to 1.0 mg per pound (/lb) body weight orally.

(ii) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight orally.

(ii) *Indications for use.* As a tranquilizer.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10165, Mar. 5, 2010]

§ 520.28 Acetazolamide.

(a) *Specifications.* A powder containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a dosage of 5 to 15 milligrams per pound of body weight daily.

(2) *Indications for use.* As an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28816, May 20, 2014]

§ 520.38 Albendazole oral dosage forms.

§ 520.38a Albendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 45.5 milligrams (mg) (4.55 percent) or 113.6 mg (11.36 percent) albendazole.

(b) *Sponsor.* See No. 054771 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Cattle.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/pound (lb) body weight (10 mg/kilogram (kg)) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni* and *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls.

(2) *Sheep.* Administer 4.45 or 11.36 percent suspension:

(i) *Amount.* 3.4 mg/lb body weight (7.5 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica* and *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcinta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams.

(3) *Goats.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/lb body weight (10 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For the treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats.

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to does during the first 30 days of pregnancy or for 30 days after removal of bucks.

[73 FR 11027, Feb. 29, 2008. Redesignated at 78 FR 66264, Nov. 5, 2013, as amended at 79 FR 28816, May 20, 2014]

§ 520.38b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*)); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotmum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995. Redesignated at 78 FR 66264, Nov. 5, 2013, as amended at 79 FR 28816, May 20, 2014]

§ 520.43 Afoxolaner.

(a) *Specifications.* Each chewable tablet contains 11.3, 28.3, 68, or 136 milligrams (mg) afoxolaner.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally once a month at a minimum dosage of 1.14 mg/pound (lb) (2.5 mg/kilogram (kg)).

(2) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*); for the treatment and control of black-legged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), lone star tick (*Amblyomma americanum*), and brown dog tick (*Rhipicephalus sanguineus*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 lb of body weight or greater, for 1 month.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 66264, Nov. 5, 2013, as amended at 79 FR 37619, July 2, 2014; 80 FR 18775, Apr. 8, 2015]

§ 520.48 Altrenogest.

(a) *Specifications.* Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

(b) *Sponsors.* See Nos. 000061, 051072, and 061623 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.36 of this chapter.

(d) Conditions of use—(1) *Horses*—(i) *Amount.* 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use.* For suppression of estrus in mares.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days by top-dressing on a portion of each gilt's daily feed.

(ii) *Indications for use.* For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

(iii) *Limitations.* Do not use in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis). Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

[66 FR 47960, Sept. 17, 2001, as amended at 68 FR 62006, Oct. 31, 2003; 72 FR 9455, Feb. 21, 2008; 74 FR 61516, Nov. 25, 2009; 77 FR 32012, May 31, 2012; 80 FR 34278, June 16, 2015; 82 FR 21690, May 10, 2017; 83 FR 13635, Mar. 30, 2018]

§ 520.62 Aminopentamide.

(a) *Specifications.* Each tablet contains 0.2 milligram (mg) aminopentamide hydrogen sulphate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg; for animals weighing 11 to 20 lbs: 0.2 mg; for animals weighing 21 to 50 lbs: 0.3 mg; for animals weighing 51 to 100 lbs: 0.4 mg; for animal weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(2) *Indications for use.* For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28816, May 20, 2014]

§ 520.82 Aminopropazine oral dosage forms.

§ 520.82a Aminopropazine.

(a) *Specifications.* Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally at a dosage of 1 to 2 milligrams per pound of body weight, repeated every 12 hours as indicated.

(2) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28816, May 20, 2014]

§ 520.82b Aminopropazine and neomycin.

(a) *Specifications.* Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base and neomycin sulfate equivalent to 50 milligrams (mg) of neomycin base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a dosage of 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated.

(2) *Indications for use.* For control of bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28816, May 20, 2014]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams (mg) amoxicillin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

(ii) *Indications for use.* Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

(ii) *Indications for use.* Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract due to *E. coli;* and skin and soft tissue (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 79 FR 28816, May 20, 2014]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount.* Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

(B) *Indications for use.* Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis;* genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis;* and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Cats*—(A) *Amount.* Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

(B) *Indications for use.* Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(C) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) *Sponsors.* See Nos. 000856 and 051311 in § 510.600(c) of this chapter.

(1) *Conditions of use. Dogs*—(i) *Amount.* Administer orally 5 mg/lb of body weight, twice a day for 5 to 7 days.

(ii) *Indications for use.* Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003; 79 FR 28816, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.88c Amoxicillin trihydrate oral suspension.

(a) *Specifications.* Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams (mg) amoxicillin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 40 mg orally twice a day using a dosing pump. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days.

(2) *Indications for use.* Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations.* Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 79 FR 28817, May 20, 2014]

§ 520.88d Amoxicillin trihydrate soluble powder.

(a) *Specifications.* Each gram of powder contains amoxicillin trihydrate equivalent to 115.4 milligrams (mg) amoxicillin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use in preruminating calves including veal calves*—(1) *Amount.* Administer 400 mg per 100 pounds of body weight twice daily by drench or in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 5525, Feb. 6, 1997; 79 FR 28817, May 20, 2014]

§ 520.88e Amoxicillin trihydrate boluses.

(a) *Specifications.* Each bolus contains amoxicillin trihydrate equivalent to 400 milligrams (mg) amoxicillin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 400 mg per 100 pounds of body weight twice daily. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 62 FR 5526, Feb. 6, 1997; 79 FR 28817, May 20, 2014]

§ 520.88f Amoxicillin trihydrate tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams (mg) amoxicillin.

(b) *Sponsors.* See Nos. 051311 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 5 mg per pound of

body weight twice daily for 5 to 7 days or 48 hours after all symptoms have subsided.

(2) *Indications for use.* For treatment of bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *Escherichia coli;* and soft tissue infections (abscesses, wounds, lacerations) due to S. aureus, *Streptococcus* spp., *E. coli*, *Proteus mirabilis*, and *Staphylococcus* spp.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28817, May 20, 2014]

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

(a) *Specifications.* Each tablet or chewable tablet contains amoxicillin trihydrate and clavulanate potassium equivalent to 50 milligrams (mg) of amoxicillin and 12.5 mg clavulanic acid, 100 mg of amoxicillin and 25 mg clavulanic acid, 200 mg amoxicillin and 50 mg clavulanic acid, or 300 mg amoxicillin and 75 mg clavulanic acid.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use of tablets and chewable tablets as in paragraph (c) of this section.

(2) No. 026637 for use of tablets as in paragraph (c) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) *Staphylococcus aureus*, non-beta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 62.5 milligrams (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, non-beta-lactamase producing *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Also, treatment of urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998; 79 FR 28817, May 20, 2014; 80 FR 34278, June 16, 2015; 82 FR 11508, Feb. 24, 2017; 82 FR 43484, Sept. 18, 2017; 82 FR 58556, Dec. 13, 2017]

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, nonbeta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and

Escherichia coli. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily. Administer 48 hours after all signs have subsided. Maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use*. Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998; 79 FR 28817, May 20, 2014]

§ 520.90 Ampicillin oral dosage forms.

§ 520.90a [Reserved]

§ 520.90b Ampicillin tablets.

(a) *Specifications*. Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use*. Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and *Pasteurella* spp., urinary tract infections (cystitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E., coli*, *P. mirabilis*, and *Enterococcus* spp.; gastrointestinal infections due to *Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., and *E. coli*. ; infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus* spp., and *Streptococcus* spp.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 79 FR 28818, May 20, 2014]

§ 520.90c Ampicillin capsules.

(a) *Specifications*. Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight, three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10 to 30 milligrams per pound of body weight or three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use*. Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 79 FR 28818, May 20, 2014]

§ 520.90d Ampicillin for oral suspension.

(a) *Specifications.* When reconstituted as directed, each milliliter contains ampicillin trihydrate equivalent to 25 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer to 10 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. In severe or acute conditions, 10 milligrams per pound of body weight 3 times daily. Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided.

(ii) *Indications for use.* Treatment of respiratory tract infections (tracheobronchitis and tonsillitis) due to *Escherichia coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., and *Proteus* spp.; bacterial gastroenteritis due to *E. coli*; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp. and *Streptococcus* spp.; bacterial dermatitis due to *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Pseudomonas* spp.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 10 to 30 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided.

(ii) *Indications for use.* Treatment of respiratory tract infections (bacterial pneumonia) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Proteus* spp.; urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Corynebacterium* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp., *Streptococcus* spp., *Bacillus* spp., and *Pasteurella* spp.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 79 FR 28818, May 20, 2014]

§ 520.90e Ampicillin for soluble powder.

(a) *Specifications.* Each gram contains ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use. Swine*—(1) *Amount.* 5 milligrams of ampicillin per pound of body weight twice daily, orally by gavage or in drinking water for up to 5 days.

(2) *Indications for use.* Oral treatment of porcine colibacillosis (*Escherichia coli*) and salmonellosis (*Salmonella* spp.) infections in swine up to 75 pounds of body weight, and bacterial pneumonia caused by *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

(3) *Limitations.* Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 79 FR 28818, May 20, 2014]

§ 520.90f Ampicillin boluses.

(a) *Specifications.* Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 055529 for use as in paragraph (d)(1) of this section;

(2) No. 054771 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use. Nonruminating calves*—(1) *Amount.* 5 milligrams per pound of body weight twice daily for up to 5 days.

(i) *Indications for use.* Oral treatment of colibacillosis caused by *Escherichia coli*, bacterial enteritis caused by *Salmonella* spp., and bacterial pneumonia caused by *Pasteurella* spp.

(ii) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount.* 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(i) *Indications for use.* Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli.*

(ii) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995; 79 FR 28818, May 20, 2014]

§ 520.100 Amprolium.

(a) *Specifications.* (1) Each milliliter of solution contains 96 milligrams (mg) amprolium (9.6 percent solution).

(2) Each gram of powder contains 200 mg amprolium (20 percent).

(3) Each ounce (28.4 grams) of crumbles contains 355 mg amprolium (1.25 percent).

(b) *Sponsors.* See sponsors in 510.600(c) of this chapter.

(1) No. 016592 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) No. 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

(c) *Related tolerances.* See §556.50 of this chapter.

(d) *Conditions of use*—(1) *Growing chickens, turkeys, and laying hens.* It is used in drinking water as follows:

(i) *Amount.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks.

(ii) *Indications for use.* For the treatment of coccidiosis.

(iii) *Limitations.* Use as the sole source of amprolium.

(2) *Calves.* Administer crumbles topdressed on or thoroughly mixed in the daily feed ration; administer concentrate solution or soluble powder as a drench or in drinking water as follows:

(i) *Indications for use and amounts*—(A) As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

(ii) *Limitations.* Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Use as the sole source of amprolium.

[71 FR 56346, Sept. 27, 2006, as amended at 72 FR 60551, Oct. 25, 2007; 73 FR 45611, Aug. 6, 2008; 73 FR 70276, Nov. 20, 2008; 74 FR 10484, Mar. 11, 2009; 76 FR 38554, July 1, 2011; 76 FR 40808, July 12, 2011; 78 FR 23, Jan. 2, 2013; 78 FR 17596, Mar. 22, 2013; 78 FR 57058, Sept. 17, 2013; 81 FR 22523, Apr. 18, 2016; 81 FR 59133, Aug. 29, 2016]

§ 520.110 Apramycin sulfate soluble powder.

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 058198 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.52 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day for 7 days.

(2) *Indications for use.* For the control of porcine colibacillosis (weanling pig

scours) caused by strains of *Escherichia coli* sensitive to apramycin.

(3) *Limitations.* Do not slaughter treated swine for 28 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988; 79 FR 28818, May 20, 2014; 81 FR 48702, July 26, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Bacitracin methylenedisalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Growing turkeys*—(i) *Amount.* 400 milligrams (mg) per gallon (gal) in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler and replacement chickens*—(i) *Amount.* 100 mg per gal in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylenedisalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 mg per gal in drinking water. Administer continuously 5 to 7 days or as long as clinical signs persist, then reduce to prevention levels (100 mg/gal).

(A) *Indications for use.* Treatment of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylenedisalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Brachyspira hyodysenteriae.* Administer continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations.* Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

(4) *Growing quail*—(i) *Amount.* 400 mg per gal in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 63 FR 38474, July 17, 1998; 64 FR 13068, Mar. 17, 1999; 76 FR 53050, Aug. 25, 2011; 79 FR 28818, May 20, 2014; 80 FR 34278, June 16, 2015]

§ 520.154b Bacitracin methylenedisalicylate and streptomycin sulfate powder.

(a) *Specifications.* Each gram of powder contains 200 units bacitracin methylenedisalicylate and streptomycin sulfate equivalent to 20 milligrams of streptomycin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 17702, Apr. 7, 2006, as amended at 79 FR 28818, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.154c Bacitracin zinc soluble powder.

(a) *Specifications.* Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Broiler chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount.* 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use.* Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

(iii) *Limitations.* Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28818, May 20, 2014]

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name. N,N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications.* The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis.*

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 13018, Mar. 8, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.246 Butorphanol tablets.

(a) *Specifications.* Each tablet contains butorphanol tartrate equivalent to 1, 5, or 10 milligrams (mg) butorphanol base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.25 mg butorphanol base per pound of body weight. Repeat at intervals of 6 to 12 hours as required. Treatment should not normally be required for longer than 7 days.

(2) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheobronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28818, May 20, 2014]

§ 520.260 n-Butyl chloride.

(a)(1) *Specifications. n*-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs and of the ascarid (*Toxocara cati*) and hookworm (*Ancylostoma tubaeforme*) from cats.

(ii)(*a*) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should be given a repeat treatment in a week or 10 days. After that they should be treated every 2 months (or as symptoms reappear) until a year old. When the puppy or kitten is a year old, one treatment every 3 to 6 months is sufficient.

(*b*) For dogs or cats that have been wormed regularly, treatment every 3 to 6 months will be sufficient. If a dog or cat has not been wormed previously and has the symptoms of large roundworms a dose should be given and repeated in 10 days. Removal of hookworms may require 3 or 4 doses at 10-day intervals.

(*c*) Puppies, dogs, cats, or kittens weighing 1 to 3 pounds should be given 2 capsules per dose which contain 272 milligrams of *n*-butyl chloride each. Such animals weighing 4 to 5 pounds should be given 3 such capsules. Animals weighing 6 to 7 pounds should be given 4 such capsules and animals weighing 8 to 9 pounds should be given 5 such capsules. Animals weighing 10 to 20 pounds should be given 3 capsules which contain 816 milligrams of *n*-butyl chloride each, animals weighing 20 to 40 pounds should be given 4 such capsules and animals weighing over 40 pounds should be given 5 such capsules with the maximum dosage being 5 capsules, each of which contains 816 milligrams of *n*-butyl chloride.

(iii) A veterinarian should be consulted before using in severely debilitated dogs or cats and also prior to repeated use in cases which present signs of persistent parasitism.

(b)(1) *Specifications.* *n*-Butyl chloride capsules contain 221, 442, 884, or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.

(2) *Sponsors.* See No. 023851 in § 510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 038782 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 054771 for 221 milligram capsules.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs.

(ii)(*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks.

(*b*) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 1¼ pound of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999; 70 FR 50182, Aug. 26, 2005; 78 FR 14669, Mar. 7, 2013; 79 FR 28818, May 20, 2014]

EDITORIAL NOTE: At 78 FR 14669, Mar. 7, 2013, § 520.260 was amended by adding paragraphs (b)(1) through (3); however, the amendment could not be incorporated because (b)(1) through (3) already existed.

§ 520.284 Cambendazole oral dosage forms.

§ 520.284a Cambendazole suspension.

(a) *Specifications.* Each fluid ounce contains 0.9 gram of cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28818, May 20, 2014. Redesignated at 81 FR 59133, Aug. 29, 2016]

§ 520.284b Cambendazole pellets.

(a) *Specifications.* The drug is in feed pellets containing 5.3 percent cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28818, May 20, 2014. Redesignated at 81 FR 59133, Aug. 29, 2016]

§ 520.284c Cambendazole paste.

(a) *Specifications.* The drug is a paste containing 45 percent cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 milligrams cambendazole per kilogram body weight (5 grams per 550 pounds (250 kilograms)) by depositing the paste on the back of the tongue using a dosing gun. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28819, May 20, 2014. Redesignated at 81 FR 59133, Aug. 29, 2016]

§ 520.292 Capromorelin.

(a) *Specifications.* Each milliliter of solution contains 30 milligrams (mg) capromorelin.

(b) *Sponsor.* See No. 086026 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 3 mg/kg once daily by mouth.

(2) *Indications for use.* For appetite stimulation in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 59133, Aug. 29, 2016]

§ 520.301 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5st caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.

(2) *Indications for use.* For relief of cough.

[43 FR 55385, Nov. 28, 1978, as amended at 79 FR 28819, May 20, 2014. Redesignated at 80 FR 13229, Mar. 13, 2015]

§ 520.302 Carnidazole tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use.* For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations.* Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989. Redesignated at 80 FR 13229, Mar. 13, 2015]

§ 520.304 Carprofen.

(a) *Specifications.* (1) Each caplet contains 25, 75, or 100 milligrams (mg) carprofen.

(2) Each chewable tablet contains 25, 75, or 100 mg carprofen.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 054771, 026637, 055529, and 062250 for use of products described in paragraph (a) as in paragraph (d) of this section.

(2) No. 000859 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999; 66 FR 63165, Dec. 5, 2001; 67 FR 6866, Feb. 14, 2002; 67 FR 65038, Oct. 23, 2002; 67 FR 65697, Oct. 28, 2002; 70 FR 30626, May 27, 2005; 71 FR 51995, Sept. 1, 2006; 72 FR 68478, Dec. 5, 2007; 74 FR 21768, May 11, 2009; 78 FR 52853, Aug. 27, 2013; 78 FR 66264, Nov. 5, 2013; 79 FR 28819, May 20, 2014. Redesignated and amended at 80 FR 13229, Mar. 13, 2015; 80 FR 34278, June 16, 2015; 80 FR 61296, Oct. 13, 2015; 82 FR 43484, Sept. 18, 2017]

§ 520.314 Cefadroxil.

(a) *Specifications.* (1) Each tablet contains 50, 100, or 200 milligrams (mg) or 1 gram of cefadroxil.

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs.* Administer 10 mg per pound (/lb) body weight twice daily orally.

(ii) *Cats.* Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use*—(i) *Dogs.* For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus.* For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus.*

(ii) *Cats.* For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *S.*

aureus, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10165, Mar. 5, 2010]

§ 520.370 Cefpodoxime tablets.

(a) *Specifications.* (1) Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(2) Each chewable tablet contains cefpodoxime proxetil equivalent to 100 or 200 mg cefpodoxime.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as follows:

(1) No. 026637 for use of product in paragraph (a)(1) of this section as in paragraph (c) of this section.

(2) No. 054771 for use of products in paragraph (a) of this section as in paragraph (c) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus pseudintermedius*, *S. aureus*, *Streptococcus canis* (group G, beta-hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 52815, Aug. 30, 2004, as amended at 78 FR 5714, Jan. 28, 2013; 79 FR 28819, May 20, 2014; 80 FR 13229, Mar. 13, 2015; 82 FR 12169, Mar. 1, 2017]

§ 520.376 Cephalexin.

(a) *Specifications.* Each chewable tablet contains 75, 150, 300, or 600 milligrams (mg) cephalexin.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 22 mg per kilogram of body weight twice daily for 28 days.

(ii) *Indications for use.* For the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a) *Specifications.* Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.

(b) *Sponsors.* See § 510.600(c) of this chapter:

(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:

(i) No. 054628 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;

(ii) No. 054771 for 100-, 250-, and 500-mg tablets;

(2) For use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section:

(i) No. 061623 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;

(ii) [Reserved]

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 25 mg per pound of body weight by mouth every 6 hours.

(2) *Indications for use*—(i) For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[77 FR 4896, Feb. 1, 2012, as amended at 78 FR 21059, Apr. 9, 2013; 79 FR 28819, May 20, 2014]

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.

(b) *Sponsors.* See Nos. 050057 and 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Special considerations.* Federal law prohibits the extralabel use of this product in food-producing animals.

(d) *Conditions of use in dogs*—(1) *Amount.* 25 mg per pound of body weight every 6 hours.

(2) *Indications for use.* For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 75398, Dec. 20, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 75 FR 55676, Sept. 14, 2010; 79 FR 28819, May 20, 2014]

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) *Specifications.* Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight every 6 hours. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals that are raised for food production. Must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 79 FR 28819, May 20, 2014]

§ 520.420 Chlorothiazide tablets and boluses.

(a)(1) *Specifications.* Each tablet contains 0.25 gram of chlorothiazide.

(2) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Usual dosage is 5 to 10 milligrams per pound of body weight two or three times daily.

(ii) *Indications for use.* For use in dogs for treatment of congestive heart failure and renal edema.

(iii) *Limitations. (a)* Dosage must be adjusted to meet the changing needs of the individual animal. In mild and responsive cases, it is suggested that a dose of 5 milligrams per pound of body weight be administered two or three times daily. In moderately edematous and moderately responsive animals, a dose of 7.5 to 10 milligrams per pound of body weight may be administered three times daily. Severe conditions may require higher doses. Certain animals may respond adequately to intermittent therapy; in these cases, the drug may be administered either every other day or for 3 to 5 days each week.

(*b*) Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. In some dogs, hypochloremic alkalosis may occur (that is, excretion of chloride in relation to sodium is excessive; the plasma bicarbonate level increases and alkalosis results). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each bolus contains 2 grams of chlorothiazide.

(2) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* 2 grams once or twice daily for 3 or 4 days.

(ii) *Indications for use.* For use in cattle as an aid in reduction of postparturient udder edema.

(iii) *Limitations.* Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. Milk taken from dairy animals during treatment and for 72 hours (six milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997; 79 FR 28819, May 20, 2014]

§ 520.434 Chlorphenesin carbamate tablets.

(a) *Specifications.* Each tablet contains 400 milligrams of chlorphenesin carbamate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 50 milligrams per pound of body weight on first day; 25 milligrams per pound of body weight each following day. Divide total daily dose into 2 or 3 equal doses—administer at 12- or 8-hour intervals.

(2) *Indications for use.* For use as an adjunct to therapy of acute inflammatory and traumatic conditions of skeletal muscles. The drug provides relief of the signs of discomfort associated with myositis, muscle sprains, traumatic injuries, stifle injuries—especially when administered before or after surgery—and invertebral disc syndrome (can be used concurrently with adrenal corticosteroids).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 16009, Mar. 16, 1979, as amended at 79 FR 28819, May 20, 2014]

§ 520.441 Chlortetracycline powder.

(a) *Specifications.* Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000010, 016592, 054771, and 069254 for use as in paragraph (d) of this section.

(2) No. 066104 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

(3) Nos. 069254 and 076475 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), (d)(4)(ii), and (d)(4)(iii) of this section.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use.* (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(*1*) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(*2*) *Limitations.* Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(*1*) Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount.* 200 to 400 milligrams per gallon.

(*1*) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 400 to 800 milligrams per gallon.

(*1*) *Indications for use.* Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(C) *Amount.* One thousand milligrams per gallon.

(*1*) *Indications for use.* Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(*2*) *Limitations.* See paragraph (d)(4)(i)(A)(*2*) of this section.

(ii) *Growing turkeys*—(A) *Amount.* 400 milligrams per gallon.

(*1*) *Indications for use.* Control of infectious synovitis caused by *M. synoviae.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 25 milligrams per pound of body weight daily.

(*1*) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Swine*—(A) *Amount.* 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days. For Nos. 016592 and 021930, do not slaughter animals for food within 5 days of treatment. For No. 016592, do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 milligrams per pound daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) Use in a drench or drinking water as follows:

(i) *Chickens*—(A) *Amount.* 200 to 400 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(*2*) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not use in laying chickens; do not administer to chickens within 24 hours of slaughter. Federal law restricts this drug to use

by or on the order of a licensed veterinarian.

(B) *Amount.* 400 to 800 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of chronic respiratory disease (CRD) and air-sac infections caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(i)(A)(*2*) of this section.

(C) *Amount.* One thousand mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of mortality due to fowl cholera caused by Pasteurella multocida susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(i)(A)(*2*) of this section.

(ii) *Growing Turkeys*—(A) *Amount.* 400 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.

(*2*) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not administer to growing turkeys within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 25 mg/lb body weight daily, for 7 to 14 days.

(*1*) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(ii)(A)(*2*) of this section.

(iii) *Swine*—(A) *Amount.* 10 mg/lb body weight daily, for 3 to 5 days.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae*, and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to swine within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 mg/lb body weight daily in divided doses, for 3 to 5 days.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Histophilus* spp., and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to cattle within 24 hours of slaughter; do not use in lactating dairy cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37324, Aug. 18, 1992]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.441, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 520.443 Chlortetracycline tablets and boluses.

(a) *Specifications.* Each tablet/bolus contains 25, 250, or 500 milligrams (mg) chlortetracycline hydrochloride.

(b) *Sponsor.* See Nos. 016592 and 054628 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use in calves*—(1) *Amount.* One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klesbsiella* spp., and *Haemophilus* spp.

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount.* One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount.* One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002. Redesignated and amended at 76 FR 49649, Aug. 11, 2011; 78 FR 21059, Apr. 9, 2013; 81 FR 17607, Mar. 30, 2016]

§ 520.445 Chlortetracycline and sulfamethazine powder.

(a) *Specifications.* Each pound of soluble powder contains chlortetracycline bisulfate equivalent to 102.4 grams (g) of chlortetracycline hydrochloride and sulfamethazine bisulfate equivalent to 102.4 g of sulfamethazine.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use in swine.* Administer in drinking water as follows:

(1) *Amount.* 250 milligrams (mg) of chlortetracycline and 250 mg of sulfamethazine per gallon.

(2) *Indications for use.* For the prevention and treatment of bacterial enteritis; as an aid in the reduction of the incidence of cervical abscesses; and as an aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations.* Use as the sole source of chlortetracycline and sulfonamide. Not to be used for more than 28 consecutive days. Withdraw 15 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 49649, Aug. 11, 2011, as amended at 81 FR 17607, Mar. 30, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.446 Clindamycin capsules and tablets.

(a) *Specifications.* (1) Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.

(2) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(3) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 054771 and 069043 for use of capsules described in paragraph (a)(1) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.

(3) No. 043806 for use of tablets described in paragraph (a)(3) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*,

B. fragilis, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 54954, Aug. 27, 2002, as amended at 68 FR 55824, Sept. 29, 2003; 69 FR 32273, June 9, 2004; 71 FR 39204, July 12, 2006; 73 FR 4077, Jan. 24, 2008; 78 FR 17596, Mar. 22, 2013; 79 FR 28819, May 20, 2014; 80 FR 76386, Dec. 9, 2015; 81 FR 17607, Mar. 30, 2016]

§ 520.447 Clindamycin solution.

(a) *Specifications.* Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors.* See Nos. 051311, 054771, 058829, 061623, and 069043 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*; dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*; and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(2) Cats—(i) *Amount.* 5.0 to 15.0 mg/lb body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *Staphylococcus aureus*, *S. intermedius*, *Streptococcus spp.*; deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*; and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus spp.*, *C. perfringens*, and *B. fragilis.*

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004; 71 FR 39543, July 13, 2006; 72 FR 19796, Apr. 20, 2007; 78 FR 17596, Mar. 22, 2013; 78 FR 30197, May 22, 2013; 79 FR 28819, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.452 Clenbuterol syrup.

(a) *Specifications.* Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use.* Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations.* Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine tablets.

(a) Specifications. Each tablet contains 5, 20, 40, or 80 milligrams (mg) clomipramine hydrochloride.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use*. For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 1762, Jan. 12, 1999, as amended at 72 FR 262, Jan. 4, 2007]

§ 520.462 Clorsulon drench.

(a) *Specifications*. The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Cattle*—(1) *Amount*. One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use*. For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations*. Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.522 Cyclosporine.

(a) *Specifications*. (1) Each cyclosporine capsule, USP (MODIFIED) contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(2) Each milliliter of cyclosporine oral solution, USP (MODIFIED) contains 100 mg cyclosporine.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*. Use capsules described in paragraph (a)(1) of this section as follow:

(i) *Amount*. Administer 5 mg per kilogram (mg/kg) of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(ii) *Indications for use*. For the control of atopic dermatitis in dogs weighing at least 4 pounds.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*. Use the solution described in paragraph (a)(2) of this section as follow:

(i) *Amount*. Administer 7 mg/kg of body weight orally as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or twice weekly to maintain the desired therapeutic effect.

(ii) *Indications for use*. For the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 54804, Sept. 19, 2003, as amended at 76 FR 78815, Dec. 20, 2011]

§ 520.530 Cythioate oral liquid.

(a) *Specifications*. Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor*. See Nos. 000859 and 054771 in § 510.600 of this chapter.

(c) *Special considerations*. Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to

cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28819, May 20, 2014]

§ 520.531 Cythioate tablets.

(a) *Specifications.* Each tablet contains 30 or 90 milligrams (mg) cythioate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 000859 for use of 30- and 90-mg tablets;

(2) No. 054771 for use of the 30-mg tablet.

(c) *Conditions of use*—(1) *Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5615, Feb. 14, 1984, as amended at 59 FR 26942, May 25, 1994; 67 FR 78355, Dec. 24, 2002; 79 FR 28819, May 20, 2014]

§ 520.534 Decoquinate.

(a) *Specifications.* Each gram of powder contains 8 milligrams (0.8 percent) decoquinate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount.* Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use.* For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii.*

(3) *Limitations.* Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

[64 FR 10103, Mar. 2, 1999, as amended at 64 FR 30386, June 8, 1999; 79 FR 28819, May 20, 2014]

§ 520.538 Deracoxib.

(a) *Specifications.* Each tablet contains 12, 25, 50, 75, or 100 milligrams (mg) deracoxib.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* Administer orally as needed, as a single daily dose based on body weight:

(i) 1 to 2 mg/kilogram (kg) (0.45 to 0.91 mg/pound (lb)), for use as in paragraph (d)(2)(i) of this section.

(ii) 1 to 2 mg/kg (0.45 to 0.91 mg/lb) for 3 days, for use as in paragraph (d)(2)(ii) of this section.

(iii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(iii) of this section.

(2) *Indications for use.* (i) For the control of pain and inflammation associated with osteoarthritis.

(ii) For the control of postoperative pain and inflammation associated with dental surgery.

(iii) For the control of postoperative pain and inflammation associated with orthopedic surgery.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 68760, Nov. 13, 2002, as amended at 68 FR 18882, Apr. 17, 2003; 72 FR 37437, July 10, 2007; 73 FR 33692, June 13, 2008; 77 FR 3928, Jan. 26, 2012]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications.* Each packet contains 10 milligrams (mg) of dexamethasone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle and horses*—(1) *Amount.* Administer 5 to 10 mg per animal the first day then 5 mg per day as required by drench or by sprinkling on a small amount of feed.

(2) *Indications for use.* As supportive therapy following parenteral steroid

administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

[79 FR 28819, May 20, 2014]

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use in cattle and horses*—(i) *Amount.* Administer orally 5 to 10 milligrams on the first day, then 5 milligrams per day as required.

(ii) *Indications for use.* As supportive therapy following parenteral steroid administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(b)(1) *Specifications.* Each tablet contains 0.25 milligram of dexamethasone.

(2) *Sponsors.* See Nos. 000061 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs and cats*—(i) *Amount.* Dogs: Administer orally 0.25 to 1.25 milligrams per day for up to 7 days. Cats: Administer orally 0.125 to 0.5 milligrams per day for up to 7 days.

(ii) *Indications for use.* As an anti-inflammatory agent.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 26273, June 23, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 50 FR 49372, Dec. 2, 1985; 52 FR 7832, Mar. 13, 1987; 55 FR 8461, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 70 FR 16934, Apr. 4, 2005; 79 FR 28819, May 20, 2014]

§ 520.540c Dexamethasone chewable tablets.

(a) *Specifications.* Each half-scored tablet contains 0.25 milligram of dexamethasone.

(b) *Sponsor.* See No. 051031 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by free-choice feeding or crumbled over food 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.

(2) *Indications for use.* As supportive therapy in nonspecific dermatosis and inflammatory conditions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 7130, Feb. 6, 1979, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28820, May 20, 2014; 82 FR 11508, Feb. 24, 2017]

§ 520.563 Dexamethasone chewable tablets.

(a) *Specifications.* Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. Administered rectally 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(2) *Indications for use.* For radiography of the gastrointestinal tract.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985; 79 FR 28820, May 20, 2014]

§ 520.580 Dichlorophene and toluene.

(a) *Specifications.* Each capsule contains 50 milligrams (mg) of dichlorophene and 60 mg of toluene, or multiples thereof.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) Nos. 017135, 023851, 051311, and 058670 for use only as a single dose.

(2) Nos. 000061 and 054771 for use in a single dose or divided-dosage regimen.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use*—(1) *Amount.* Administer as follows:

(i) Single dose: Administer 100 mg of dicholorophene and 120 mg of toluene per pound of body weight.

(ii) Divided dose: Administer 100 mg of dichlorophene and 120 mg of toluene per 5 pounds of body weight (20 and 24 mg per pound) daily for 6 days.

(2) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and as an aid in removing tapeworms (*Taenia pisiformis*, *Dipylidium caninum*, and *Echinococcus granulosus*) from dogs and cats.

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward. Repeat treatment in 2 to 4 weeks in animals subject to reinfection.

[45 FR 10332, Feb. 15, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.580, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 520.581 Dichlorophene tablets.

(a) *Specifications.* Each tablet contains 1 gram of dichlorophene.

(b) *Sponsor.* See 023851 in § 510.600(c) of this chapter.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use. Dogs*—(1) *Amount.* Single dose of 1 tablet (1 gram of dichlorophene) for each 10 pounds of body weight.

(2) *Indications for use.* It is used as an aid in the removal of tapeworms (*Taenia pisiformis* and *Dipylidium caninum*).

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward.

[45 FR 10333, Feb. 15, 1980]

§ 520.600 Dichlorvos.

(a) *Chemical name.* 2,2-Dichlorvinyl dimethyl phosphate.

(b) [Reserved]

(c) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.180 of this chapter.

(e) *Conditions of use in swine.* (1) It is recommended for the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* spp.), large round-worm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(2) The preparation should be added to the indicated amount of feed as set forth in paragraph (e)(2) of this section and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.08 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.08 ounce of dichlorvos
20–30	4	0.33	12
31–40	5	0.56	9
41–60	6	1.00	6
61–80	5	1.00	5
81–100	4	1.00	4
Adult Gilts, Sows, and Boars	16	4.00	4

(3) Do not use this product on animals either simultaneously or within a

few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(f) *Conditions of use in dogs.* (1) For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

(2) The drug is in capsule form for direct administration and in pellet form for administration in about one-third of the regular canned dog food ration or in ground meat. Dogs may be treated with any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 milligrams of the active ingredient per pound of body weight. One-half of the single recommended dosage may be given, and the other half may be administered 8 to 24 hours later. This split dosage schedule should be used in animals which are very old, heavily parasitized, anemic, or otherwise debilitated. The drug should not be used in dogs weighing less than 2 pounds.

(3) In some dogs, efficacy against *Trichurias vulpis* (whipworm) may be erratic. Dogs that do not develop a negative stool for *Trichuris vulpis* ova 10 to 14 days following initial treatment should be re-treated. If a negative stool is not obtained in 10 to 14 days following re-treatment, alternate means of therapy should be considered.

(4) Do not use in dogs infected with *Dirofilaria immitis.*

(5) Do not use with other anthelmintics, taeniacides, antifilarial agents, muscle relaxants, or tranquilizers.

(6) The drug is a cholinesterase inhibitor. Not for use simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(7) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g) *Conditions of use in horses when administered in grain.* (1) It is recommended for the removal and control of bots (*Gastrophilus intestinalis, G. nasalis*), large strongyles (*Strongylus vulgaris, S. equinus, S. edentatus*), small strongyles (of the genera *Cyathostomum, Cylicocercus, Cylicocyclus, Cylicodontophorus, Triodontophorus, Poteriostomum, Gyalocephalus*), pinworms (*Oxyuris equi*), and large roundworm (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(2) For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or a diagnostic laboratory prior to worming.

(3) It is administered in the grain portion of the ration at a dosage of 14.2 milligrams to 18.5 milligrams per pound of body weight as a single dose. It may be administered at one-half of the single recommended dosage and repeated 8 to 12 hours later in the treatment of very aged, emaciated or debilitated subjects or those reluctant to consume medicated feed. In suspected cases of severe ascarid infection sufficient to cause concern over mechanical blockage of the intestinal tract, the split dosage should be utilized.

(4) Do not use in horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia or colic. Do not administer in conjunction with or within 1 week of administration of muscle relaxant drugs, phenothiazine derived tranquilizers or central nervous system depressant drugs. Horses should not be subjected to insecticide treatment for 5 days prior to or after treating with the drug. Do not administer to horses afflicted with chronic alveolar emphysema (heaves) or related respiratory conditions. The product is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals.

(5) Do not use in animals other than horses, ponies, and mules. Do not use in horses, ponies, and mules intended for food purposes. Do not allow fowl access to feed containing this preparation or to fecal excrement from treated animals.

(h) *Conditions of use in horses when administered orally by syringe.* (1) It is recommended for the removal and control of first, second, and third instar bots (*Gastrophilus intestinalis* and *G. nasalis*), sexually mature and sexually immature (4th stage) ascarids (*Parascaris equorum*) in horses and foals.

(2) The product is in the form of a gel which is administered directly from a syringe onto the horse's tongue. The product is administered at a dosage level of 20 milligrams of dichlorvos per kilogram of body weight for the removal of bots and ascarids. The same dosage level is repeated every 21 to 28 days for the control of bots and ascarids. For the control of bots only, the repeat dosage is 10 milligrams per kilogram of body weight every 21 to 28 days during bot fly season.

(3) Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides or chemicals. Do not administer in conjunction with or within 1 week of administration of muscle-relaxant drugs, phenothiazine derived tranquilizers, or central nervous system depressants.

(4) Do not use in horses which are severly debilitated or suffering from diarrhea or severe constipation, infectious disease, toxemia, or colic. Do not administer to horses affected with chronic alveolar emphysema (heaves) or other respiratory conditions.

(5) Do not use in horses intended for food purposes.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(i) *Conditions of use in dogs, cats, puppies, and kittens.* (1) Each tablet contains 2, 5, 10, or 20 milligrams of dichlorvos.

(2) It is administered orally at 5 milligrams of dichlorvos per pound of body weight.

(3) Dogs and puppies: Removal and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(4) Cats and kittens: Removal and control of intestinal roundworms (*Toxocara cati* and *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme* and *Uncinaria stenocephala*).

(5) Dichlorvos is a cholinesterase inhibitor. Do not use simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(6) Do not use in animals under 10 days of age or 1 pound of body weight.

(7) Do not administer to animals showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or recently exposed to or showing signs of infectious disease.

(8) Do not use in dogs or puppies infected with *Dirofilaria immitis.*

(9) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 48 FR 40704, Sept. 9, 1983; 51 FR 28546, Aug. 8, 1986; 62 FR 35076, June 30, 1997; 64 FR 18571, Apr. 15, 1999; 78 FR 21059, Apr. 9, 2013]

§ 520.606 Diclazuril.

(a) *Specifications.* Each 100 grams (g) of pellets contain 1.56 g diclazuril.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milligram (mg) per kilogram (0.45 mg per pound) of body weight in the daily grain ration for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 20943, Apr. 27, 2007]

§ 520.608 Dicloxacillin.

(a) *Specifications.* Each capsule contains dicloxacillin sodium monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin.

(b) *Sponsor.* See No. 054771 in § 510.600 (c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally 5 to 10 milligrams per pound of body weight, three times daily. In severe cases, up to 25 milligrams per pound of body weight three times daily.

(2) *Indications for use*. For the treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to dicloxacillin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992, as amended at 79 FR 28820, May 20, 2014]

§ 520.620 Diethylcarbamazine oral dosage forms.

§ 520.622 Diethylcarbamazine citrate oral dosage forms.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) *Sponsors*. (1) [Reserved]

(2) See 054771 in § 510.600(c) of this chapter for use of 100, 200, and 300 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs.

(3) See 061623 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(4) [Reserved]

(5) See No. 000061 in § 510.600(c) of this chapter for use of 60, 120, or 180 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(6) See No. 054628 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use*—(1) *Dosage/indications for use*. (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

(2) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 76 FR 17777, Mar. 31, 2011; 77 FR 4896, Feb. 1, 2012; 78 FR 21059, Apr. 7, 2013; 79 FR 28820, May 20, 2014]

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications*. Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]

(c)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used in dogs between 4 weeks and 8 months of age for the removal of ascarids (*Toxacara canis*) and in animals over 4 weeks of age for the prevention of heartworm disease (*Dirofilaria immitis*).

(ii) The drug is administered (*a*) for removal of ascarids at a dosage of 50 milligrams per pound of body weight divided into two equal doses and administered 8 to 12 hours apart (morning and night), orally or mixed with either dry or wet food, and (*b*) for prevention of heartworm disease at a dosage of 3 milligrams per pound of body weight daily, orally or in food, in heartworm endemic areas, from the beginning of mosquito activity, during the mosquito season, and for 2 months following the end thereof.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis.* Use of the drug is contraindicated in dogs with active *D. immitis* infections.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 28265, July 9, 1976; 44 FR 3967, Jan. 19, 1979; 47 FR 14150, Apr. 2, 1982; 47 FR 35186, Aug. 13, 1982; 49 FR 33997, Aug. 28, 1984; 50 FR 41489, Oct. 11, 1985; 53 FR 47027, Oct. 18, 1988; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 77 FR 4897, Feb. 1, 2012; 78 FR 21059, Apr. 9, 2013; 79 FR 28820, May 20, 2014]

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Specifications.* Each chewable tablet contains 30, 45, 60, 120, 150, or 180 milligrams of diethylcarbamazine citrate.

(b) *Sponsors.* See drug listing nos. in § 510.600(c) of this chapter for identification of sponsors as follows:

(1) [Reserved]

(2) For 054771, use of 60, 120, or 180 milligram tablets as in paragraph (c)(2)(ii) of this section.

(3) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(iii) of this section.

(4) For 061133, use of 60-, 120-, or 180-milligram tablets as in paragraph (c)(2)(i) of this section.

(5) For 000061, use of 60-milligram tablets as in paragraph (c)(2)(i) of this section.

(6) For 054628, use of 30, 60, 120, or 180 milligram tablets as in paragraph (c)(2)(i) of this section.

(c) *Conditions of use*—(1) *Amount.* 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(2) *Indications for use.* (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats.

(ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.

(iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 6941, Feb. 17, 1978]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.622c, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 520.623 Diethylcarbamazine and oxibendazole chewable tablets.

(a) *Specifications.* Each tablet contains either 60, 120, or 180 milligrams of diethylcarbamazine citrate with 45, 91, or 136 milligrams of oxibendazole, respectively.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally to dogs at a dosage level of 6.6 milligrams of diethylcarbamazine citrate per kilogram of body weight (3 milligrams per pound of body weight) and 5.0 milligrams of oxibendazole per kilogram of

body weight (2.27 milligrams per pound of body weight).

(2) *Indications for use.* For prevention of infection with *Dirofilaria immitis* (heartworm disease) and *Ancylostoma caninum* (hookworm infection) and for removal and control of *Trichuris vulpis* (whipworm infection) and mature and immature stages of intestinal *Toxocara canis* (ascarid infection).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 28768, July 16, 1985, as amended at 53 FR 45759, Nov. 14, 1988; 54 FR 3776, Jan. 26, 1989; 54 FR 6804, Feb. 14, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28820, May 20, 2014]

§ 520.645 Difloxacin.

(a) *Specifications.* Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(i) *Amount.* Administer 5 to 10 mg per kilogram (2.3 to 4.6 mg per pound) of body weight orally once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

(ii) *Indications for use.* For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations.* Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, Mar. 5, 2010]

§ 520.666 Dirlotapide.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007, as amended at 79 FR 28820, May 20, 2014]

§ 520.763 Dithiazanine oral dosage forms.

§ 520.763a Dithiazanine tablets.

(a) *Specifications.* Each tablet contains 10, 50, 100, or 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* Administer orally immediately after feeding as follows:

(i) For large roundworms (*Toxocara canis, Toxascaris leonina*): 10 mg per pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum, Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For Strongyloides (*Strongyloides canis, Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitus*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28820, May 20, 2014]

§ 520.763b Dithiazanine powder.

(a) *Specifications.* Each tablespoon of powder contains 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* Administer orally by mixing in food as follows:

(i) For large roundworms (*Toxocara canis, Toxascaris leonina*): 10 mg per pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum, Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For Strongyloides (*Strongyloides canis, Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitus*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28820, May 20, 2014]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of suspension contains 69 milligrams (mg) dithiazanine iodide and 83 mg piperazine base (as piperazine citrate).

(b) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; ¾ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10¼ ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum;* small strongyles; large strongyles, *Strongylus vulgaris;* and pinworms, *Oxyuris equi.*

(3) *Limitations.* Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013; 79 FR 28820, May 20, 2014]

§ 520.766 Domperidone.

(a) *Specifications.* Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) *Indications for use.* For prevention of fescue toxicosis in periparturient mares.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 67031, Nov. 1, 2010]

§ 520.784 Doxylamine.

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Horses: Administer orally 1 to 2 milligrams (mg) per pound (/lb) of body weight per day divided into 3 or 4 equal doses. Dogs and cats: Administer orally 2 to 3 mg/lb of body weight per day divided into 3 or 4 equal doses.

(2) *Indications for use.* For use when antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 79 FR 28821, May 20, 2014]

§ 520.804 Enalapril.

(a) *Specifications.* Each tablet contains 1.0, 2.5, 5.0, 10, or 20 milligrams (mg) of enalapril maleate.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally 0.5 to 1.0 mg

of enalapril maleate per kilogram of body weight per day.

(2) *Indications for use.* For the treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28821, May 20, 2014, as amended at 80 FR 34278, June 16, 2015]

§ 520.812 Enrofloxacin.

(a) *Specifications.* Each tablet contains:

(1) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(2) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) Nos. 000859 and 026637 for use of product described in paragraph (a)(1) of this section.

(2) No. 058198 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally as a single, daily dose or divided into two equal doses at 12-hour intervals.

(i) *Dogs.* 5 to 20 mg per kilogram (/kg) (2.27 to 9.07 mg per pound (/lb)) of body weight.

(ii) *Cats.* 5 mg/kg (2.27 mg/lb) of body weight.

(2) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[78 FR 30197, May 22, 2013, as amended at 78 FR 52853, Aug. 27, 2013]

§ 520.816 Epsiprantel.

(a) *Specifications.* Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis.*

(2) *Cats*—(i) *Amount.* 1.25 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of feline cestodes *D. caninum* and *T. taeniaeformis.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28821, May 20, 2014]

§ 520.823 Erythromycin.

(a) *Specifications.* Each gram of powder contains erythromycin phosphate equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Broiler and replacement chickens*—(i) *Amount.* Administer 0.500 gram per gallon for 5 days.

(ii) *Indications for use.* As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Replacement chickens and chicken breeders*—(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

(ii) *Indications for use.* As an aid in the control of infectious coryza due to *Haemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Growing turkeys*—(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

(ii) *Indications for use.* As an aid in the control of blue comb (nonspecific

infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations.* Do not use in turkeys producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 79 FR 28821, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.852 Estriol.

(a) *Specifications.* Each tablet contains 1 milligram (mg) estriol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer at an initial dose of 2 mg per dog per day. The dosage may be titrated to as low as 0.5 mg per dog every second day, depending on response.

(2) *Indications for use.* For the control of estrogen-responsive urinary incontinence in ovariohysterectomized female dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 78150, Dec. 16, 2011]

§ 520.863 Ethylisobutrazine.

(a) *Specifications.* Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally 2 to 5 milligrams per pound of body weight once daily.

(2) *Indications for use.* As a tranquilizer.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 79 FR 28821, May 20, 2014]

§ 520.870 Etodolac.

(a) *Specifications.* Each tablet contains 150, 300, or 500 milligrams (mg) of etodolac.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 10 to 15 mg per kilogram (4.5 to 6.8 mg per pound) of body weight per day orally.

(2) *Indications for use.* For the management of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 51300, Sept. 25, 1998, as amended at 68 FR 51705, Aug. 28, 2003; 75 FR 10166, Mar. 5, 2010; 79 FR 28821, May 20, 2014]

§ 520.903 Febantel oral dosage forms.

§ 520.903a Febantel paste.

(a) *Specifications.* Each gram of paste contains 455 milligrams (45.5 percent) febantel.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer paste orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use.* For removal of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); ascarids (*Parascaris equorum*—sexually mature and immature); pinworms (*Oxyuris equi*—adult and 4th stage larva); and various small strongyles in horses, foals, and ponies.

(3) *Limitations.* Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[79 FR 28821, May 20, 2014]

§ 520.903b Febantel suspension.

(a) *Specifications.* Each ounce of suspension contains 2.75 grams (9.3 percent ounce) febantel.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight). Administer by stomach tube or drench, or by mixing well into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use*. For removal of ascarids (*Parascaris equorum*—adult and sexually immature), pinworms (*Oxyuris equi*—adult and 4th stage larvae), large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), and various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Special considerations*. Febantel suspension may be used in combination with trichlorfon oral liquid in accordance with the provisions of § 520.2520c, this section, and the following conditions:

(1) Combine 1 part febantel suspension with 5 parts trichlorfon liquid.

(2) Allow animal to consume a portion of daily grain ration; administer mixture by stomach tube at rate of 18 milliliters per 100 pounds of body weight.

[45 FR 8587, Feb. 8, 1980, as amended at 79 FR 28821, May 20, 2014]

§ 520.903c [Reserved]

§ 520.903d Febantel and praziquantel paste.

(a) *Specifications*. Each gram of paste contains 34 milligrams of febantel and 3.4 milligrams of praziquantel.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) Dogs and cats (over 6 months of age): 10 milligrams of febantel and 1 milligram of praziquantel per kilogram of body weight (1 gram of paste per 7.5 pounds body weight) administered by mouth or in the food once daily for 3 days.

(ii) Puppies and kittens (less than 6 months of age): 15 milligrams of febantel and 1.5 milligrams of praziquantel per kilogram of body weight (1 gram of paste per 5 pounds body weight) administered by mouth on a full stomach once daily for 3 days.

(2) *Indications for use*. (i) Dogs and puppies: For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(ii) Cats and kittens: For removal of hookworms (*Ancylostoma tubaeforme*), ascarids (*Toxocara cati*) and tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 19167, May 7, 1985, as amended at 53 FR 48533, Dec. 1, 1988; 56 FR 50813, Oct. 9, 1991; 79 FR 28821, May 20, 2014]

§ 520.903e Febantel tablets.

(a) *Specifications*. Each scored tablet contains 27.2 milligrams of febantel for use in dogs, puppies, cats, and kittens or 163.3 milligrams of febantel for use in dogs, puppies, and cats.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats*. Ten milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(ii) *Puppies and kittens fewer than 6 months of age*. Fifteen milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(2) *Indications for use*. (i) For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*) and whipworms (*Trichuris vulpis*) in dogs and puppies.

(ii) For removal of hookworms (*Ancylostoma tubaeforme*) and ascarids (*Toxocara cati*) in cats and kittens.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 50655, Oct. 8, 1991, as amended at 79 FR 28821, May 20, 2014]

§ 520.905 Fenbendazole oral dosage forms.

§ 520.905a Fenbendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) fenbendazole for use as in paragraphs (e)(1), (2), (3), and (4) of this section; or 200 mg fenbendazole for use as in paragraphs (e)(5) and (6) of this section.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* (1) See § 500.25 of this chapter.

(2) Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (e) of this section and for treating infections of stomach bot as provided in § 520.2520, have been shown to be compatible and not to interfere with one another.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally 5 mg per kilogram (/kg) (2.3 mg per pound (/lb)) for the control of large strongyles, small strongyles, and pinworms; 10 mg/kg for the control of ascarids.

(ii) *Indications for use.* For the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles (*Cyanthostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Triodontophorus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

(iii) *Limitations.* Administer by dose syringe or suitable plastic syringe. Do not use in horses intended for human consumption.

(2) *Cattle including dairy cows of breeding age*—(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of lungworm (*Dictyocaulus viviparus*); stomach worm (adults)—brown stomach worm (*Ostertagia ostertagi*); stomach worms (adults and 4th-stage larvae)—barberpole worm (*Haemonchus contortus* and *H. placei*) and small stomach worm (*Trichostongylus axei*); intestinal worms (adults and 4th-stage larvae)—hookworm (*Bunostonmum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Beef cattle*—(i) *Amount.* Administer orally 10 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of stomach worm (4th stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi*, and tapeworm, *Moniezia benedeni*.

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta*.

(iii) *Limitations.* Goats must not be slaughtered for food within 6 days following last treatment. Do not use in lactating goats.

(5) *Chickens*—(i) *Amount.* Administer orally via drinking water at a daily dose of 1 mg/kg body weight (0.454 mg/lb) for 5 consecutive days.

(ii) *Indications for use.* For the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens intended to become breeding chickens, and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens.

(iii) *Limitations.* Not for use in laying hens and replacement chickens intended to become laying hens.

(6) *Swine, except for nursing piglets*—(i) *Amount.* Administer orally via the drinking water at a daily dose of 2.2 mg/kg of body weight (1.0 mg/lb) for 3 consecutive days.

(ii) *Indications for use.* For the treatment and control of lungworms: Adult *Metastrongylus apri*, adult *M. pudendotectus;* gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (*Ascaris suum*); nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*): Adult and larvae (L2, L3, L4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and kidney worms: Adult and larvae *Stephanurus dentatus.*

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days from the last treatment.

[42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998; 66 FR 47960, Sept. 17, 2001; 68 FR 26205, May 15, 2003; 74 FR 17770, Apr. 17, 2009; 74 FR 61516, Nov. 25, 2009; 76 FR 17336, Mar. 29, 2011; 80 FR 76386, Dec. 9, 2015; 81 FR 22523, Apr. 18, 2016]

§ 520.905b Fenbendazole granules.

(a) *Specifications.* Each gram of granules contains 222 milligrams (mg) fenbendazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.

(ii) *Indications for use.* For the control of infections of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Sprinkle the appropriate amount of drug on a small amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food.

(2) *Dogs*—(i) *Amount.* 50 mg/kg daily for 3 consecutive days.

(ii) *Indications for use.* For the treatment and control of ascarids (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed.

(3) *Zoo and wildlife animals*—(i) *Amount.* 10 mg/kg per day for 3 days.

(ii) *Indications for use.* For control of internal parasites of *Felidae* and *Ursidae* as follows:

(A) Lion (*Panthera leo*) and Tiger (*Panthera tigris*): Ascarid (*Toxocara cati, Toxascaris leonina*), Hookworm (*Ancylostoma* spp.).

(B) Cheetah (*Acinonyx jubatus*): Ascarid (*Toxocara cati, Toxascaris leonina*).

(C) Puma (*Felis concolor*), Panther (*Panthera* spp.), Leopard (*Panthera pardus*), Jaguar (*Panthera onca*): Ascarid (*Toxocara cati, Toxascaris leonina*), Hookworm (*Ancylostoma* spp.), Tapeworm (*Taenia hydatigena, T. krabbei, T. taeniaeformis*).

(D) Black Bear (*Ursus americanus*): Ascarid (*Baylisascaris transfuga, Toxascaris leonina*), Hookworm (*Ancylostoma caninum*), Tapeworm (*Taenia hydatigena, T. krabbei*).

(E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga, Toxascaris leonina*).

(iii) *Limitations.* Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994; 66 FR 47960, Sept. 17, 2001; 67 FR 47450, July 19, 2002; 71 FR 19429, Apr. 14, 2006; 74 FR 61516, Nov. 25, 2009]

§ 520.905c Fenbendazole paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Indications for use and amounts*—(A) For control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*): 2.3 mg per pound (/lb) of body weight, or for foals and weanlings (less than 18 months of age), 4.6 mg/lb of body weight. Retreatment at intervals of 6 to 8 weeks may be required.

(B) For control of arteritis caused by the fourth-stage larvae of S. vulgaris: 4.6 mg/lb of body weight daily for 5 days. Treatment should be initiated in the spring and repeated in 6 months.

(C) For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third-stage (hypobiotic), late third-stage, and fourth-stage larvae: 4.6 mg/lb of body weight daily for 5 consecutive days.

(D) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 2.3 mg/lb of body weight. Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of lungworms (*Dictyocaulus viviparus*), stomach worms (*Haemonchus contortus*, *Ostertagia ostertagi*, *Trichostrongylus axei*), and intestinal worms (*Bunostomum phlebotomum*, *Nematodirus helvetianus*, *Cooperia punctata*, *C. oncophora*, *Trichostrongylus colubriformis*, and *Oesophagostomum radiatum*).

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[72 FR 24185, May 2, 2007, as amended at 74 FR 61516, Nov. 25, 2009; 76 FR 17337, Mar. 29, 2011]

§ 520.905d Fenbendazole powder.

(a) *Specifications.* (1) Each 2-ounce packet contains 2.27 grams (4 percent) of fenbendazole plus other inert ingredients.

(2) Each 4-ounce packet contains 1.7 grams (1.5 percent) of fenbendazole plus other inert ingredients.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of the 4-percent product.

(2) See No. 051311 in § 510.600(c) of this chapter for use of the 1.5-percent product.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use.* It is administered to swine as follows:

(1) *Amount.* 3 milligrams fenbendazole per kilogram body weight per day (1.36 milligrams per pound per day).

(2) *Indications for use.* For removal and control of large roundworms (*Ascaris suum*); lungworms (*Metastrongylus apri*); nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*); whipworms (*Trichuris suis*); and kidneyworms (*Stephanurus dentatus*—mature and immature).

(3) *Limitations.* Thoroughly mix the contents of the packet(s) with swine ration and administer according to label directions. Feed as sole ration for 3 consecutive days. Can be fed to pregnant sows. No prior withdrawal of feed or water is necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 18090, Apr. 27, 1984, as amended at 49 FR 20485, May 15, 1984; 66 FR 47960, Sept. 17, 2001; 70 FR 32489, June 3, 2005; 74 FR 61516, Nov. 25, 2009]

§ 520.905e Fenbendazole blocks.

(a) *Specifications.* (1) Each pound of molasses block contains 750 milligrams of fenbendazole.

(2) Each pound of protein block contains 750 milligrams of fenbendazole.

(b) *Sponsor*. See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.275 of this chapter.

(d) *Conditions of use*—(1) *Amount*. 0.1 pound of block per 100 pounds of body weight per day for 3 days. Total dose for the 3-day period is 2.27 milligrams of fenbendazole per pound of body weight for mature cattle.

(2) *Indications for use*. For removal and control of infections of lungworms (*Dictyocaulus viviparus*) and gastrointestinal roundworms (*Haemonchus contortus*, *Ostertagia ostertagi*, *Trichostrongylus axei*, *Bunostomum phlebotomum*, *Nematodirus helvetianus*, *Cooperia oncophora* and *C. punctata*, *Trichostrongylus colubriformis*, and *Oesophagostomum radiatum*) in beef cattle.

(3) *Limitations*. Administer free choice of beef cattle on pasture that have become accustomed to nonmedicated block feeding during an adaptation period of 12 to 19 days. Molasses block: Cattle must not be slaughtered within 11 days following last treatment. Protein block: Cattle must not be slaughtered within 16 days following last treatment; do not use in dairy cattle of breeding age. Animals maintained under conditions of constant worm exposure may require retreatment within 6 to 8 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 41783, Nov. 19, 1986, as amended at 54 FR 20787, May 15, 1989; 66 FR 47960, Sept. 17, 2001; 74 FR 61516, Nov. 25, 2009]

§ 520.928 Firocoxib tablets.

(a) *Specifications*. Each chewable tablet contains 57 or 227 milligrams (mg) firocoxib.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 mg/kg (2.27 mg/lb) body weight. Administer once daily for osteoarthritis. Administer approximately 2 hours before soft tissue or orthopedic surgery.

(ii) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis; and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer one 57-mg tablet to horses weighing 800 to 1,300 lb once daily for up to 14 days.

(ii) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 51171, Aug. 18, 2004, as amended at 73 FR 2808, Jan. 16, 2008; 73 FR 64885, Oct. 31, 2008; 81 FR 67151, Sept. 30, 2016]

§ 520.930 Firocoxib paste.

(a) *Specifications*. Each milligram (mg) of paste contains 0.82 mg firocoxib.

(b) *Sponsors*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.1 mg per kilogram (0.045 mg per pound) body weight daily for up to 14 days.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 5788, Feb. 3, 2006]

§ 520.955 Florfenicol.

(a) *Specifications*. Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

(b) *Sponsors*. See Nos. 000061, 054925, and 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.283 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount*. Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis*.

(3) *Limitations*. Do not slaughter within 16 days of last treatment. Federal

law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 78357, Dec. 24, 2002, as amended at 72 FR 262, Jan. 4, 2007; 78 FR 52854, Aug. 27, 2013; 82 FR 12169, Mar. 1, 2017]

§ 520.960 Flumethasone.

(a) *Specifications.* Each tablet contains 0.0625 milligram of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs:* Administer orally from 0.0625 to 0.25 milligram daily in divided doses.

(ii) *Cats:* Administer orally from 0.03125 to 0.125 milligram daily in divided doses.

(2) *Indications for use*—(i) *Dogs:* It is used for musculoskeletal conditions due to inflammation of muscles or joints and accessory structures, where permanent structural changes do not exist, such as arthritis, the disc syndrome, and myositis.

(ii) *Dogs and cats:* It is used in certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 7131, Feb. 6, 1979, as amended at 61 FR 5506, Feb. 13, 1996; 79 FR 28821, May 20, 2014]

§ 520.970 Flunixin.

(a) *Specifications.* (1) Each 10-gram (g) packet of granules contains flunixin meglumine equivalent to 250 milligrams (mg) of flunixin.

(2) Each 30-g syringe of paste contains flunixin meglumine equivalent to 1,500 mg of flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of products described in paragraph (a).

(2) No. 061623 for use of the product described in paragraph (a)(2).

(c) *Conditions of use in horses*—(1) *Amount.* 0.5 mg per pound of body weight per day for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 53051, Aug. 25, 2011, as amended at 79 FR 74020, Dec. 15, 2014]

§ 520.980 Fluoxetine.

(a) *Specifications.* Each chewable tablet contains 8, 16, 32, or 64 milligrams (mg) fluoxetine hydrochloride.

(b) *Sponsor.* See No. 055246 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 1 to 2 mg per kilogram body weight once daily.

(2) *Indications for use.* For the treatment of canine separation anxiety in conjunction with a behavior modification plan.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 6463, Feb. 12, 2007, as amended at 79 FR 74020, Dec. 15, 2014; 82 FR 21690, May 10, 2017]

§ 520.998 Fluralaner.

(a) *Specifications.* Each chewable tablet contains 112.5, 250, 500, 1000, or 1400 milligrams (mg) fluralaner.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg per pound (/lb) (25 mg per kilogram) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(2) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of *A. americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 37619, July 2, 2014]

§ 520.1010 Furosemide.

(a) *Specifications.* (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use of dosage forms and strengths listed in paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000061 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(3) Nos. 058829 and 069043 for use of syrup in paragraph (a)(4) of this section for conditions of use in paragraph (d)(2)(i) and (d)(2)(ii)(A) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount.* 1 to 2 mg per pound (/lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) *Indications for use.* For treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) *Dogs*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use*—(A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) *Cats*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use.* For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

[66 FR 47960, Sept. 17, 2001, as amended at 69 FR 74419, Dec. 14, 2004; 70 FR 50182, Aug. 26, 2005; 70 FR 76396, Dec. 27, 2005; 74 FR 61516, Nov. 25, 2009; 78 FR 17596, Mar. 22, 2013; 81 FR 17607, Mar. 30, 2016]

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications.* Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*

(3) *Limitations.* Do not slaughter treated swine for food for at least 3 days following treatment. Federal law

restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997; 71 FR 13542, Mar. 16, 2006; 81 FR 94989, Dec. 27, 2016]

§ 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications.* Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use.* In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations.* For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997; 78 FR 17596, Mar. 22, 2013; 81 FR 22523, Apr. 18, 2016]

§ 520.1044c Gentamicin sulfate powder.

(a) *Specifications.* Each gram of powder contains gentamicin sulfate equivalent to:

(1) 16.7, 66.7, or 333.3 milligrams (mg) gentamicin.

(2) 333.3 mg gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) No. 000061 for products described in paragraph (a)(1) of this section.

(2) Nos. 057561 and 061623 for product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water for 3 consecutive days as follows:

(i) For colibacillosis: Gentamicin sulfate equivalent to 25 mg of gentamicin per gallon of drinking water to provide 0.5 mg per pound of body weight per day;

(ii) For swine dysentery: Gentamicin sulfate equivalent to 50 mg of gentamicin per gallon of drinking water to provide 1 mg per pound of body weight per day. Treatment may be repeated if dysentery recurs.

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*

(3) *Limitations.* Withdrawal period: 10 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 4226, Jan. 27, 2012, as amended at 81 FR 94989, Dec. 27, 2016]

§ 520.1060 Glucose and glycine.

(a) *Specifications.* Each packet of powder contains 8.82 grams sodium chloride, 4.20 grams potassium phosphate, 0.5 gram citric acid anhydrous, 0.12 gram potassium citrate, 6.36 grams aminoacetic acid (glycine), and 44.0 grams glucose.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in calves*—(1) *Amount.* Dissolve each packet in 2 quarts of warm water and administer to each calf as follows:

(i) *Scouring and/or dehydrated calves.* Feed 2 quarts of solution, twice daily for 2 days (four feedings). No milk or milk replacer should be fed during this period. For the next four feedings (days 3 and 4), use 1 quart of solution together with 1 quart of milk replacer. Thereafter, feed as normal.

(ii) *Newly purchased calves.* Feed 2 quarts of solution instead of milk as the first feed upon arrival. For the next scheduled feeding, use 1 quart of solution mixed together with 1 quart of milk or milk replacer. Thereafter, feed as normal.

(2) *Indications for use.* For control of dehydration associated with diarrhea (scours); and as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(3) *Limitations.* The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. A veterinarian should be consulted in severely scouring calves. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

[79 FR 28821, May 20, 2014]

§ 520.1084 Grapiprant.

(a) *Specifications.* Each tablet contains 20, 60, or 100 milligrams (mg) grapiprant.

(b) *Sponsor.* See No. 086026 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.9 mg/lb (2 mg/kg) once daily by mouth.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 36789, June 8, 2016]

§ 520.1100 Griseofulvin.

(a) *Specifications*—(1) The powder complies with U.S.P. for griseofulvin, microsize.

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 061623 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount and indications for use*—(A) For equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of this section daily for not less than 10 days as follows: adults, 1 bolus; yearlings, one-half to 1 bolus; and foals, one-half bolus.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(A) Daily (single or divided) dose as follows: For animals weighing up to 6 pounds: 62.5 milligrams; for animals weighing 6 to 18 pounds: 125 milligrams; for animals weighing 18 to 36 pounds: 250 milligrams; for animals weighing 36 to 48 pounds: 375 milligrams; for animal weighing 48 to 75 pounds: 500 milligrams.

(B) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight × body weight × number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes, T. rubrum, T. schoenleini, T. sulphurem, T. verrucosum, T. interdigitale, Epidermophyton floccosum, Microsporum gypseum, M. canis, M. audouini.*

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989; 71 FR 38073, July 5, 2006; 77 FR 28253, May 14, 2012; 78 FR 28822, May 20, 2014]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Specifications.* Each packet contains 141.5 grams haloxon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-

inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(d) *Related tolerances.* See § 556.310 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Dissolve each packet in 32 fluid ounces of water and administer as follows: For animals weighing up to 100 pounds: ½ fluid ounce; for animals weighing 100 to 150 pounds: ¾ fluid ounce; for animals weighing 150 to 200 pounds: 1 fluid ounce; for animals weighing 200 to 300 pounds: 1 ½ fluid ounces; for animals weighing 300 to 450 pounds: 2 fluid ounces; for animals weighing 450 to 700 pounds: 3 fluid ounces; for animals weighing 700 to 1,000 pounds: 4 fluid ounces; for animals weighing 1,000 to 1,200 pounds: 5 fluid ounces; for animals weighing over 1,200 pounds: 6 fluid ounces. Retreat in 3 to 4 weeks.

(2) *Indications for use.* For control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations.* Do not treat dairy animals of breeding age. Do not treat within 1 week of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 78 FR 28822, May 20, 2014]

§ 520.1120b Haloxon boluses.

(a) *Specifications.* Each bolus contains 10.1 grams of haloxon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.310 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administered one bolus per 500 pounds body weight (35 to 50 milligrams per kilogram of body weight). Retreat in 3 to 4 weeks.

(2) *Indications for use.* For control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations.* Do not treat dairy animals of breeding age or older. Do not treat within 1 week of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 61591, Oct. 29, 1979; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 78 FR 28822, May 20, 2014]

§ 520.1130 Hetacillin.

(a) *Specifications.* (1) Each capsule or tablet contains hetacillin potassium equivalent to 50, 100, or 200 milligrams (mg) of ampicillin.

(2) Each milliliter of suspension contains hetacillin potassium equivalent to 50 mg of ampicillin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs.* Administer 5 mg per pound (/lb) of body weight orally, twice daily. In severe infections, administer 5 mg/lb three times daily, or up to 10 mg/lb twice daily. For stubborn urinary tract infections, administer up to 20 mg/lb twice daily.

(ii) *Cats.* Administer 50 mg twice daily.

(2) *Indications for use.* For the treatment of respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections associated with strains of organisms susceptible to hetacillin potassium.

(3) *Limitations.* Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

[75 FR 10166, Mar. 5, 2010]

§ 520.1156 Imidacloprid.

(a) *Specifications.* Each chewable tablet contains 7.5 or 37.5 milligrams (mg) imidacloprid.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer daily one 7.5-mg chewable tablet to dogs weighing 4 to 22 pounds (lb) or one 37.5-mg chewable table to dogs weighing 23 to 110 lb.

(2) *Indications for use.* Kills adult fleas and is indicated for the treatment of flea infestations on dogs and puppies 10 weeks of age and older and weighing 4 lb or greater.

(3) *Limitations.* Do not give to puppies younger than 10 weeks of age or to dogs weighing less than 4 lb. Do not give more than one tablet a day.

[80 FR 18775, Apr. 8, 2015]

§ 520.1157 Iodinated casein.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* ⅕ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 22469, May 30, 1984, as amended at 78 FR 28822, May 20, 2014]

§ 520.1158 Iodochlorhydroxyquin.

(a) *Specifications.* Each bolus contains 10 grams of iodochlorhydroxyquin.

(b) *Sponsor.* See No. 054771 in § 510.600 (c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 1 bolus (10 grams) daily for a 1,000-pound horse.

(2) *Indications for use.* For treatment of equine diarrhea.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 8054, Feb. 25, 1983, as amended at 50 FR 41489, Oct. 11, 1985; 78 FR 28822, May 20, 2014]

§ 520.1182 Iron dextran suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* Administer 100 mg (1.8 mL) orally by automatic dose dispenser.

(2) *Indications for use.* For the prevention of iron deficiency anemia in baby pigs.

(3) *Limitations.* Treat each pig within 24 hours of farrowing.

[70 FR 32489, June 3, 2005]

§ 520.1189 Itraconazole.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) of itraconazole.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 5 mg/kilogram (kg) (0.5 mL/kg) of body weight once daily on alternating weeks for 3 treatment cycles.

(2) *Indications for use.* For the treatment of dermatophytosis caused by *Microsporum canis* in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[82 FR 12169, Mar. 1, 2017]

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 050604 for use of a 1.87 percent paste as in (e)(1) of this section and a 0.153 percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 000859, 051311, 054925, and 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C.*

brevicapsulatus, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); and sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*).

(iii) *Limitations.* For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000; 67 FR 71820, Dec. 3, 2002; 68 FR 43294, July 22, 2003; 69 FR 59131, Oct. 4, 2004; 70 FR 8514, Feb. 22, 2005; 71 FR 40010, July 14, 2006; 71 FR 67298, Nov. 21, 2006; 73 FR 34184, June 17, 2008; 74 FR 6542, Feb. 10, 2009; 78 FR 17596, Mar. 22, 2013]

§ 520.1193 Ivermectin tablets and chewables.

(a) *Specifications.* (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 069043 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs.* For use in dogs 6 weeks of age and older as follows:

(i) *Amount.* 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound (lb)), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(2) *Cats.* For use in cats 6 weeks of age and older as follows:

(i) *Amount.* Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use.* To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

[67 FR 11230, Mar. 13, 2002, as amended at 67 FR 21996, May 2, 2002; 69 FR 43735, July 22, 2004; 81 FR 17607, Mar. 30, 2016]

§ 520.1194 Ivermectin meal.

(a) *Specifications*. Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount*. Administer 136 micrograms (mcg) ivermectin per pound (/lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use*. For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large Mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): G*asterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Limitations. Do not use in horses intended for human consumption.

[70 FR 1817, Jan. 11, 2005, as amended at 70 FR 19262, Apr. 13, 2005]

§ 520.1195 Ivermectin liquid.

(a) *Specifications*—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000859, 050604, 054925, and 058005 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) No. 058829 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms (mcg) per kilogram (/kg) of body weight as a single dose by stomach tube or as an oral drench.

(ii) *Indications for use*. For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages):

Gasterophilus spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults), *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(B) Large Strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. endentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); Small Strongyles including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); Ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); Hairworms (*Trichostongylus axei* (adult)); Large mouth Stomach Worms (*Habronema muscae* (adult)); Stomach Bots (*Gastrophilus* spp. (oral and gastric stages)); Lungworms (*Dictyocaulus arnfieldi* (adult and fourth-stage larvae)); intestinal threadworms (*Strongyloides westeri* (adult)); Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Sheep*—(i) *Amount.* 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) *Indications for use.* For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (*Haemonchus contortus, H. placei* (adults only), *Ostertagia circumcincta, Trichostrongylus axei, T. colubriformis, Cooperia oncophora* (adults only), *C. curticei, Oesophagostomum columbianum, O. venulosum* (adults only), *Nematodirus battus, N. spathiger, S. papillosus* (adults only), *Chabertia ovina* (adult only), *Trichuris ovis* (adults only)); lungworms (*D. filaria*); and all larval stages of the nasal bot *Oestrus ovis.*

(iii) *Limitations.* For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

[67 FR 50597, Aug. 5, 2002, as amended at 69 FR 57173, Sept. 24, 2004; 71 FR 13542, Mar. 16, 2006; 71 FR 38072, July 5, 2006; 72 FR 9456, Feb. 21, 2008; 78 FR 17596, Mar. 22, 2013; 79 FR 10964, Feb. 27, 2014]

§ 520.1196 Ivermectin and pyrantel tablets.

(a) *Specifications.* Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg and 114 mg, or 272 µg and 227 mg, respectively.

(b) *Sponsors.* See Nos. 050604, 051311, and 063604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer a minimum of 6 µg of ivermectin and 5 mg of pyrantel per kilogram (2.72 µg and 2.27 mg per pound) of body weight monthly.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for up to a month (30 days) after infection and treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina,* and adult hookworms *Ancylostoma caninum, A. braziliense,* and *Uncinaria stenocephala.*

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997; 66 FR 35756, July 9, 2001; 67 FR 21996, May 2, 2002; 68 FR 55823, Sept. 29, 2003; 78 FR 28822, May 20, 2014]

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances. See § 556.344 of this chapter.*

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not

more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms *Haemonchus placei*, *Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum;* lungworms *Dictyocaulus viviparus;* grubs *Hypoderma* spp.; sucking lice *Linognathus vituli*, *Solenopotes capillatus;* mange mites *Psoroptes ovis*, *Sarcoptes scabiei*, and ticks *Amblyomma americanum*.

(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000]

§ 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains:

(1) 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(2) 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel.

(3) 0.0187 mg (1.87 percent) ivermectin and 0.2338 mg (23.38 percent) praziquantel.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.—

(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.

(2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

(3) No. 050604 for use of products described in paragraph (a)(3) of this section as in paragraphs (d)(1)(iii), (d)(2)(iii) and (d)(3) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount*—(i) 200 micrograms (mcg) per kilogram (/kg) ivermectin (91 mcg per pound (/lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.

(ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.

(iii) 200 mcg/kg ivermectin (91 mcg/lb) and 2.5 mg/kg praziquantel (1.14 mg/lb).

(2) *Indications for use*—(i) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum;* Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus; Cyathostomum* spp. including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

(ii) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris*

(also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp.; *Cylicocyclus* spp.; *Cylicostephanus* spp., *Cylicodontophorus* spp.; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp.; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) For treatment and control of the following parasites in horses over 5 months of age: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum;* Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus; Cyathostomum* spp. including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

(3) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

[68 FR 55309, Sept. 25, 2003, as amended at 69 FR 49808, Aug. 12, 2004; 70 FR 65835, Nov. 1, 2005; 79 FR 37619, July 2, 2014]

§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet contains:

(1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;

(2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;

(3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or

(4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer monthly according to body weight as follows:

(i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.

(ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.

(iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(3) of this section.

(iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(4) of this section.

(v) Greater than 100 lb: use the appropriate combination of tablets.

(2) *Indications for use.* Prevents canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis*, *Toxascaris leonina*), hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*) and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 65052, Nov. 7, 2006, as amended at 78 FR 28822, May 20, 2014]

§ 520.1200 Ivermectin, fenbendazole, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet contains either:

(1) 68 micrograms (µg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or

(2) 27 µg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer tablets to provide 6 µg per kilogram (/kg) ivermectin, 100 mg/kg fenbendazole, and 5 mg/kg praziquantel.

(2) *Indications for use.* For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 33692, June 13, 2008, as amended at 74 FR 61516, Nov. 25, 2009]

§ 520.1204 Kanamycin, bismuth subcarbonate, activated *attapulgite.*

(a) *Specifications*—(1) Each 5 milliliters (mL) of suspension contains 100 milligrams (mg) kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite (aluminum magnesium silicate).

(2) Each tablet contains 100 mg kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mL of suspension or 1 tablet per 20 pounds body weight every 8 hours. Maximum dose: 5 mL of suspension or 3 tablets every 8 hours. Dogs under 10 pounds: 2.5 mL of suspension or ½ tablet every 8 hours. A recommended initial loading dose should be twice the amount of a single dose.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of the associated diarrhea.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999; 71 FR 43968, Aug. 3, 2006; 78 FR 28822, May 20, 2014]

§ 520.1242 Levamisole.

§ 520.1242a Levamisole powder.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, 362.7, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 054771 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 057561 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section.

(4) No. 059130 for use of 46.8-, 362.7-, and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), (e)(1)(iii), (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for use of an 18.15-g package as in paragraph (e)(3) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* It is used as an anthelmintic as follows:

(1) *Cattle*—(i) *Amount.* 8 milligrams per kilogram (mg/kg) body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*); intestinal worms (*T. longispicularis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*); and lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult your veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* 8 mg/kg body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*); intestinal worms (*Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), and lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter for food within 72 hours of treatment. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult veterinarian before using in severely debilitated animals.

(3) *Swine*—(i) *Amount.* 8 mg/kg body weight in drinking water.

(ii) *Indications for use.* Effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(iii) *Limitations.* Do not administer within 72 hours of slaughter for food. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine.

[69 FR 9753, Mar. 2, 2004, as amended at 69 FR 33839, June 17, 2004; 70 FR 2353, Jan. 13, 2005; 77 FR 28253, May 14, 2012; 78 FR 28822, May 20, 2014]

§ 520.1242b Levamisol boluses or oblets.

(a) *Specifications.* Each bolus contains 2.19 grams levamisol hydrochloride. Each oblet contains 0.184 grams levamisol hydrochloride.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Required labeling.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Related tolerances.* See § 556.350 of this chapter.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer orally 2.19-gram boluses as a single dose as follows: 250 to 450 pounds, ½ bolus; 450 to 750 pounds, 1 bolus; and 750 to 1,050 pounds, 1½ boluses.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Consult veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* Administer orally one 0.184-gram oblet for each 50 pounds of body weight.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms

(*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult a veterinarian before using in severely debilitated animals.

[78 FR 28822, May 20, 2014]

§ 520.1242c Levamisol and piperazine.

(a) *Specifications.* (1) Each ounce of solution contains 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) A soluble powder which when constituted with water contains in each fluid ounce 0.45 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 5.0 grams of piperazine base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Aqueous solution: administer by stomach tube or drench 1 fluid ounce per 100 pounds of body weight. Reconstituted soluble powder: administer by stomach tube 1 fluid ounce per 125 pounds of body weight. If reinfection occurs, re-treat animals at 6- to 8-week intervals.

(2) *Indications for use.* An anthelmintic effective against infections of large strongyles (*Strongylus vulgaris, S. edentatus*), small strongyles (*Cylicocercus* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp., *Cylicotetrapedon* spp.), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28823, May 20, 2014]

§ 520.1242d Levamisole resinate.

(a) *Specifications.* The drug is levamisole adsorbed on a resin, in a concentration equivalent to 10 percent levamisole hydrochloride. Each 2.05-ounce (58.1 gram) packet contains levamisole equivalent to 5.806 grams of levamisole hydrochloride.

(b) *Sponsor.* See No. 043781 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* In swine it is used as follows:

(1) *Amount.* The equivalent of 8 milligrams per kilogram of body weight, as a single dose, mixed in the animal's ration.

(2) *Indications for use.* For the removal of and control of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and swine kidney worms (*Stephanurus dentatum*).

(3) *Limitations.* For pigs from weaning to market weight, mix one 58.1-gram packet of levamisole resinate containing the equivalent of 10-percent levamisole hydrochloride in 40 pounds of feed and administer 1 pound of medicated feed per 40 pounds of body weight as sole ration. For breeding swine, mix 1 packet of the 10-percent resinate in 16 pounds of feed and administer 1 pound of medicated feed per 100 pounds of body weight as sole ration. Administer as single doses. Withhold regular feed overnight and administer medicated feed the following morning. Do not withhold water during fasting. Do not treat within 72 hours of slaughter. Salivation or muzzle foam may be observed. The reaction will disappear a short time after feeding. If pigs are infected with mature lungworms, coughing and vomiting may be observed. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 18171, Apr. 28, 1978, as amended at 45 FR 3574, Jan. 18, 1980]

§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) *Specifications.* Each tablet contains 907 milligrams of levamisole hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount.* The equivalent of 8 milligrams of levamisole hydrochloride per kilogram of body weight, as a single dose.

(2) *Indications for use.* See § 520.1242a(f)(3)(ii).

(3) *Limitations.* Withholding water from pigs before treatment is not necessary. Add one tablet for each 2½ gallons of water; mix thoroughly. Allow 1 gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[45 FR 6087, Jan. 25, 1980, as amended at 67 FR 63055, Oct. 10, 2002; 78 FR 28823, May 20, 2014]

§ 520.1242f Levamisol gel.

(a) *Specifications.* Each gram of gel contains 115 milligrams (11.5 percent) levamisol hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Eight milligrams of levamisole hydrochloride per kilogram of body weight, as a single oral dose.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not administer to cattle within 6 days of slaughter for food; do not administer to dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) *Breeding swine*—(i) *Amount.* Eight milligrams per kilogram of body weight (3.6 milligrams per pound) as a single oral dose.

(ii) *Conditions of use.* For treating breeding swine infected with the following nematodes: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and kidney worms (*Stephanurus dentatus*).

(iii) *Limitations.* May require retreatment in 4 to 5 weeks. Do not use within 11 days of slaughter for food. Consult your veterinarian for assistance before using in severely debilitated animals and in the diagnosis, treatment, and control of parasitism.

[47 FR 22517, May 25, 1982; 47 FR 30242, July 13, 1982, as amended at 48 FR 11429, Mar. 18, 1983; 51 FR 29215, Aug. 15, 1986; 67 FR 63055, Oct. 10, 2002; 78 FR 28823, May 20, 2014]

§ 520.1242g Levamisole resinate and famphur paste.

(a) *Specifications.* The drug is a paste containing 11.6 percent levamisole resinate (50 percent potency) and 23.6 percent famphur.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Do not use any cholinesterase-inhibiting drugs, pesticides, insecticides, or chemicals on cattle simultaneously or within a few days before or after treatment with this product.

(d) *Related tolerances.* See §§ 556.273 and 556.350 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* 8 milligrams of levamisole hydrochloride (equivalent) and 30 milligrams of famphur activity per kilogram of body weight.

(2) *Indications for use.* For treatment of cattle infected with the following parasites: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), lungworms (*Dictyocaulus*), cattle grubs (*Hypoderma*), biting lice (*Bovicola*), and sucking lice (*Linognathus, Solenoptes*).

(3) *Limitations.* Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54 FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992; 62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997; 78 FR 28823, May 20, 2014]

§ 520.1248 Levothyroxine.

(a) *Specifications.* Each tablet contains 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, or 1.0 milligrams (mg) levothyroxine sodium.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by mouth 0.1 mg/10 pounds of body weight (0.022 mg/kilogram) as a single dose every 24 hours or as a divided dose every 12 hours.

(2) *Indications for use.* For replacement therapy for diminished thyroid function in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 22523, Apr. 18, 2016]

§ 520.1263 Lincomycin.

§ 520.1263a Lincomycin tablets and syrup.

(a) *Specifications.* (1) Each ounce of syrup contains lincomycin hydrochloride equivalent to either 25 or 50 milligrams (mg) lincomycin.

(2) Each tablet contains lincomycin hydrochloride equivalent to either 25 or 50 mg lincomycin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 10 mg per pound of body weight every 12 hours, or 7 mg per pound of body weight every 8 hours, for up to 12 days.

(2) *Indications for use.* For infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28823, May 20, 2014]

§ 520.1263b [Reserved]

§ 520.1263c Lincomycin powder.

(a) *Specifications.* Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 016592 and 054771 for use as in paragraph (d) of this section.

(2) Nos. 054925, 061623, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Tolerances.* See § 556.360 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.

(ii) *Indications for use.* For the treatment of swine dysentery (bloody scours).

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding. For No. 054925: Do not slaughter swine for 6 days following last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Chickens*—(i) *Amount.* 64 milligrams per gallon of drinking water.

(ii) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin.

Not for use in layer and breeder chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Honey bees*—(i) *Amount.* Mix 100 milligrams lincomycin with 20 grams confectioners'/powdered sugar and dust over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or late in the fall and consumed by the bees before the main honey flow begins to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000; 67 FR 17284, Apr. 10, 2002; 67 FR 71819, Dec. 3, 2002; 67 FR 78356, Dec. 24, 2002; 68 FR 3817, Jan. 27, 2003; 70 FR 1818, Jan. 11, 2005; 77 FR 20988, Apr. 9, 2012; 77 FR 29217, May 17, 2012; 78 FR 28823, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.1265 Lincomycin and spectinomycin powder.

(a) *Specifications.* The following salts of lincomycin and spectinomycin are present in a soluble powder in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base:

(1) Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate.

(2) Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use of product described in paragraph (a)(1) of this section.

(2) Nos. 057561, 061623, and 066104 for use of product described in paragraph (a)(2) of this section.

(c) *Tolerances.* See §§ 556.360 and 556.600 of this chapter.

(d) *Conditions of use in chickens*—(1) *Amount.* 2 grams of antibiotic activity per gallon of drinking water; administer as the sole source of water for the first 5 to 7 days of life.

(2) *Indications for use.* As an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 13220, Mar. 22, 2004, as amended at 70 FR 40881, July 15, 2005; 71 FR 71038, Dec. 8, 2006; 77 FR 56770, Sept. 14, 2012; 78 FR 28823, May 20, 2014; 81 FR 94989, Dec. 27, 2016]

§ 520.1284 Liothyronine.

(a) *Specifications.* Each tablet contains 60 or 120 micrograms (μg) liothyronine as the sodium salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally to dogs at levels up to 12.8 μg per kilogram (/kg) of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8 μg/kg of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(2) *Indications for use.* For treatment of hypothyroidism in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28823, May 20, 2014]

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) Tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) Flavored tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A) or (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(3) Flavored tablets containing 90 or 204.9 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A) or (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(4) Flavored tablets containing 135 or 270 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Minimum of 10 mg lufenuron per kilogram (4.5 mg per pound (lb)) of body weight, once a month.

(ii) *Indications for use*—(A) For the prevention and control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in dogs and puppies 4 weeks of age and older.

(2) *Cats*—(i) *Amount.* Minimum of 30 mg lufenuron per kilogram (13.6 mg/lb) of body weight, once a month.

(ii) *Indications for use*—(A) For the control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(3) of this section as in paragraph (c)(2)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in cats and kittens 4 weeks of age and older.

[68 FR 51905, Aug. 29, 2003]

§ 520.1289 Lufenuron suspension.

(a) *Specifications.* Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

[60 FR 20402, Apr. 26, 1995, as amended at 62 FR 8371, Feb. 25, 1997]

§ 520.1310 Marbofloxacin.

(a) *Specifications.* Each tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 1.25 mg per pound (/lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use.* For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[64 FR 39919, July 23, 1999, as amended at 66 FR 46369, Sept. 5, 2001; 78 FR 28823, May 20, 2014]

§ 520.1315 Maropitant.

(a) *Specifications.* Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* (i) For prevention of acute vomiting in dogs 2 to 7 months of age, administer a minimum dose of 2.0 mg per kilogram (/kg) body weight once daily for up to 5 consecutive days.

(ii) For prevention of acute vomiting in dogs 7 months of age and older, administer a minimum dose of 2.0 mg/kg

body weight once daily until resolution of acute vomiting.

(iii) For prevention of vomiting due to motion sickness in dogs 4 months of age and older, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 9243, Mar. 1, 2007, as amended at 78 FR 28823, May 20, 2014; 80 FR 53459, Sept. 4, 2015]

§ 520.1320 Mebendazole.

(a) *Specifications.* (1) Each gram of powder contains either 40 or 166.7 milligrams of mebendazole.

(2) Each gram of paste contains 200 milligrams of mebendazole.

(3) Each milliliter of suspension contains 33.3 milligrams of mebendazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use.* For treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*); small strongyles; and mature and immature (4th larval stage) pinworms (*Oxyuris equi*).

(iii) *Limitations.* The drug is compatible with carbon disulfide. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer 100 milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder by mixing with a small quantity of food, preferably before the regular meal.

(ii) *Indications for use.* The drug is used for treatment of infections of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28823, May 20, 2014]

§ 520.1326 Mebendazole and trichlorfon oral dosage forms.

§ 520.1326a Mebendazole and trichlorfon powder.

(a) *Specifications.* Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorofon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorofon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for the treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi.*)

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 10759, Feb. 19, 1980, as amended at 46 FR 52330, Oct. 27, 1981. Redesignated at 51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997; 78 FR 28824, May 20, 2014]

§ 520.1326b Mebendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams of mebendazole and 454 milligrams of trichlorfon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not administer simultaneously or within a few days before or after treatment

with, or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997; 78 FR 28824, May 20, 2014]

§ 520.1330 Meclofenamic acid granules.

(a) *Specifications.* Each gram of granules contains 5 milligrams (5 percent) meclofenamic acid.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milligram per pound of body weight (1 gram per 1000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(2) *Indications for use.* For the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28824, May 20, 2014]

§ 520.1331 Meclofenamic acid tablets.

(a) *Specifications.* Each tablet contains either 10 or 20 milligrams of meclofenamic acid.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 1.1 milligrams per kilogram (0.5 milligram per pound) daily for 5 to 7 days.

(2) *Indications for use.* For the relief of signs and symptoms of chronic inflammatory disease involving the musculoskeletal system.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 43385, Oct. 25, 1985, as amended at 53 FR 23390, June 22, 1988; 78 FR 28824, May 20, 2014]

§ 520.1341 Megestrol.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams of megestrol acetate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally, intact, or crushed and mixed with food as follows:

(i) For the postponement of estrus by proestrus treatment: 1 milligram per pound of body weight per day for 8 days.

(ii) For the postponement of estrus by anestrus treatment: 0.25 milligram per pound of body weight per day for 32 days.

(iii) For alleviation of false pregnancy: 1 milligram per pound of body weight per day for 8 days.

(2) *Indications for use.* For the postponement of estrus and the alleviation of false pregnancy in female dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 78 FR 28824, May 20, 2014]

§ 520.1367 Meloxicam.

(a) *Specifications*—(1) Each milliliter of suspension contains 0.5 milligrams (mg) meloxicam.

(2) Each milliliter of suspension contains 1.5 mg meloxicam.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section:

(1) No. 000010 for use of the products described in paragraph (a) of this section; and

(2) Nos. 013744 and 055529 for use of the product described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 42968, July 21, 2003, as amended at 69 FR 69523, Nov. 30, 2004. Redesignated and amended at 78 FR 57058, Sept. 17, 2013; 80 FR 53459, Sept. 4, 2015]

§ 520.1372 Methimazole.

(a) *Specifications.* Each tablet contains 2.5 or 5 milligrams (mg) methimazole.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* The starting dose is 2.5 mg every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 levels and clinical response.

(2) *Indications for use.* For the treatment of hyperthyroidism.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 27707, June 11, 2009]

§ 520.1380 Methocarbamol.

(a) *Specifications.* Each tablet contains 500 milligrams (mg) of methocarbamol.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 60 mg per pound of body weight in two or three equally divided doses, followed each following day by 30 to 60 mg per pound of body weight, usually not to exceed 14 to 21 days.

(2) *Indications for use.* As an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28824, May 20, 2014]

§ 520.1408 Methylprednisolone.

(a) *Specifications.* Each tablet contains 1, 2, or 4 milligrams (mg) of methylprednisolone.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054628 for use of 1- and 2-mg tablets.

(2) No. 054771 for use of 1- and 4-mg tablets.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 5 to 15 pounds (lbs): 2 mg; 15 to 40 lbs: 2 to 4 mg; 40 to 80 lbs: 4 to 8 mg. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed.

(2) *Indications for use.* As an anti-inflammatory agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28824, May 20, 2014]

§ 520.1409 Methylprednisolone and aspirin.

(a) *Specifications.* Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Under 15 pounds, ¼ to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily. Administer total daily dose in divided doses 6 to 10 hours apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* As an anti-inflammatory and analgesic agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21566, May 13, 1983, as amended at 78 FR 28824, May 20, 2014]

§ 520.1422 Metoserpate hydrochloride.

(a) *Chemical name.* Methyl-*o*-methyl-18-epireserpate hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.410 of this chapter.

(d) *Conditions of use.* It is used in drinking water for replacement chickens as follows:

(1) *Amount.* 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use.* As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations.* To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount.* 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use.* As an aid in control of hysteria.

(ii) *Limitations.* To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

[40 FR 13838, Mar. 27, 1975, as amended at 76 FR 17337, Mar. 29, 2011; 78 FR 28824, May 20, 2014]

§ 520.1430 Mibolerone.

(a) *Specifications.* Each milliliter contains 100 micrograms of mibolerone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 30 micrograms for animals weighing 1 to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, German Shepherds, or German Shepherd mix. Administer daily, orally or in a small amount of food, at least 30 days before expected initiation of heat, and continue daily as long as desired, but not for more than 24 months.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 15625, Apr. 14, 1978, as amended at 78 FR 28824, May 20, 2014]

§ 520.1441 Milbemycin oxime.

(a) *Specifications*—(1) *Dogs.* Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats.* Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(b) *Sponsor.* See 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and puppies*—(i) *Amount.* For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis,* control of hookworm infections caused by *Ancylostoma caninum,* and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.

(iii) *Limitations.* Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats and kittens*—(i) *Amount.* 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use

by or on the order of a licensed veterinarian.

[55 FR 25301, June 21, 1990, as amended at 55 FR 49888, Dec. 3, 1990; 58 FR 5608, Jan. 22, 1993; 60 FR 50097, Sept. 28, 1995; 61 FR 43654, Aug. 26, 1996; 63 FR 29352, May 29, 1998; 63 FR 41189, Aug. 3, 1998. Redesignated at 77 FR 47512, Aug. 9, 2012]

§ 520.1443 Milbemycin oxime and lufenuron.

(a) *Specifications*—(1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(b) *Sponsor*. See No. 051311 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use*—(A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998; 68 FR 51905, Aug. 29, 2003. Redesignated at 77 FR 47512, Aug. 9, 2012, as amended at 80 FR 18776, Apr. 8, 2015]

§ 520.1445 Milbemycin oxime and praziquantel.

(a) *Specifications*. Each chewable tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime and 228 mg praziquantel.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer orally, once a month, a minimum dosage of 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)) milbemycin oxime and 2.28 mg/lb of body weight (5 mg/kg) praziquantel.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, *E. granulosus*, and *Dipylidium caninum*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012, as amended at 82 FR 58556, Dec. 13, 2017]

§ 520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.

(a) *Specifications*. Each tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime, 46 mg lufenuron, and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime, 115 mg lufenuron, and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime, 230 mg lufenuron, and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime, 460 mg lufenuron, and 228 mg praziquantel.

(b) *Sponsor*. See No. 051311 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 mg milbemycin oxime, 10

mg lufenuron, and 5 mg of praziquantel per kilogram of body weight, once a month.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis;* for the prevention and control of flea populations (*Ctenocephalides felis*); and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 4225, Jan. 27, 2012, as amended at 80 FR 18776, Apr. 8, 2015; 83 FR 13635, Mar. 30, 2018]

§ 520.1450 Morantel tartrate oral dosage forms.

§ 520.1450a Morantel tartrate bolus.

(a) *Specifications.* Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* One bolus per 500 pounds of body weight (4.4 milligrams per pound of body weight) as a single oral dose. Boluses may be divided in half for more accurate dosing as follows: up to 325 pounds, ½ bolus; 326 to 600 pounds, 1 bolus; 601 to 900 pounds, 1½ boluses; and 901 to 1,200 pounds, 2 boluses.

(2) *Indications for use.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(3) *Limitations.* Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. Do not treat within 14 days of slaughter.

[46 FR 50949, Oct. 16, 1981. Redesignated at 49 FR 47831, Dec. 7, 1984, and amended at 51 FR 9005, Mar. 17, 1986; 78 FR 28825, May 20, 2014]

§ 520.1450b Morantel tartrate cartridge.

(a) *Specifications.* The drug product consists of a stainless-steel cylinder having both ends closed with polyethylene diffusing discs and containing a morantel tartrate paste. The paste contains 22.7 grams of morantel tartrate equivalent to 13.5 grams of morantel base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum.*

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 106 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 47831, Dec. 7, 1984, as amended at 51 FR 23415, June 27, 1986; 51 FR 41081, Nov. 13, 1986; 78 FR 28825, May 20, 2014]

§ 520.1450c Morantel tartrate sustained-release trilaminate cylinder/sheet.

(a) *Specifications.* The drug product consists of a trilaminated, perforated, plastic sheet formed into a cylinder having plastic plugs in its ends. The core lamina contains 19.8 grams of morantel tartrate equivalent to 11.8 grams of morantel base.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum.*

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 102 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[56 FR 13396, Apr. 2, 1991, as amended at 78 FR 28825, May 20, 2014]

§ 520.1451 Moxidectin tablets.

(a) *Specifications.* Each tablet contains 30, 68, or 136 micrograms of moxidectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.

(2) *Indications for use.* To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 37713, July 15, 1997, as amended at 78 FR 28825, May 20, 2014]

§ 520.1452 Moxidectin gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (2 percent) moxidectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus.* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. radiatus; Cyliocostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Gyalocephalus capitatus*; and *Petrovinema poculatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); and horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Do not use in horses intended for human consumption.

[62 FR 42902, Aug. 11, 1997, as amended at 64 FR 66105, Nov. 24, 1999; 68 FR 51445, Aug. 27, 2003; 69 FR 24959, May 5, 2004; 70 FR 75017, Dec. 19, 2005; 78 FR 28825, May 20, 2014]

§ 520.1453 Moxidectin and praziquantel gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (mg) (2.0 percent) moxidectin and 125 mg (12.5 percent) praziquantel.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* Administer by mouth as a single dose: 0.4 mg moxidectin per kilogram and 2.5 mg praziquantel per kilogram (2.2 pounds) body weight.

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): (*Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp., including *C. insigne, C. leptostomum, C. nassatus*, and *C. radiatus*; *Cylicostephanus* spp., including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus*; *Coronocyclus* spp., including *C. coronatus, C. labiatus,* and *C. labratus*; *Gyalocephalus capitatus*; and *Petrovinema poculatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars); and tapeworms: *Anoplocephala perfoliata* (adults). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Do not use in horses intended for human consumption.

[68 FR 51446, Aug. 27, 2003, as amended at 69 FR 21956, Apr. 23, 2004; 70 FR 75017, Dec. 19, 2005; 78 FR 28825, May 20, 2014]

§ 520.1454 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in sheep*—(1) *Amount.* Administer 1 mL per 11 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) *Indications for use.* For the treatment and control of the adult and L4 larval stages of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*.

(3) *Limitations.* Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use in female sheep providing milk for human consumption.

[70 FR 76163, Dec. 23, 2005, as amended at 76 FR 48714, Aug. 9, 2011; 82 FR 21690, May 10, 2017]

§ 520.1468 Naproxen.

(a) *Specifications.* Each gram of granules contains 500 milligrams (mg) (50 percent) naproxen.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 10 mg per kilogram of body weight twice daily top dressed on feed for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28825, May 20, 2014]

§ 520.1484 Neomycin.

(a) *Specifications*—(1) Each ounce of powder contains 20.3 grams (g) neomycin sulfate (equivalent to 14.2 g neomycin base).

(2) Each milliliter of solution contains 200 milligrams (mg) neomycin sulfate (equivalent to 140 mg neomycin base).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 054771 and 054925 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 016592, 054771, 058005, and 061623 for use of product described in paragraph (a)(1) as in paragraphs (e)(1) and (e)(2) of this section.

(3) Nos. 016592, 054771, 054925, and 058005 for use of product described in paragraph (a)(2) as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Special labeling considerations.* Labeling shall bear the following warning statements: ''A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Conditions of use*—(1) *Cattle, swine, sheep, and goats*—(i) *Amount.* 10 mg per pound (/lb) of body weight per day (22 mg per kilogram (/kg)) in divided doses for a maximum of 14 days.

(ii) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

(iii) *Limitations.* Discontinue treatment prior to slaughter as follows: Cattle, 1 day; sheep, 2 days; swine and goats, 3 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* 10 mg/lb of body weight per day (22 mg/kg) for 5 days.

(ii) *Indications for use.* For the control of mortality associated with *E. coli* susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 56866, Sept. 28, 2006, as amended at 71 FR 68738, Nov. 28, 2006; 78 FR 17596, Mar. 22, 2013; 78 FR 28825, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.1510 Nitenpyram.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 058198 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), and (d)(2) of this section.

(2) No. 051311 for use as in paragraphs (d)(1)(i)(B) and (d)(1)(ii)(B) of this section.

(c) *Special considerations.* The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1443(d)(1) is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron

tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003, as amended at 80 FR 18776, Apr. 8, 2015]

§ 520.1604 Oclacitinib.

(a) *Specifications.* Each tablet contains 3.6, 5.4, or 16 milligrams (mg) of oclacitinib as oclacitinib maleate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally 0.18 to 0.27 mg/per pound of body weight (0.4 to 0.6 mg/kg body weight) twice daily for up to 14 days; then administered once daily for maintenance therapy.

(2) *Indications for use.* For control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 42007, July 15, 2013]

§ 520.1615 Omeprazole.

(a) *Specifications.* Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use in horses*—(1) *Amount*—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use.* (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations.* Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004, as amended at 71 FR 59374, Oct. 10, 2006]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

[71 FR 14643, Mar. 23, 2006, as amended at 75 FR 26646, May 12, 2010]

§ 520.1618 Orbifloxacin suspension.

(a) *Specifications.* Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) *Indications for use.* For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Proteus mirabilis*, *Escherichia coli*, and *Enterococcus faecalis* and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, coagulase-positive staphylococci, *Pasteurella multocida*, *Proteus mirabilis*, *Pseudomonas* spp., *Klebsiella pneumoniae*, *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *E. faecalis*, β-hemolytic streptococci (Group G), and *Streptococcus equisimilis*.

(2) *Cats*—(i) *Amount*. 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *S. aureus*, *E. coli*, and *P. multocida*.

[75 FR 26646, May 12, 2010]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications*—(1) *Powder for suspension*. Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets*. Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 10 milligrams per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations*—(i) *Powder for suspension*. For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets*. The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior to administration is not necessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[44 FR 35211, June 19, 1979, as amended at 46 FR 26301, May 12, 1981; 46 FR 60570, Dec. 11, 1981; 49 FR 28549, July 13, 1984; 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1629 Oxfendazole paste.

(a)(1) *Specifications*. Each gram of paste contains 0.375 gram oxfendazole (37.5 percent).

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications*. Each gram of paste contains 185 milligrams of oxfendazole (18.5 percent).

(2) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.495 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use*. The drug is used in cattle for the removal and control of the following worms: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata*, *C. oncophora*, and *C. mcmasteri*—adult, L4); and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations*. For use in cattle only. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 11 days after treatment. Do

not use in female dairy cattle of breeding age. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 38250, Sept. 28, 1984, as amended at 58 FR 39443, July 23, 1993; 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1630 Oxfendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains:

(1) 90.6 milligrams (mg) oxfendazole (9.06 percent).

(2) 225.0 mg oxfendazole (22.5 percent).

(b) *Sponsor.* See Nos. 000010 and 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances. See* § 556.495 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter. If labeled for administration by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 10 mg per kilogram (/kg) of body weight by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks.

(ii) *Indications for use.* For removal of large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus, S. vulgaris,* and *S. equinus*), and small strongyles.

(iii) *Limitations.* Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for human consumption.

(2) *Cattle.* Use the products described in paragraphs (a)(1) and (a)(2) of this section as follows:

(i) *Amount.* 4.5 mg/kg of body weight by dose syringe. Treatment may be repeated in 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata, C. oncophora,* and *C. surnabada*—adult, L4), and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations.* Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[55 FR 46943, Nov. 8, 1990, as amended at 56 FR 8710, Mar. 1, 1991; 61 FR 5506, Feb. 13, 1996; 72 FR 10596, Mar. 9, 2007; 73 FR 45610, Aug. 6, 2008; 75 FR 10166, Mar. 5, 2010; 78 FR 28825, May 20, 2014]

§ 520.1631 Oxfendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 28.5 milligrams oxfendazole and 454.5 milligrams trichlorfon.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2.5 milligrams of oxfendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of bots (*Gasterophilus intestinalis,* 2nd and 3rd instars; *G. nasalis,* 3rd instar) and the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), pinworms (*Oxyuris equi*), adult and 4th stage larvae; large strongyles (*Strongylus edentatus, S. vulgaris,* and *S. equinus*); and small strongyles.

(3) *Limitations.* Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water before use is unnecessary. Administer with caution to sick or debilitated horses. Not for use in horses intended for food. Do not administer to mares during the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not use this product in animals simultaneously with, or within a few days before or after treatment with or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 50291, Dec. 10, 1985, as amended at 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1638 Oxibendazole.

(a) *Specifications*—(1) Each gram of paste contains 227 milligrams (mg) (22.7 percent) oxibendazole.

(2) Each milliliter of suspension contains 100 mg (10 percent) oxibendazole.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Suspension product described in paragraph (a)(2) of this section shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use in horses*—(1) *Amount*. For uses other than for threadworms (*Strongyloides westeri*), 10 mg oxibendazole per kilogram (/kg) body weight; for threadworms (*Strongyloides westeri*), 15 mg/kg. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Administer suspension product by stomach tube in 3 to 4 pints of warm water, or by top dressing or mixing into a portion of the normal grain ration.

(2) *Indications for use*. For removal and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small strongyles (genera *Cylicostephanus*, *Cylicocyclus*, *Cyathostomum*, *Triodontophorus*, *Cylicodontophorus*, and *Gyalocephalus*); large roundworms (*Parascaris equorum*); pinworms (*Oxyuris equi*) including various larval stages; and threadworms (*Strongyloides westeri*).

(3) *Limitations*. Do not use in horses intended for human consumption.

[78 FR 28825, May 20, 2014]

§ 520.1660 Oxytetracycline.

§ 520.1660a Oxytetracycline and carbomycin.

(a) *Specifications*. (1) Oxytetracycline: The antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(2) Carbomycin: The antibiotic substance produced by growth of *Streptomyces halstedii* or the same antibiotic substance produced by any other means.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations*. The quantities of oxytetracycline in paragraph (e) of this section refer to the activity of oxytetracycline hydrochloride and the quantities of carbomycin listed refer to the activity of an appropriate standard.

(d) *Related tolerances*. See §§ 556.110 and 556.500 of this chapter.

(e) *Conditions of use*. It is used as oxytetracycline hydrochloride plus carbomycin base in drinking water of chickens as follows:

(1) *Amount*. Administer 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon for not more than 5 days.

(2) *Indications for use*. As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by *Mycoplasma gallisepticum* and secondary bacterial organisms associated with chronic respiratory disease such as *E. coli*.

(3) *Limitations*. Not for use in chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 78 FR 28825, May 20, 2014; 81 FR 94989, Dec. 27, 2016]

§ 520.1660b Oxytetracycline hydrochloride capsules.

(a) *Specifications*. The drug is in capsule form with each capsule containing 125 or 250 milligrams of oxytetracycline hydrochloride. Oxytetracycline is the antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by *Brucella bronchiseptica*, tonsilitis caused by

Streptococcus hemolyticus, bacterial enteritis caused by *Escherichia coli*, urinary tract infections caused by *Escherichia coli*, and wound infections caused by *Staphylococcus aureus*.

(2) The drug is administered orally to dogs and cats at a dosage level of 25–50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the severity and degree of involvement and the susceptibility of the infectious agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsidered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 78 FR 28825, May 20, 2014]

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications*. Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors*. For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See No. 054771 for use of 250 and 500 milligram tablets.

(c) *Tolerances*. See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1)(i) *Amount*. 250 milligrams per 100 pounds of body weight every 12 hours (5 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use*. For control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(2)(i) *Amount*. 500 milligrams per 100 pound of body weight every 12 hours (10 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use*. For treatment of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(3) *Limitations*. Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily). For sponsor No. 054771: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998; 70 FR 16394, Apr. 4, 2005; 78 FR 28825, May 20, 2014]

§ 520.1660d Oxytetracycline powder.

(a) *Specifications*. The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz, 3.09 and 3.91 lb; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78

oz.; pail: 5 lb). Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz).

(7) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 and 9.6 oz.; pails: 2 and 5 lb); each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb).

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and, 19.75 oz, and 3.91 lb; pails: 3.09 and 5 lb).

(10) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.74 oz; pails: 5 lb).

(b) *Sponsor*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 016592 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

(3) No. 066104 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 057561 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 061623 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, sheep, and honeybees.

(6) No. 069254 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(7) No. 061623 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(c) *Related tolerances*. See § 556.500 of this chapter.

(d) *Conditions of use*. (1) It is used in drinking water as follows:

(i) *Chickens*—(A)(*1*) *Amount*. Administer 200 to 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B)(*1*) *Amount*. Administer 400 to 800 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use*. Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Turkeys*—(A)(*1*) *Amount*. Administer 200 to 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use*. Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B)(*1*) *Amount*. Administer 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by

Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(C)(*1*) *Amount.* Administer 25 milligrams per pound of body weight daily for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Growing turkeys. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Swine*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Do not use for more than 14 consecutive days.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

(C) Withdraw zero days prior to slaughter those products sponsored by Nos. 054771, 057561, 061623, and 069254 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Do not use for more than 14 consecutive days.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(v) *Sheep*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Not to be used for more than 14 consecutive days.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) Withdraw 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) It is used in the food of honey bees as follows:

(i) *Amount.* 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture. The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals.

(ii) *Indications for use.* For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

(iii) The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1660d, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 520.1696 Penicillin.

§ 520.1696a [Reserved]

§ 520.1696b Penicillin G powder.

(a) *Specifications.* Each gram of powder contains penicillin G potassium

equivalent to 1.54 million units of penicillin G.

(b) *Sponsors.* See Nos. 010515, 016592, 054771, 061623 and 076475 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use in turkeys*— (1) *Amount.* 1,500,000 units per gallon drinking water for 5 days.

(2) *Indications for use.* Treatment of erysipelas caused by *Erysipelothrix rhusiopathiae.*

(3) *Limitations.* Discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992, as amended at 59 FR 42493, Aug. 18, 1994; 60 FR 26359, May 17, 1995; 62 FR 55160, Oct. 23, 1997; 65 FR 10705, Feb. 29, 2000; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 68 FR 26204, May 15, 2003; 69 FR 9946, Mar. 3, 2004; 69 FR 41428, July 9, 2004; 77 FR 20988, Apr. 9, 2012; 78 FR 28825, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 36789, June 8, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.1696c Penicillin V powder.

(a) *Specifications.* When reconstituted, each milliliter contains 25 milligrams (40,000 units) of penicillin V.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*— (1) *Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin, and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 77 FR 20988, Apr. 9, 2012; 78 FR 28826, May 20, 2014]

§ 520.1696d Penicillin V tablets.

(a) *Specifications.* Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

(b) *Sponsors.* See Nos. 050604 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*— (1) *Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994; 78 FR 28826, May 20, 2014]

§ 520.1705 Pergolide.

(a) *Specifications.* Each tablet contains 1 milligram (mg) peroglide (as pergolide mesylate).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally at a starting dose of 2 micrograms/kilograms (μ/kg) once daily. Dosage may be adjusted to effect, not to exceed 4 μg/kg daily.

(2) *Indications for use.* For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 15960, Mar. 19, 2012, as amended at 81 FR 22523, Apr. 18, 2016]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) of phenylbutazone. Each bolus contains 1, 2, or 4 gram g of phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-mg or 1-g tablets, or 2- or 4-g boluses, in dogs and horses.

(2) Nos. 054628 and 069043 for use of 100- or 200-mg or 1-g tablets in dogs and horses.

(3) Nos. 054771 and 061623 for use of 100-mg or 1-g tablets in dogs and horses.

(4) [Reserved]

(5) No. 000143 for use of 1-g tablets in horses.

(6) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 20 mg per pound of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* 1 to 2 g per 500 pounds of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 8192, Feb. 13, 2008, as amended at 74 FR 1146, Jan. 12, 2009; 76 FR 11331, Mar. 2, 2011; 76 FR 17777, Mar. 31, 2011; 78 FR 21060, Apr. 9, 2013; 78 FR 28826, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.1720b Phenylbutazone granules.

(a) *Specifications.* Each package of granules contains 1 or 8 grams of phenylbutazone.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for 8-gram package.

(2) No. 059320 for 1-gram package.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily as required. by adding to a portion of the usual grain ration.

(2) *Indications for use.* For the treatment of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 28826, May 20, 2014]

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section.

(2) No. 017030 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007; 77 FR 4897, Feb. 1, 2012; 78 FR 28826, May 20, 2014; 79 FR 74020, Dec. 15, 2014]

§ 520.1720d Phenylbutazone gel.

(a) *Specifications.* Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter. require bioequivalency and safety information.

(c) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system of horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 78 FR 28826, May 20, 2014]

§ 520.1720e Phenylbutazone powder.

(a) *Specifications*—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 027053 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.

(2) *Indications for use.* For the relief of inflammatory conditions associated with the musculosketetal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27956, May 18, 2007]

§ 520.1760 Phenylpropanolamine.

(a) *Specifications.* Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(b) *Sponsors.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 2 mg/kg of body weight twice daily.

(2) *Indications for use.* For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 15961, Mar. 19, 2012]

§ 520.1780 Pimobendan.

(a) *Specifications.* Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a case-by-case basis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27733, May 17, 2007, as amended at 79 FR 18158, Apr. 1, 2014]

§ 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

§ 520.1802a Piperazine-carbon disulfide complex suspension.

(a) *Specifications.* Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and ponies*—(1) *Amount.* Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum),* bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongyles* spp.), and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 52781, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications.* Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and ponies*—(1) *Amount.* For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Withhold feed overnight or for 8 to 10 hours. Give water just before and/or after treatment. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics or other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[45 FR 52782, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.

(a) *Specifications.* Each fluid ounce contains 5 grams of piperazine-carbon disulfide complex and 0.83 gram of phenothiazine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and ponies*—(1) *Amount.* Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, and large strongyles (*Strongylus* spp.).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 52782, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1803 Piperazine citrate capsules.

(a) *Specifications.* Each capsule contains piperazine citrate equivalent to 140 milligrams of piperazine base.

(b) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in 1/2 of the regular feeding and when the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfection may occur. Repeat treatment if indicated.

(2) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(3) *Limitations.* Severely debilitated animals should not be treated except on the advice of a veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 54 FR 38515, Sept. 19, 1989; 78 FR 28826, May 20, 2014]

§ 520.1804 Piperazine phosphate capsules.

(a) *Specifications.* Each capsule contains 120, 300, or 600 milligrams of piperazine phosphate monohydrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 60 milligrams of piperazine phosphate monohydrate per pound of body weight.

(2) *Indications for use*—(i) *Dogs.* It is used for the removal of large roundworms (ascarids) *Toxocara canis* and *Toxascaris leonina.*

(ii) *Cats.* It is used for the removal of large roundworms (ascarids) *Toxocara mystax* and *Toxacaris leonina.*

(3) *Limitations.* Administer in animal's food or milk. For animals up to 1 year of age administer every 2 or 3

months; for animals over 1 year old, administer periodically as necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 6941, Feb. 17, 1978; 43 FR 9804, Mar. 10, 1978, as amended at 46 FR 20158, Apr. 3, 1981; 69 FR 31878, June 8, 2004; 78 FR 28826, May 20, 2014]

§ 520.1805 Piperazine phosphate with thenium closylate tablets.

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate) or 500 milligrams piperazine hexahydrate (as piperazine phosphate) and 250 milligrams thenium (as thenium closylate).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally to dogs as follows:

NUMBER OF TABLETS AT EACH OF THE TWO DOSES

Animal weight (lb)	375 mg	750 mg
2 but less than 5	½	.....
5 but less than 10	1	½
10 or heavier	2	1

(2) *Indications for use.* For removal of immature (fourth stage larvae) and adult hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) and ascarids (*Toxocara canis*) from weaned pups and adult dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 32747, July 28, 1978, as amended at 47 FR 55476, Dec. 10, 1982; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 78 FR 28826, May 20, 2014]

§ 520.1806 Piperazine suspension.

(a) *Specifications.* Each milliliter of suspension contains piperazine monohydrochloride equivalent to 33.5 milligrams (mg) piperazine base.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25(c) of this chapter.

(d) *Conditions of use in dogs*—(1) *Indications for use.* For the removal of roundworms (*Toxocara canis*and *Toxascaris leonina*).

(2) *Dosage.* Administer 20 to 30 mg piperazine base per pound body weight as a single dose.

(3) *Limitations.* Administer by mixing into the animal's ration to be consumed at one feeding. For animals in heavily contaminated areas, reworm at monthly intervals. Not for use in unweaned pups or animals less than 3 weeks of age.

[70 FR 17319, Apr. 6, 2005]

§ 520.1807 Piperazine.

(a) *Specifications.* A soluble powder or liquid containing piperazine dihydrochloride or dipiperazine sulfate, equivalent to 17, 34, or 230 grams of piperazine per pound or 100 milliliters.

(b) *Sponsor.* See No. 015565 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.513 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* 50 milligrams per bird under 6 weeks, 100 milligrams per bird over 6 weeks.

(ii) *Indications for use.* For removal of large roundworm (*Ascaridia* spp.).

(iii) *Limitations.* For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 14 days prior to slaughter. Do not use for chickens producing eggs for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Turkeys*—(i) *Amount.* 100 milligrams per bird up to 12 weeks and 200 milligrams per bird over 12 weeks.

(ii) *Indications for use.* For removal of large roundworm (*Ascaridia* spp.).

(iii) *Limitations.* For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 14 days prior to slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Swine*—(i) *Amount.* 50 milligrams per pound of body weight.

(ii) *Indications for use.* For removal of large roundworm (*Ascaris suum*) and nodular worms (*Oesophagostomum* spp.).

(iii) *Limitations.* For use in drinking water or feed. Use as sole source of drinking water. Prepare fresh solution daily. Use as 1-day single treatment. Withdraw 21 days prior to slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[64 FR 23018, Apr. 29, 1999, as amended at 79 FR 28827, May 20, 2014]

§ 520.1840 Poloxalene.

(a) *Specifications.* Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use as in paragraphs (d)(1) and (d)(3) of this section.

(2) No. 051311 for use as in paragraph (d)(4) of this section.

(3) No. 067949 for use as in paragraph (d)(2) of this section.

(4) No. 066104 for use as in paragraph (d)(3) of this section.

(c) [Reserved]

(d) *Conditions of use.* (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 oz. of block (1.5 grams poloxalene) per 100 lbs. of body weight per day.

(3) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle. A 53-percent poloxalene top dressing on individual rations of ground feed. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat use of the drug if animals are exposed to bloat-producing conditions for more than 12 hours after the last treatment. Do not exceed the double dose in any 24-hour period.

(4) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle. Administer in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 ounce of block (1.5 grams of poloxalene) per 100 pounds of body weight per day. Provide access to blocks at least 7 days before exposure to bloat-producing conditions.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39857, Aug. 29, 1975; 42 FR 41854, Aug. 19, 1977; 50 FR 5385, Feb. 8, 1985; 54 FR 33501, Aug. 15, 1989; 56 FR 50653, Oct. 8, 1991; 58 FR 26523, May 4, 1993; 60 FR 55659, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001; 69 FR 62811, Oct. 28, 2004; 70 FR 32489, June 3, 2005; 78 FR 28826, May 20, 2014]

§ 520.1846 Polyoxyethylene (23) lauryl ether blocks.

(a) *Specifications.* Each molasses-based block contains 2.2 percent polyoxyethylene (23) lauryl ether.

(b) *Sponsor.* See No. 067949 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2 grams of polyoxyethylene (23) lauryl ether per 100 kilograms of body weight per day (1 pound of block per 500 kilogram (1,100 pound) animal per day).

(2) *Indications for use.* For reduction of the incidence of bloat (alfalfa and clover) in pastured cattle.

(3) *Limitations.* Administer free-choice to beef cattle and nonlactating dairy cattle only. Initially, provide one block per five head of cattle. Start treatment 10 to 14 days before exposure to bloat-producing pastures. Do not allow cattle access to other sources of salt while being fed this product. Do not feed this product to animals without adequate forage/roughage consumption.

[50 FR 48189, Nov. 22, 1985, as amended at 56 FR 9841, Mar. 8, 1991; 69 FR 62811, Oct. 28, 2004]

§ 520.1855 Ponazuril.

(a) *Specifications.* Each gram of paste contains 150 milligrams (mg) ponazuril.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 15 mg per kilogram (kg) (6.81 mg per pound (lb)) body weight as the first dose, followed by 5 mg/kg (2.27 mg/lb) body weight once daily for a period of 27 additional days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 43774, Aug. 21, 2001, as amended at 79 FR 28827, May 20, 2014; 80 FR 34278, June 16, 2015; 80 FR 53459, Sept. 4, 2015]

§ 520.1860 Pradofloxacin.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) pradofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 3.4 mg/lb (7.5 mg/kg) body weight once daily for 7 consecutive days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida, Streptococcus canis, Staphylococcus aureus, Staphylococcus felis,* and *Staphylococcus pseudintermedius.*

(3) *Limitations.* Federal law prohibits the extralabel use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 76863, Dec. 31, 2012, as amended at 79 FR 28827, May 20, 2014]

§ 520.1870 Praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 34 milligrams (mg) praziquantel.

(2) 11.5 or 23 mg praziquantel.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 pounds (lb) and under, ½ tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1½ tablets (51 mg); 16 to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 3 tablets (102 mg); 46 to 60 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.

(ii) *Indications for use*—(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis.*

(B) For removal of the canine cestode *Echinococcus granulosus,* and for removal and control of the canine cestode *Echinococcus multilocularis.*

(iii) *Limitations*—(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis.*

(ii) *Dosage.* Cats 4 pounds and under, 11.5 mg; 5 to 11 pounds, 23 mg; over 11 pounds, 34.5 mg.

(iii) *Limitations.* Administer directly by mouth or crumbled and in feed. Not intended for use in kittens less than 6 weeks of age. For OTC use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 60570, Dec. 11, 1981, as amended at 47 FR 26377, June 18, 1982; 55 FR 2234, Jan. 23, 1990; 58 FR 7864, Feb. 10, 1993; 58 FR 42853, Aug. 12, 1993; 68 FR 57351, Oct. 3, 2003; 69 FR 62181, Oct. 25, 2004; 78 FR 17596, Mar. 22, 2013; 81 FR 17607, Mar. 30, 2016]

§ 520.1871 Praziquantel and pyrantel.

(a) *Specifications.* (1) Each tablet contains 13.6 milligrams (mg) praziquantel and 54.3 mg pyrantel base (as pyrantel pamoate), 18.2 mg praziquantel and 72.6 mg pyrantel base (as pyrantel pamoate), or 27.2 mg praziquantel and 108.6 mg pyrantel base (as pyrantel pamoate).

(2) Each chewable tablet contains 30 mg praziquantel and 30 mg pyrantel pamoate or 114 mg praziquantel and 114 mg pyrantel pamoate.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as in paragraph (d) of this chapter.

(1) See No. 000859 for use of tablets described in paragraph (a)(1) of this section for use as in paragraph (d)(1) of this section.

(2) See No. 051311 for use of tablets described in paragraph (a)(2) of this section for use as in paragraph (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Cats*—(i) *Dosage.* Administer a minimum dose of 2.27 mg praziquantel and 9.2 mg pyrantel pamoate per pound of body weight according to the dosing tables on labeling. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated.

(ii) *Indications for use.* For removal of tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*), hookworms (*Ancylostoma tubaeforme*), and large roundworms (*Toxocara cati*) in cats and kittens.

(iii) *Limitations.* Not for use in kittens less than 2 months of age or weighing less than 2.0 pounds. Consult your veterinarian before giving to sick or pregnant animals.

(2) *Dogs*—(i) *Amount.* Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) *Indications for use.* For the treatment and control of roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) in dogs and puppies.

[58 FR 58652, Nov. 3, 1993, as amended at 72 FR 16270, Apr. 4, 2007; 75 FR 54018, Sept. 3, 2010]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) *Specifications.* Each tablet or chewable tablet contains either:

(1) Tablet No. 1: 22.7 milligrams praziquantel, 22.7 milligrams pyrantel base, and 113.4 milligrams febantel; or

(2) Tablet No. 2: 68 milligrams praziquantel, 68 milligrams pyrantel base, and 340.2 milligrams febantel.

(3) Tablet No. 3: 136 milligrams (mg) praziquantel, 136 mg pyrantel base, and 680.4 mg febantel.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer as a single dose directly by mouth or in a small amount of food as follows:

Weight of animal		Number of tablets per dose		
Kilograms	Pounds	Tablet no. 1	Tablet no. 2	Tablet no. 3
0.9 to 1.8	2 to 4	1/2.		
2.3 to 3.2	5 to 7	1.		
3.6 to 5.4	8 to 12	1 1/2.		
5.9 to 8.2	13 to 18 ...	2.		
8.6 to 11.4	19 to 25 ...	2 1/2.		
11.8 to 13.6 ..	26 to 30 ...	.....	1.	
14.1 to 20.0 ..	31 to 44 ...	.....	1 1/2.	
20.4 to 27.2 ..	45 to 60 ...	.....	2	1
27.7 to 40.9 ..	61 to 90 ...	.....	.....	1 1/2
41.3 to 54.5 ..	91 to 120	.....	.....	2

(ii) *Indications for use.* For the removal of tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*); hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*); ascarids (*Toxocara canis*, *Toxascaris leonina*); and whipworms (*Trichuris vulpis*) and for the removal and control of tapeworm *Echinococcus multilocularis* in dogs.

(iii) *Limitations.* Do not use in pregnant animals. Do not use in dogs weighing less than 0.9 kilogram (2 pounds) or puppies less than 3 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 33908, July 1, 1994, as amended at 61 FR 29651, June 12, 1996; 68 FR 22293, Apr. 28, 2003; 71 FR 6677, Feb. 9, 2006]

§ 520.1880 Prednisolone.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams prednisolone.

(b) *Sponsor.* See No. 061690 in § 510.600(c)(2) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 2.5 milligrams per 4.5 kilograms (10 pounds) body weight per day. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* For use as an anti-inflammatory agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 4718, Feb. 7, 1992, as amended at 60 FR 57832, Nov. 22, 1995; 63 FR 148, Jan. 5, 1998; 79 FR 28827, May 20, 2014]

§ 520.1900 Primidone.

(a) *Specifications.* Each tablet contains 50 or 250 milligrams of primidone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 054628 for use of 250 milligram tablets.

(2) No. 054771 for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs*—(1) *Amount.* Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.

(2) *Indications for use.* For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 61594, Dec. 6, 1977, as amended at 43 FR 55386, Nov. 28, 1978; 46 FR 8467, Jan. 27, 1981; 46 FR 57477, Nov. 24, 1981; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35076, June 30, 1997; 78 FR 21060, Apr. 9, 2013; 79 FR 28827, May 20, 2014]

§ 520.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each capsules contains either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide); or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Capsules described in paragraph (a)(1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a)(2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(2) *Indications for use.* For the treatment of gastrointestinal disturbances associated with emotional stress.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28827, May 20, 2014]

§ 520.1921 Prochlorperazine, isopropamide, and neomycin.

(a) *Specifications.* Each capsule contains either:

(1) Capsule No. 1: 3.33 milligrams of prochlorperazine (as the dimaleate), 1.67 milligrams of isopropamide (as the iodide), and 25 milligrams of neomycin base (as the sulfate); or

(2) Capsule No. 3: 10 milligrams of prochlorperazine (as the dimaleate), 5 milligrams of isopropamide (as the iodide), and 75 milligrams of neomycin base (as the sulfate).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer capsules orally twice daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 3
10 to 20	1	
20 to 30	2	
Over 30	3	1
Over 60		2

(2) *Indications for use.* For the treatment infectious bacterial gastroenteritis associated with emotional stress.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28827, May 20, 2014]

§ 520.1962 Promazine.

(a) *Specifications.* Conforms to N.F. XII for promazine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.45 to 0.9 milligrams per pound of body weight mixed with an amount of feed that will be readily consumed.

(2) *Indications for use.* For quieting excitable, unruly, or intractable horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28827, May 20, 2014]

§ 520.2002 Propiopromazine.

(a) *Specifications.* Each chewable tablet contains 10 or 20 milligrams of propiopromazine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.5 to 2.0 milligrams per pound of body weight once or twice daily, depending upon the degree of tranquilization desired.

(2) *Indications for use.* For oral administration as a tranquilizer. As an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking, car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28827, May 20, 2014]

§ 520.2041 Pyrantel pamoate chewable tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to 22.7 or 113.5 milligrams pyrantel base.

(b) *Sponsor.* See Nos. 066916, 017135, and 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Provides at least 2.27 milligrams pyrantel base per pound body weight for dogs weighing more than 5 pounds, and at least 4.54 milligrams of pyrantel base per pound body weight for dogs weighing 5 pounds or less.

(2) *Indications for use*—(i) *In dogs and puppies.* For removal of ascarids (*Toxocara canis; Toxascaris leonina*) and hookworms (*Ancylostoma caninum; Uncinaria stenocephala*).

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis.*

(3) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001; 67 FR 21996, May 2, 2002; 81 FR 22523, Apr. 18, 2016; 82 FR 12169, Mar. 1, 2017]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to 22.7, 45.4, or 113.5 milligrams of pyrantel base.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used for dogs as follows:

(1) *Amount.* For dogs weighing over 5 pounds, use at least 2.27 milligrams of pyrantel base per pound of body weight; for dogs weighing 5 pounds or less, use at least 4.54 milligrams of pyrantel base per pound of body weight.

(2) *Indications for use.* For removal and control of large roundworms (ascarids) (*Toxocara canis* and *Toxascaris leonina*), and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(3) *Limitations.* Administer orally directly or in a small amount of food. To prevent reinfection of *T. canis* in puppies, lactating bitches after whelping, and adult dogs; treat puppies 2, 3, 4, 6, 8, and 10 weeks of age; treat lactating bitches 2 to 3 weeks after whelping; routinely treat adult dogs monthly. Do not withhold food prior to or after treatment. The presence of these parasites should be confirmed by laboratory fecal examination. A followup fecal examination should be conducted

2 to 4 weeks after first treatment regimen to determine the need for re-treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 52700, Nov. 14, 1978, as amended at 49 FR 22073, May 25, 1984; 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993]

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications.* (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 054771, 058829, and 069043 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 000859, 054771, and 058829 for use of the products described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses and ponies.* It is used as follows:

(i) *Amount.* 3 mg per pound (/lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

(iii) *Limitations.* Do not use in horses intended for human consumption. When the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(2) *Dogs.* It is used as follows:

(i) *Dogs and puppies*—(A) *Amount.* 2.27 mg/lb body weight as a single dose in the animal's feed bowl by itself or mixed in a small quantity of food.

(B) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(C) *Limitations.* Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) *Dogs, puppies, and lactating bitches after whelping*—(A) *Amount.* 2.27 mg/lb body weight.

(B) *Indications for use.* To prevent reinfections of *T. canis.*

(C) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

[67 FR 43248, June 27, 2002, as amended at 68 FR 54803, Sept. 19, 2003; 68 FR 55199, Sept. 23, 2003; 68 FR 55825, Sept. 29, 2003; 75 FR 52622, Aug. 27, 2010; 76 FR 17337, Mar. 29, 2011; 78 FR 17596, Mar. 22, 2013; 79 FR 28827, May 20, 2014; 80 FR 76386, Dec. 9, 2015; 81 FR 17607, Mar. 30, 2016]

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications*—(1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).

(2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

(2) No. 017135 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

(3) No. 061623 for use of product described in paragraph (a)(3) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use.* It is used in horses and ponies as follows:

(1) *Amounts and indications for use*—(i) 3 mg per pound (/lb) body weight as single oral dose for removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

(ii) 6 mg/lb body weight as single oral dose for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*).

(2) *Limitations.* Do not use in horses intended for human consumption.

[70 FR 29447, May 23, 2005, as amended at 76 FR 17337, Mar. 29, 2011; 78 FR 17596, Mar. 22, 2013; 79 FR 28827, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.2045 Pyrantel tartrate powder.

(a) *Specifications.* Each gram of powder contains 106 milligrams (10.6 percent) or 113 milligrams (11.3 percent) pyrantel tartrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of 11.3 percent powder as in paragraph (d)(1) and 10.6 percent powder as in paragraph (d)(2) and of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration. Do not administer by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(iii) *Limitations.* Do not treat severely debilitated animals with this drug. Do not use in horses intended for human consumption.

(2) *Swine*—(i) *Amount.* Add to feed at 0.4 gram pyrantel tartrate per pound of non-pelleted ration. The ration is administered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(ii) *Indications for use.* For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(iii) *Limitations.* Consult veterinarian before using in severely debilitated animals. Do not treat within 24 hours of slaughter.

[79 FR 28827, May 20, 2014]

§ 520.2046 Pyrantel tartrate pellets.

(a) *Specifications.* (1) Each gram of pellets contains 12.5 milligrams (mg) (1.25 percent) pyrantel tartrate; or

(2) Each gram of pellets contains 21.1 mg (2.11 percent) pyrantel tartrate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 054771 for use of products described in paragraph (a) as in paragraph (c) of this section.

(2) No. 061623 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer as a single dose at 12.5 mg per 2.2 pounds of body weight mixed with the usual grain ration.

(2) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(3) *Limitations.* Do not treat severely debilitated animals with this drug. Do not use in horses intended for human consumption.

[79 FR 28828, May 20, 2014]

§ 520.2075 Robenacoxib.

(a) *Specifications.* Each tablet contains 10, 20, or 40 milligrams (mg) robenacoxib for use in dogs, or 6 mg robenacoxib for use in cats.

(b) *Sponsors.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.91 mg/lb (2 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs weighing at least 5.5 lb (2.5 kg)

and at least 4 months of age for a maximum of 3 days.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.45 mg/lb (1 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 4 months of age for a maximum of 3 days.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 18648, Apr. 5, 2011, as amended at 79 FR 10964, Feb. 27, 2014; 81 FR 59133, Aug. 29, 2016]

§ 520.2086 Sarolaner.

(a) *Specifications.* Each chewable tablet contains 5, 10, 20, 40, 80, or 120 milligrams (mg) sarolaner.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once a month at the recommended minimum dosage of 0.9 mg/lb (2 mg/kg).

(2) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 22523, Apr. 18, 2016, as amended at 82 FR 12169, Mar. 1, 2017]

§ 520.2098 Selegiline.

(a) *Specifications.* Each tablet contains 2, 5, 10, 15, or 30 milligrams (mg) selegiline hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amounts and indications for use.* (i) Administer 1 mg per kilogram (0.45 mg per pound) of body weight once daily for control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) Administer 0.5 to 1.0 mg per kilogram of body weight once daily for the control of clinical signs associated with canine cognitive dysfunction syndrome.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28828, May 20, 2014]

§ 520.2100 Selenium and vitamin E.

(a) *Specifications.* Each capsule contains:

(1) 2.19 milligrams (mg) sodium selenite (equivalent to 1 mg selenium) and 56.2 mg (68 I.U.) vitamin E as d-alpha tocopheryl acid succinate; or

(2) 0.548 mg sodium selenite (equivalent to 0.25 mg selenium) and 14 mg (17 I.U.) vitamin E as d-alpha tocopheryl acid succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Dogs over 20 pounds: Administer 1 capsule described in paragraph (a)(1) per 20 pounds of body weight to a maximum of 5 capsules. Repeat at 3 day intervals until a satisfactory therapeutic response is observed. Maintenance dosage is 1 capsule per 40 pounds of body weight every 3 to 7 days, or longer, as required.

(ii) Dogs under 20 pounds: Administer 1 capsule described in paragraph (a)(2) per 5 pounds of body weight with a minimum of 1 capsule. Repeat at 3-day intervals until a satisfactory response is observed. Maintenance dosage is 1 capsule per 10 pounds of body weight every 3 to 7 days, or longer, as required.

(2) *Indications for use.* As an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28828, May 20, 2014]

§ 520.2123 Spectinomycin oral dosage forms.

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 054771 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008, as amended at 79 FR 28828, May 20, 2014]

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts*—(i) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(ii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008, as amended at 81 FR 94990, Dec. 27, 2016]

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 016592, 054771, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

[73 FR 6607, Feb. 5, 2008, as amended at 78 FR 17596, Mar. 22, 2013; 79 FR 28828, May 20, 2014; 81 FR 22523, Apr. 18, 2016]

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 90, 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

(b) *Sponsor.* See No. 058198 in § 510.600 of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer tablets once a month at a recommended minimum dosage of 13.5 mg per pound (30 mg per kilogram) of body weight.

(ii) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) for 1 month on dogs and puppies 14 weeks of age and older and 3.3 pounds of body weight or greater.

(2) *Cats*—(i) *Amount.* Administer tablets once a month at a minimum dosage of 22.5 mg per pound (50 mg per kilogram) of body weight.

(ii) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*C. felis*) for 1 month on cats and kittens 14 weeks of age and

older and 2 pounds of body weight or greater.

[77 FR 60623, Oct. 4, 2012, as amended at 81 FR 48702, July 26, 2016]

§ 520.2134 Spinosad and milbemycin.

(a) *Specifications.* Each chewable tablet contains 140 milligrams (mg) spinosad and 2.3 mg milbemycin oxime, 270 mg spinosad and 4.5 mg milbemycin oxime, 560 mg spinosad and 9.3 mg milbemycin oxime, 810 mg spinosad and 13.5 mg milbemycin oxime, or 1,620 mg spinosad and 27 mg milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer once a month at a minimum dosage of 13.5 mg/pound (lb) (30 mg/kilogram (kg)) of body weight spinosad and 0.2 mg/lb (0.5 mg/kg) of body weight milbemycin oxime.

(2) *Indications for use.* To kill fleas; for the prevention and treatment of flea infestations (*Ctenocephalides felis*); for the prevention of heartworm disease (*Dirofilaria immitis*); and for the treatment and control of adult hookworm (*Ancylostoma caninum*), adult roundworm (*Toxocara canis* and *Toxascaris leonina*), and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and 5 lbs of body weight or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 12563, Mar. 8, 2011, as amended at 81 FR 48702, July 26, 2016]

§ 520.2150 Stanozolol.

(a) *Specifications.* Each tablet or chewable tablet contains 2 milligrams stanozolol.

(b) *Sponsor.* No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs:* Administered orally to small breeds, ½ to 1 tablet twice daily for several weeks; to large breeds, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

(ii) *Cats:* Administered orally ½ to 1 tablet twice daily for several weeks.

(2) *Indications for use.* As an anabolic steroid treatment.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28828, May 20, 2014]

§ 520.2158 Streptomycin.

(a) *Specifications.* Each milliliter of solution contains 250 milligrams (25 percent) streptomycin sulfate.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.610 of this chapter.

(d) *Conditions of use.* Use in drinking water as follows:

(1) *Calves*—(i) *Amount.* 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 10 to 15 mg/pound of body weight (1.0 to 1.5 grams per gallon) for up to 4 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Chickens*—(i) *Amount.* 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.

(iii) *Limitations.* Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 58 FR 47211, Sept. 8, 1993; 63 FR 51821, Sept. 29, 1998. Redesignated and amended at 79 FR 28828, May 20, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 18776, Apr. 8, 2015; 80 FR 61296, Oct. 13, 2015]

§ 520.2170 Sulfabromomethazine.

(a) *Specifications.* Each bolus contains 15 grams of sulfabromomethazine sodium.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.620 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 90 milligrams per pound body weight orally. Repeat in 48 hours if necessary

(2) *Indications for use.* Treatment of necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum;* colibacillosis (scours) caused by *Escherichia coli;* bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; acute metritis and acute mastitis caused by *Streptococcus* spp.

(3) *Limitations.* Milk taken from animals within 96 hours (8 milkings) of latest treatment must not be used for food. Do not administer within 18 days of slaughter.

[47 FR 30243, July 13, 1982, as amended at 62 FR 63270, Nov. 28, 1997; 79 FR 28829, May 20, 2014]

§ 520.2184 Sulfachloropyrazine.

(a) *Specifications.* Each gram of powder contains 476 milligrams of sodium sulfachloropyrazine monohydrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.625 of this chapter.

(d) *Conditions of use in chickens.* It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:

(1) *Amount.* Administer in drinking water as 0.03 percent solution for 3 days.

(2) *Indications for use.* For the treatment of coccidiosis.

(3) *Limitations.* Withdraw 4 days prior to slaughter. Do not use in chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28829, May 20, 2014, as amended at 81 FR 94990, Dec. 27, 2016]

§ 520.2200 Sulfachlorpyridazine.

(a) *Specifications.* (1) Sodium sulfachlorpyridazine powder.

(2) Each bolus contains 2 grams sulfachlorpyridazine.

(3) Each tablet contains 250 milligrams (mg) sulfachlorpyridazine.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Calves*—(i) *Amount.* Administer 30 to 45 mg sulfachlorpyridazine powder per pound (/lb) of body weight per day in milk or milk replacer, or in a bolus, in divided doses twice daily for 1 to 5 days.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(iii) *Limitations.* Treated ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer 20 to 35 mg/lb body weight per day, in divided doses twice daily for 1 to 5 days:

(A) In drinking water or

(B) For individual treatment, in an oral suspension containing 50 mg per milliliter.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs*—(i) *Amount.* Administer tablets orally at 500 mg per 10 to 15 lb of body weight daily, in two or three divided doses.

(ii) *Indications for use.* As an aid in the treatment of infectious tracheobronchitis and infections caused by *E. coli*, and in the treatment of infections caused by other Gram-positive and Gram-negative organisms

that are susceptible to sulfonamide therapy.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10166, Mar. 5, 2010, as amended at 79 FR 28829, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

(b) *Sponsor.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 70054, Dec. 2, 2004, as amended at 73 FR 53686, Sept. 17, 2008; 75 FR 69586, Nov. 15, 2010]

§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.

(a) *Specifications.* Each 195-gram (g) packet of powder contains 78 g sulfamerazine, 78 g sulfamethazine, and 39 g sulfaquinoxaline.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.670 and 556.685 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amounts and indications for use*—(A) As an aid in the control of coccidiosis caused by *Eimeria tenella* and *E. necatrix* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. If bloody droppings appear, repeat at 0.025 percent level for 2 more days. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations.* Do not treat chickens within 14 days of slaughter for food. Do not medicate chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amounts and indications for use*—(A) As an aid in the control of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations.* Do not treat turkeys within 14 days of slaughter for food. Do not medicate turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13001, Mar. 14, 2006, as amended at 79 FR 28829, May 20, 2014; 80 FR 34278, June 16, 2015; 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) *Specifications.* (1) Each ounce of solution contains 3.75 grams (12.5 percent) sulfadimethoxine.

(2) Each 107 grams of powder contains the equivalent of 94.6 grams sulfadimethoxine as sulfadimethoxine sodium.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) Nos. 016592, 054628, 054771, 054925, and 057561 for use of the product described in paragraph (a)(1) of this section.

(2) Nos. 054771, 054925, 057561, 058829, 061623, and 066104 for use of the product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use*—(1) *Broiler and replacement chickens*—(i) *Amount.* Administer 1.875 grams per gallon (0.05 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use.* For treatment of outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) *Limitations.* Withdraw 5 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* Administer 0.938 grams per gallon (0.025 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use.* Growing turkeys: For treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations.* Withdraw 5 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* 1.18 to 2.36 grams per gallon (0.031 to 0.062 percent) of drinking water. As a drench, administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days. If no improvement within 2 to 3 days, reevaluate diagnosis. Do not treat beyond 5 days.

(ii) *Indications for use.* Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

(iii) *Limitations.* Withdraw 7 days before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

[79 FR 28829, May 20, 2014, as amended at 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2220b Sulfadimethoxine suspension.

(a) *Specifications.* Each milliliter of suspension contains 50 milligrams (mg) sulfadimethoxine.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily.

(2) *Indications for use.* For the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28829, May 20, 2014]

§ 520.2220c Sulfadimethoxine tablet.

(a) *Specifications.* Each tablet contains 125, 250, or 500 milligrams (mg) sulfadimethoxine.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 25 milligrams (mg) per pound of body weight on the first day followed by 12.5 milligrams (mg) per pound of body weight per day until the animal is free of symptoms for 48 hours.

(2) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28829, May 20, 2014]

§ 520.2220d Sulfadimethoxine bolus.

(a) *Specifications.* Each bolus contains 2.5, 5, or 15 grams sulfadimethoxine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.

(2) *Indications for use*. For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations*. Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[79 FR 28829, May 20, 2014]

§ 520.2220e Sulfadimethoxine extended-release bolus.

(a) *Specifications*. Each extended-release bolus contains 12.5 grams sulfadimethoxine.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.640 of this chapter.

(d) *Conditions of use in beef cattle and non-lactating dairy cattle*—(1) *Amount*. Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.

(2) *Indications for use*. For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations*. Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2220f Sulfadimethoxine and ormetoprim tablet.

(a) *Specifications*. Each tablet contains 120 milligrams (mg) (100 mg sulfadimethoxine and 20 mg ormetoprim), 240 mg (200 mg sulfadimethoxine and 40 mg ormetoprim), 600 mg (500 mg sulfadimethoxine and 100 mg ormetoprim), or 1200 mg (1000 mg sulfadimethoxine and 200 mg ormetoprim).

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. On the first day of treatment, administer 25 mg per pound (55 mg per kilogram) of body weight. Then follow with a daily dosage of 12.5 mg per pound (27.5 mg per kilogram) of body weight. Do not exceed a total of 21 consecutive days.

(2) *Indications of use*. Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *E. coli*, *Staphylococcus* spp., and *Proteus mirabilus* susceptible to ormetoprim-potentiated sulfadimethoxine.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine solution.

(a) *Specifications*. Each milliliter of solution contains 62.5 milligrams (mg) sodium sulfaethoxypyridazine.

(b) *Sponsor*. See No. 054771 § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.650 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount*. Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days. Use as the sole source of sulfonamide.

(ii) *Indications for use*. For treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Do not treat within 10 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* For use at 2.5 grams per gallon. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; and as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2240b Sulfaethoxypyridazine tablets.

(a) *Specifications*—(1) Each tablet contains 2.5 or 15 grams sulfaethoxypyridazine.

(2) Each extended-release tablet contains 5 grams sulfaethoxypyridazine.

(b) *Sponsor.* See No. 054771 § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use in cattle*—(1) *2.5- or 15-gram tablets*—(i) *Amount.* Administer 25 milligrams per pound of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *15-gram extended-release tablets*—(i) *Amount.* Administer 100 milligrams per pound of body weight. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (*E. coli, Streptococci, Staphylococci, Sphaerophorus necrophorus* and Gram-negative rods including *Pasteurella*); and for use prophylactically during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Not for use in lactating dairy cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2260 Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690 in § 510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.

(2) *Related tolerance in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer as a single dose 100 milligrams of sulfamethazine per pound of body weight the first day and 50 milligrams per pound of body weight on each following day.

(ii) *Indications for use.* For treatment of diseases caused by organisms susceptible to sulfamethazine.

(A) *Beef cattle and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis* and *Eimeria zurnii*).

(B) *Horses.* Treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles

(*Streptococcus equi*), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations.* Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Do not treat cattle within 10 days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(b)(1) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of 5-gram sulfamethazine bolus.

(2) *Related tolerances in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use.* Ruminating beef and dairy calves. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacilloosis) caused by *E. coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *F. necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *E. bovis* and *E. zurnii*.

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follows recomended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

[54 FR 15751, Apr. 19, 1989; 54 FR 19283, May 4, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 64 FR 66383, Nov. 26, 1999; 67 FR 78355, Dec. 24, 2002; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011; 79 FR 28830, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.2260b Sulfamethazine sustained-release boluses.

(a)(1) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine prolonged-release bolus.

(2) *Conditions of use*—(i) *Amount.* Depending on the duration of therapeutic levels desired, administer boluses as a single dose as follows: 3½ days—1 bolus (22.5 grams) per 200 pounds of body weight; 5 days—1 bolus per 100 pounds of body weight.

(ii) *Indications for use.* Beef and nonlactating cattle for sustained treatment of shipping fever pneumonia caused or complicated by *Pasteurella multocida;* as an aid in the treatment of foot rot, mastitis, pneumonia, metritis, bacterial enteritis, calf diphtheria, and septicemia when caused or complicated by bacteria susceptible to sulfamethazine.

(iii) *Limitations.* Cattle that are acutely ill should be treated parenterally with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of a 27-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 27 grams (1 bolus) for each 150 pounds of body weight as a single dose.

(ii) *Indications for use.* For nonlactating cattle for the treatment of infections caused by organisms sensitive to sulfamethazine such as hemorrhagic septicemia (shipping fever complex), bacterial pneumonia, foot rot, and calf diphtheria and as an aid in the control of bacterial diseases usually associated with shipping and handling of cattle.

(iii) *Limitations.* If no response within 2 to 3 days, reevaluate therapy; do not crush tablets; treated animals must not be slaughtered for food within 28 days after the latest treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter for use of a 32.1-gram sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 32.1 grams (1 bolus) per 200 pounds of body weight.

(ii) *Indications for use.* For beef and nonlactating dairy cattle for the treatment of diseases caused by sulfamethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *E. coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, and acute mastitis and acute metritis caused by *Streptococcus* spp.)

(iii) *Limitations.* After 72 hours, all animals should be reexamined for persistence of observable disease signs. If signs are present, consult a veterinarian. It is strongly recommended that a second dose be given to provide for an additional 72 hours of therapy, particularly in more severe cases. The dosage schedule should be used at each 72-hour interval. Animals should not receive more than 2 doses because of the possibility of incurring residue violations. This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision; *follow dosages carefully*. Fluid intake must be adequate at all times throughout the 3-day therapy, Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Do not treat animals within 12 days of slaughter.

(d)(1) *Sponsor.* See 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine sustained release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer 1 bolus (22.5 grams) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use.* Beef and nonlactating dairy cattle for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), bacterial pneumonia (*Pasteurella* spp.), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), colibacillosis (bacterial scours) (*Escherichia coli*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.) and acute metritis (*Streptococcus* spp.).

(iii) *Limitations.* Cattle that are acutely ill should be treated by injection with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; if treated animals do not respond within 2 to 3 days, consult a veterinarian.

(e)(1) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter for use of an 8.02-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer 2 boluses (8.02 grams per bolus) per 100 pounds of body weight, as a single dose.

(ii) *Indications for use.* Administer orally to ruminating calves for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bacterial pneumonia (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), and calf diptheria (*Fusobacterium necrophorum*).

(iii) *Limitations.* For use in ruminating replacement calves only; 72 hours after dosing all animals should be reexamined for persistence of disease signs; if signs are present, consult a veterinarian; do not slaughter animals for food for at least 12 days after the last dose; this product has not been shown to be effective for nonruminating calves; exceeding two consecutive doses may cause violative tissue residue to remain beyond the withdrawal time; do not use in calves under 1 month of age or calves being fed an all milk diet.

(f)(1) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter for use of a

30-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer at the rate of 1 bolus (30 grams per bolus) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use.* Administer orally to beef cattle and nonlactating dairy cattle for the treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; bacterial pneumonia associated with *Pasteurell* spp.; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; acute mastitis and metritis caused by *Streptococcus* spp.

(iii) *Limitations.* For use in beef cattle and nonlactating dairy cattle only; if symptoms persist for 2 or 3 days after use, consult a veterinarian; do not slaughter animals for food for at least 8 days after the last dose; do not use in lactating dairy cattle; do not administer more than two consecutive doses.

(g) *Related tolerances.* See §556.670 of this chapter.

(h)(1) *Sponsor.* See No. 000010 in §510.600(c) of this chapter for use of an 8.25-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer at the rate of 1 bolus (8.25 grams per bolus) per 50 pounds of body weight, as a single dose. If signs of disease are significantly reduced, it is recommended that a second dose be given to provide an additional 72 hours of therapy.

(ii) *Indications for use.* Administer orally to ruminating beef and dairy calves for treatment of the following diseases when caused by one or more of the listed pathogenic organisms susceptible to sulfamethazine: bacterial pneumonia associated with *Pasteurella* spp.; colibacillosis (bacterial scours) caused by *Escherichia coli;* coccidiosis caused by *Eimeria bovis* and *E. zurnii;* and calf diphtheria caused by *Fusobacterium necrophorum.*

(iii) *Limitations.* Do not use in calves to be slaughtered under 1 month of age or calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older. If symptoms persist after 3 days, consult a veterinarian. Do not administer more than 2 consecutive doses. Do not slaughter animals for food for at least 8 days after the last dose. Do not crush bolus.

[46 FR 36132, July 14, 1981, as amended at 48 FR 18803, Apr. 26, 1983; 48 FR 32760, July 19, 1983; 49 FR 29057, July 18, 1984; 50 FR 49372, Dec. 2, 1985; 51 FR 30212, Aug. 25, 1986; 53 FR 40727, Oct. 18, 1988; 54 FR 14341, Apr. 11, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 70 FR 8290, Feb. 18, 2005; 78 FR 17596, Mar. 22, 2013; 79 FR 28830, May 20, 2014; 81 FR 22523, Apr. 18, 2016]

§520.2260c Sulfamethazine sustained-release tablets.

(a) *Specifications.* Each extended-release tablet contains 8 grams sulfamethazine.

(b) *Sponsor.* See No. 054771 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.670 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 8 grams (1 tablet) per 45 pounds of body weight as a single dose.

(2) *Indications for use.* In calves for sustained treatment of pneumonia caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli;* and calf diptheria caused by *Fusobacterium necrophorum.*

(3) *Limitations.* Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 26763, June 10, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 79 FR 28830, May 20, 2014]

§520.2261 Sulfamethazine sodium oral dosage forms.

§520.2261a Sulfamethazine solution.

(a) *Specifications.* Each milliliter of solution contains 125 milligrams (12.5 percent) sulfamethazine sodium.

(b) *Sponsors.* See No. 016592 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.670 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer in drinking water to provide: Cattle and swine 112.5 milligrams of sulfamethazine sodium per pound of body weight per day on the first day and 56.25 milligrams per pound of body weight on subsequent days; Chickens, 61 to 89 milligrams of sulfamethazine sodium per pound of body weight per day, and turkeys 53 to 130 milligrams of sulfamethazine sodium per pound of body weight per day, depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors.

(2) *Indications for use.* For treatment and control of diseases caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine.* Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella, Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella* Pullorum). In turkeys for control of coccidiosis (*Eimeria meleagrimitis, Eimeria adenoeides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease, in chickens, medicate for 6 consecutive days; coccidiosis, in chickens and turkeys, medicate as in paragraph (c) of this section, then reduce amount of medication to one-half for 4 additional days.

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982; 67 FR 78355, Dec. 24, 2002; 70 FR 32489, June 3, 2005; 74 FR 36112, July 22, 2009; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011; 79 FR 28831, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 36789, June 8, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2261b Sulfamethazine powder.

(a) *Specifications.* A soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Sponsors.* See Nos. 016592 and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* Administer in drinking water to provide 58 to 85 milligrams (mg) per pound (/lb) of body weight per day.

(ii) *Indications for use.* For control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella, E. necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella* Pullorum).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate chickens producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48

hours beyond the remission of disease symptoms. Medicated chickens must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* Administer in drinking water to provide 50 to 124 mg/lb of body weight per day

(ii) *Indications for use.* For control of coccidiosis (*E. meleagrimitis*, *E. adenoeides*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated turkeys must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Swine*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use.* For treatment of porcine colibacillosis (bacterial scours) (*E. coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 15 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated swine must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Cattle*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use in beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*F. necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.)

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated cattle must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 70303, Dec. 4, 2006, as amended at 75 FR 10166, Mar. 5, 2010; 79 FR 28831, May 20, 2014; 80 FR 61296, Oct. 13, 2015; 81 FR 17607, Mar. 30, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2280 Sulfamethizole and methenamine.

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 1 tablet per 20 pounds of body weight 3 times

per day until clinical signs are alleviated. To reduce the possibility of relapse, continue therapy for a week to 10 days.

(2) *Indications for use.* For treatment of urinary tract infections such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. As an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 13561, Apr. 5, 1985; 79 FR 28831, May 20, 2014]

§ 520.2325 Sulfaquinoxaline oral dosage forms.

§ 520.2325a Sulfaquinoxaline powder and solution.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) To No. 016592 for use of a 25-percent sulfaquinoxaline soluble powder and a 20-percent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To Nos. 016592 and 054771 for use of a 31.92-percent sulfaquinoxaline solution (sodium and potassium salts) as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) No. 054771 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(b) *Related tolerances.* See § 556.685 of this chapter.

(c) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti.*

(ii) Administer at the 0.04 percent level for 2 or 3 days, skip 3 days then administer at the 0.025 percent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 percent level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(2) *Turkeys.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides.*

(ii) Administer at the 0.025 percent level for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(3) *Chickens and turkeys.* (i) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(ii) Administer at the 0.04 percent level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. If cholera has become established as the respiratory or chronic form, use feed medicated with sulfaquinoxaline. Poultry which have survived typhoid outbreaks should not be kept for laying house replacements or breeders unless tests show they are not carriers.

(4) *Cattle and calves.* (i) For the control and treatment of outbreaks of coccidiosis caused by *Eimeria bovis* or *E. zurnii.*

(ii) Administer at the 0.015-percent level for 3 to 5 days in drinking water medicated with sulfaquinoxaline solution.

(iii) In lieu of treatment as provided in paragraph (e)(4)(ii) of this section, administer 1 teaspoon of 25-percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations.* May cause toxic reactions unless the drug is evenly mixed in water at dosages indicated and used according to directions. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, cattle, and calves must actually consume enough medicated water which provides a recommended dosage of approximately 10 to 45 milligrams per pound per day in chickens, 3.5 to 55 milligrams per pound per day in turkeys, and approximately 6 milligrams per pound per day in cattle and calves depending on the age, class of

animal, ambient temperature, and other factors. A withdrawal period has not been established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Make fresh drinking water daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 3964, Jan. 28, 1983, as amended at 48 FR 26762, June 10, 1983; 55 FR 29843, July 23, 1990; 59 FR 28769, June 3, 1994; 59 FR 33197, June 28, 1994; 61 FR 24443, May 15, 1996; 61 FR 63711, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 65 FR 10705, Feb. 29, 2000; 69 FR 41427, July 9, 2004; 69 FR 60547, Oct. 12, 2004; 74 FR 36112, July 22, 2009; 78 FR 17596, Mar. 22, 2013; 79 FR 28831, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 36789, June 8, 2016; 81 FR 59134, Aug. 29, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2325b Sulfaquinoxaline drench.

(a) *Specifications.* A soluble powder containing 25 percent sulfaquinoxaline.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* Administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(2) *Indications for use.* For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zuernii.*

(3) *Limitations.* Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[79 FR 28831, May 20, 2014, as amended at 82 FR 12169, Mar. 1, 2017]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications.* Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer one tablet orally per 4 pounds of body weight.

(2) *Indications for use.* Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.

(3) *Limitations.* Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.

[43 FR 60895, Dec. 29, 1978, as amended at 79 FR 28831, May 20, 2014]

§ 520.2340 Tepoxalin.

(a) *Specifications.* Each tablet contains 30, 50, 100, or 200 milligrams (mg) tepoxalin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 10 mg per kilogram (/kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 34795, June 11, 2003]

§ 520.2345 Tetracycline.

§ 520.2345a Tetracycline capsules.

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams (mg) tetracycline hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 25 mg per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 50182, Aug. 26, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 79 FR 28831, May 20, 2014]

§ 520.2345b Tetracycline tablets.

(a) *Specifications.* Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(3) *Limitations.* Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345c Tetracycline boluses.

(a) *Specifications.* Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations.* Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(2) *Amount.* 10 milligrams per pound of body weight per day in two divided doses.

(i) *Indications for use.* Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, bacterial enteritis caused by *E. coli,* and salmonella organisms susceptible to tetracycline.

(ii) *Limitations.* Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline.

[57 FR 37328, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28831, May 20, 2014; 81 FR 67151, Sept. 30, 2016]

§ 520.2345d Tetracycline powder.

(a) *Specifications.* Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors.* See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 054771: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) No. 066104: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(3) Nos. 016592 and 054771: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(4) Nos. 054925, 057561, 061623, and 076475: 324 grams per pound as in paragraph (d) of this section.

(5) No. 016592: 25 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use.* It is administered in drinking water as follows:

(1) *Calves*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae (Haemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 066104 and within 5 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae (Haemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 066104 and within 4 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Chickens*—(i) *Amount.* Chronic respiratory disease: 400 to 800 milligrams per gallon. Infectious synovitis: 200 to 400 milligrams per gallon.

(ii) *Indications for use.* Control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Turkeys*—(i) *Amount.* For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 17693, Apr. 14, 1994, as amended at 59 FR 19133, Apr. 22, 1994; 62 FR 5319, Feb. 5, 1997; 62 FR 35076, June 30, 1997; 62 FR 46668, Sept. 4, 1997; 62 FR 55160, Oct. 23, 1997; 64 FR 37673, July 13, 1999; 67 FR 78355, Dec. 24, 2002; 70 FR 16934, Apr. 4, 2005; 70 FR 67353, Nov. 7, 2005; 71 FR 13542, Mar. 16, 2006; 75 FR 10166, Mar. 5, 2010; 75 FR 12981, Mar. 18, 2010; 76 FR 17338, Mar. 29, 2011; 77 FR 20988, Apr. 9, 2012; 78 FR 21060, Apr. 9, 2013; 79 FR 28831, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2345e Tetracycline solution.

(a) *Specifications.* Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *Escherichia coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(iii) *Limitations.* Administer orally; continue treatment until symptoms have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(iii) *Limitations.* Administer orally; continue treatment until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.

(a) *Specifications.* Each capsule contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin.

(b) *Sponsor.* No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic per pound of body weight (1 capsule for each 6 pounds) every 12 hours.

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin, or 180 milligrams of tetracycline hydrochloride and 180 milligrams of novobiocin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds).

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride, 60 milligrams of novobiocin, and 1.5 milligrams of prednisolone or 180 milligrams of tetracycline hydrochloride, 180 milligrams of novobiocin, and 4.5 milligrams of prednisolone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic and 0.25 milligram of prednisolone per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds) every 12 hours for 48 hours. Treatment is to be continued with novobiocin and tetracycline alone at the same dose schedule for an additional 3 days or longer as needed.

(2) *Indications for use.* Treatment of acute and chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli,* when it is necessary to initially reduce the severity of associated clinical signs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28832, May 20, 2014]

§ 520.2362 Thenium closylate.

(a) *Specifications.* Each tablet contains thenium closylate equivalent to 500 milligrams thenium base.

(a) *Specifications.* Thenium closylate tablets contain thenium closylate equivalent to 500 milligrams thenium as base in each tablet.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Dogs weighing over 10 pounds: Administer 1 tablet as a single dose. Dogs weighing 5 to 10 pounds: Administered one-half tablet twice during a single day. Repeat treatment after 2 or 3 weeks.

(2) *Indications for use.* For treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 53477, Dec. 7, 1976; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 79 FR 28832, May 20, 2014]

§ 520.2380 Thiabendazole oral dosage forms.

§ 520.2380a Thiabendazole top dressing and mineral protein block.

(a) *Specifications.* Conforms to N.F. XII.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 051311 for use as in paragraph (d)(1)(i) of this section.

(2) No. 050604 for use as in paragraph (d)(1)(ii) of this section.

(3) No. 012286 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Route of administration.* In feed, as a top dressing.

(*a*) *Amount.* 2 grams per 100 pounds of body weight.

(*b*) *Indications for use.* For control of large strongyles, small strongyles, pinworms, and threadworms (including members of the genera *Strongylus, Cyathostomum, Cylicobrachytus,* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum, Oxyuris,* and *Strongyloides*).

(*c*) *Limitations.* Add to the usual feed of horses mixed into that amount of the feed normally consumed at one feeding. Warning: Not for use in horses intended for food.

(ii) *Route of administration.* In feed.

(*a*) *Amount.* 2 grams per 100 pounds of body weight.

(*1*) *Indications for use.* For control of large and small strongyles, *Strongyloides,* and pinworms of the genera *Strongylus, Cyathostomum, Cylicobrachytus* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum, Oxyuris,* and *Strongyloides.*

(*2*) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(*b*) *Amount.* 4 grams per 100 pounds of body weight.

(*1*) *Indications for use.* For control of ascarids of the genus *Parascaris.*

(*2*) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(2) *Cattle*—(i) *Route of administration.* In feed block.

(ii) *Amount.* 3.3 percent block consumed at the recommended level of 0.11 pound per 100 pounds of body weight per day.

(iii) *Indications for use.* For control of infections of gastrointestinal roundworms (*Trichostrongylus, Haemonchus, Ostertagia* and *Cooperia*).

(iv) *Limitations.* Administer to cattle on pasture or range accustomed to mineral protein block feeding for 3 days. Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or diagnostic laboratory prior to worming. Animals maintained under conditions of constant worm exposure may require re-treatment within 2 to 3 weeks. Animals that are severely parasitized, sick, or off feed should be isolated and a veterinarian consulted for advice concerning treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 62 FR 63271, Nov. 28, 1997; 70 FR 32489, June 3, 2005; 73 FR 35340, June 23, 2008; 79 FR 28832, May 20, 2014]

§ 520.2380b Thiabendazole drench or paste.

(a) *Specifications.* Conforms to N.F. XII.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Horses.* As a single liquid oral dose, administered as a drench or by stomach tube; or as an oral paste.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(*a*) *Indications for use.* For the control of infections of large strongyles (*Strongylus vulgaris, Strongylus endentatus*), small strongyles (*Cyathastomum, Cylicobrachytus* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum*), pinworms (*Oxyuris*), and threadworms (*Strongyloides*).

(*b*) *Limitations.* Not for use in horses to be slaughtered for food purposes. When administered by stomach tube, for use only by or on the order of a licensed veterinarian. When for use as a liquid oral drench or an oral paste, consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii) *Amount.* 4 grams per 100 pounds of body weight.

(*a*) *Indications for use.* For control of infections of ascardis (*Parascaris*).

(*b*) *Limitations.* Not for use in horses to be slaughtered for food purposes. When administered by stomach tube, use only by or on the order of a licensed veterinarian. When for use as a liquid oral drench or an oral paste, consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Pigs.* As an oral paste.

(i) *Amount.* 200 milligrams for each 5 to 7 pounds of body weight per dose.

(ii) *Indications for use.* For control of infections with *Strongyloides ransomi.* These infections are commonly found in Southeastern United States.

(iii) *Limitations.* Administer to baby pigs (1 to 8 weeks of age). Treatment may be repeated in 5 to 7 days if necessary. Before treatment, obtain an accurate diagnosis from a veterinarian or diagnostic laboratory. Do not treat within 30 days of slaughter.

(3) *Cattle.* Orally as a drench and in paste form using a dosing gun designed for the product.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*).

(*b*) *Limitations.* For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

(ii) *Amount.* 5 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of infections of *Cooperia spp.* or severe infections of other species in paragraph (e)(3)(i)(*a*) of this section.

(*b*) *Limitations.* For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

(4) *Sheep and goats.* Orally, as a drench.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms in sheep and goats. (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active from 3 hours to 3 days following treatment against ova and larvae passed by sheep (good activity against *Trichostrongylus colubriformis* and *axei, Ostertagia spp., Bunostomum spp., Nematodirus spp.,* and *Strongyloides spp.;* less effective against *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; in severe infections in

sheep, treatment should be repeated in 2 to 3 weeks.

(5) *Goats.* Orally, as a drench.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; treatment should be repeated in 2 to 3 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 41 FR 47424, Oct. 29, 1976; 62 FR 63271, Nov. 28, 1997; 79 FR 28832, May 20, 2014]

§ 520.2380c Thiabendazole bolus.

(a) *Specifications.* Conforms to N.F. XII.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Cattle.* In a bolus.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (general *Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*).

(*b*) *Limitations.* As a single oral dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 pounds of body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*). Control of infections with *Cooperia spp.*

(*b*) *Limitations.* As a single oral dose; as a drench or bolus; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Sheep and goats.* In a bolus.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms in sheep and goats (general *Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active from 3 hours to 3 days following treatment against ova and larvae passed by sheep (good activity against *T. colubriformis* and *axei, Ostertagia spp., Bunostomum spp., Nematodirus spp.,* and *Strongyloides spp.;* less effective against *Haemonchus* contortus and *Oesophagostomum spp.*).

(iii) *Limitations.* As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; in severe infections in sheep, treatment should be repeated in 2 to 3 weeks.

(3) *Goats.* In a bolus.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* As a single oral dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; treatment should be repeated in 2 to 3 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 62 FR 63271, Nov. 28, 1997; 79 FR 28832, May 20, 2014]

§ 520.2380d Thiabendazole and piperazine citrate.

(a) *Specifications.* Each fluid ounce of suspension contains 2 grams of thiabendazole and 2.5 grams of piperazine (from piperazine citrate).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 ounce of suspension per 100 pounds of body weight by stomach tube or as a drench.

(2) *Indications for use.* For the control of large strongyles, small strongyles, pinworms, *Strongyloides* and ascarids (including members of the genera *Strongylus* spp., *Cyathostomum* spp., *Cylicobrachytus* spp. and related genera *Craterostomum* spp., *Oesophagodontus* spp., *Poteriostomum* spp., *Oxyuris* spp., *Strongyloides* spp., and *Parascaris* spp.).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 28832, May 20, 2014]

§ 520.2380e Thiabendazole and triclorfon.

(a) *Specifications.* The drug contains 5 grams of thiabendazole with 4.5 grams of trichlorfon, or 20 grams of thiabendazole with 18 grams of trichlorfon.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 2 grams of thiabendazole with 1.8 grams of trichlorfon per 100 pounds of body weight sprinkled on the animals' usual daily ration of feed, or may be mixed in 5 to 10 fluid ounces of water and administered by stomach tube or drench.

(2) *Indications for use.* For the treatment and control of bots (*Gasterophilus* spp.), large strongyles (*Strongylus* spp.), small strongyles (genera *Cyathostomum, Cylicobrachytus, Craterostomum, Oesophagodontus, Poteriostomum*), pinworms (*Oxyuris* spp., *Strongyloides* spp.), and ascarids (*Parascaris* spp.).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 23071, May 28, 1975, as amended at 48 FR 48229, Oct. 18, 1983; 79 FR 28832, May 20, 2014]

§ 520.2380f Thiabendazole and piperazine phosphate.

(a) *Specifications.* Each ounce of water dispersible powder contains 6.67 grams of thiabendazole and 8.33 grams of piperazine (as piperazine phosphate).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight. Use a single oral dose. Administer as a drench or by stomach tube suspended in 1 pint of warm water; by dose syringe suspended in ½ ounce of water for each 100 pounds of body weight; or sprinkled over a small amount of daily feed.

(2) *Indications for use.* Treatment of infections of large strongyles (genus *Strongylus*), small strongyles (genera *Cyathostomum, Cylicobrachytus*, and related genera *Craterostomum, Oesophagodontus, Poteriostomum*), pinworms (*Oxyuris*), threadworms (*Strongyloides*), and ascarids (*Parascaris*) in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. If the label bears directions for administration by stomach tube or drench, it shall also bear the statement ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''; if not labeled for use by stomach tube or drench, the label shall bear the statement, ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.''

[46 FR 18963, Mar. 27, 1981, as amended at 46 FR 52330, Oct. 27, 1981; 62 FR 63271, Nov. 28, 1997; 79 FR 28832, May 20, 2014]

§ 520.2455 Tiamulin.

(a) *Specifications.* (1) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(2) Each milliliter (mL) of solution contains 125 mg (12.5 percent) tiamulin hydrogen fumarate.

(3) Each mL of solution contains 123 mg (12.3 percent) tiamulin hydrogen fumarate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 058198 for products described in paragraphs (a)(1) and (a)(2) of this section.

(2) No. 066104 for the product described in paragraph (a)(1) of this section.

(3) No. 054771 for the product described in paragraph (a)(3) of this section.

(c) *Related tolerances.* See § 556.732 of this chapter.

(d) *Conditions of use in swine*—(1) *Amounts and indications for use.* Administer in drinking water for 5 consecutive days:

(i) 3.5 mg per (/) lb of body weight daily for treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin.

(ii) 10.5 mg/lb of body weight daily for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(2) *Limitations.* Use as only source of drinking water. Prepare fresh medicated water daily. Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

[70 FR 75017, Dec. 19, 2005, as amended at 74 FR 7180, Feb. 13, 2009; 75 FR 54492, Sept. 8, 2010; 77 FR 56770, Sept. 14, 2012; 78 FR 17596, Mar. 22, 2013; 80 FR 13229, Mar. 13, 2015]

§ 520.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of concentrate solution contains 250 milligrams (mg) tilmicosin as tilmicosin phosphate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water at a concentration of 200 mg per liter for 5 consecutive days.

(2) *Indications for use*—(i) For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(ii) For the control of swine respiratory disease associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(3) *Limitations.* Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 18158, Apr. 1, 2014, as amended at 81 FR 17608, Mar. 30, 2016; 81 FR 48702, July 26, 2016]

§ 520.2473 Tioxidazole oral dosage forms.

§ 520.2473a Tioxidazole granules.

(a) *Specifications.* Each gram of granules contains 200 milligrams of tioxidazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 milligrams per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* For administration with feed: Sprinkle required amount of granules on a small amount of the usual grain ration and mix. Prepare for each horse individually. Withholding of feed or water not necessary. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment,

and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[50 FR 52772, Dec. 26, 1985; 51 FR 2693, Jan. 21, 1986, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.2473b Tioxidazole paste.

(a) *Specifications*. Each plastic syringe contains 6.25 grams of tioxidazole.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams of tioxidazole per pound of body weight as a single dose.

(ii) *Indications for use*. Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations*. Administer orally by inserting the nozzle of the syringe through the space between front and back teeth and deposit the required dose on the base of the tongue. Before dosing, make sure the horse's mouth contains no feed. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[52 FR 43059, Nov. 9, 1987]

§ 520.2475 Toceranib.

(a) *Specifications*. Each tablet contains 10, 15, or 50 milligrams (mg) toceranib as toceranib phosphate.

(b) *Sponsor*. See No. 054771 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer an initial dose of 3.25 mg per kilogram (1.48 mg per pound) body weight, orally every other day.

(ii) *Indications for use*. For the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[74 FR 28875, June 18, 2009, as amended at 79 FR 28832, May 20, 2014]

§ 520.2483 Triamcinolone.

(a) *Specifications*. (1) Each tablet contains 0.5 milligram (mg) or 1.5 mg triamcinolone acetonide.

(2) Each 15 grams of powder contains 10 mg triamcinolone acetonide.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Special considerations*. See § 510.410 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*. Use tablets described in paragraph (a)(1) of this section as follows:

(i) *Amount*. Administer 0.05 mg per pound (/lb) of body weight daily by mouth; up to 0.1 mg per pound (/lb) of body weight daily, if response to the smaller dose is inadequate. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide tablets should be administered beginning 5 to 7 days after the injection.

(ii) *Indications for use*. As an anti-inflammatory agent.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*. Use oral powder described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Administer 0.005 to 0.01 mg/lb of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide oral powder should be administered beginning 3 or 4 days after the injection.

(ii) *Indications for use*. As an anti-inflammatory agent.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[75 FR 10166, Mar. 5, 2010]

§ 520.2520 Trichlorfon oral dosage forms.

§ 520.2520a Trichlorfon and atropine.

(a) *Specifications.* (1) For trichlorfon: O,O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in mice*—(1) *Amount.* Administer 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter continuously for 7 to 14 days as the sole source of drinking water.

(2) *Indications for use.* For the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28832, May 20, 2014]

§ 520.2520b Trichlorfon boluses.

(a) *Specifications.* Each bolus contains either 7.3, 10.9, 14.6, or 18.2 g of trichlorfon.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 18.2 milligrams per pound of body weight, except for strongyles use 36.4 milligrams per pound of body weight.

(2) *Indications for use.* For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48127, July 18, 1980. Redesignated and amended at 79 FR 28833, May 20, 2014]

§ 520.2520c Trichlorfon granules.

(a) *Specifications.* Each package contains either 18.2 or 36.4 g of trichlorfon.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 18.2 milligrams per pound of body weight.

(2) *Indications for use.* For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48128, July 18, 1980. Redesignated and amended at 79 FR 28833, May 20, 2014]

§ 520.2520d Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.

(a) *Specifications.* Each 54.10 grams (1.91 ounces) of water dispersible powder contains 9.10 grams of trichlorfon, 6.25 grams of phenothiazine, and the equivalent of 20.0 grams of piperazine base (as piperazine dihydrochloride).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

[48 FR 2757, Jan. 21, 1983. Redesignated and amended at 79 FR 28833, May 20, 2014]

EDITORIAL NOTE: At 79 FR 28833, May 20, 2014, § 520.2520d was amended in part by redesignating paragraph (e) as (c). This action could not be performed because paragraph (e) did not exist.

§ 520.2582 Trifluprom azine.

(a) *Specifications.* Each tablet contains 10 or 25 milligrams (mg) trifluprom azine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 1 to 2 mg per pound of body weight daily, followed by 1 mg daily.

(2) *Indications for use.* For relief of anxiety, to help control psychomotor over-activity, and to increase the tolerance of animals to pain and pruritus. For use in various clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28833, May 20, 2014]

§ 520.2598 Trilostane.

(a) *Specifications.* Each capsule contains 5, 10, 30, 60, or 120 milligrams (mg) trilostane.

(b) *Sponsor*. See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. The starting dose is 1.0 to 3.0 milligrams per pound (2.2 to 6.7 milligrams per kilogram) once a day.

(2) *Indications for use*. For treatment of pituitary-dependent hyperadrenocorticism. For treatment of hyperadrenocorticism due to adrenocortical tumor.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 21767, May 11, 2009, as amended at 74 FR 30464, June 26, 2009; 80 FR 53460, Sept. 4, 2015]

§ 520.2604 Trimeprazine and prednisolone tablets.

(a) *Specifications*. Each tablet contains 5 milligrams (mg) trimeprazine tartrate and 2 mg prednisolone.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally an initial dosage: for dogs weighing up to 10 pounds, ½ tablet twice daily; for dogs weighing 11 to 20 pounds, 1 tablet twice daily; for dogs weighing 21 to 40 pounds, 2 tablets twice daily; and for dogs weighing over 40 pounds, 3 tablets twice daily. After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms.

(2) *Indications for use*. For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28833, May 20, 2014]

§ 520.2605 Trimeprazine and prednisolone capsules.

(a) *Specifications*. Each capsule contains:

(1) 3.75 milligrams (mg) trimeprazine in sustained released form (as trimeprazine tartrate) and 1 mg prednisolone (Capsule No. 1); or

(2) 7.5 mg trimeprazine in sustained release form (as trimeprazine tartrate) and 2 mg prednisolone (Capsule No. 2).

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally once daily an initial dosage:

(i) For dogs weighing up to 10 pounds: one Capsule No. 1;

(ii) For dogs weighing 11 to 20 pounds, one Capsule No. 2 or two Capsule No. 1;

(iii) For dogs weighing 21 to 40 pounds, two Capsule No. 2 or four Capsule No. 1; and

(iv) For dogs weighing over 40 pounds, three Capsule No. 2 or six Capsule No. 1. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms.

(2) *Indications for use*. For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28833, May 20, 2014]

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications*. Each tablet contains 30 milligrams (mg) (5 mg trimethoprim and 25 mg sulfadiazine), 120 mg (20 mg trimethoprim and 100 mg sulfadiazine), 480 mg (80 mg trimethoprim and 400 mg sulfadiazine) or 960 mg (160 mg trimethoprim and 800 mg sulfadiazine).

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at 30 mg per kilogram of body weight (14 milligrams per pound) once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(2) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28833, May 20, 2014]

§ 520.2611 Trimethoprim and sulfadiazine paste.

(a) *Specifications.* Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 30802, May 31, 2006, as amended at 79 FR 28834, May 20, 2014]

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

(b) *Sponsors.* See sponsor numbers in § 510.600 of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) for use as in paragraph (c)(1) of this section.

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* Administer 24 mg combined active ingredients per kilogram of body weight (2.7 mL/100 lb) twice daily for 10 days.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus.*

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 63872, Oct. 25, 2013]

§ 520.2613 Trimethoprim and sulfadiazine powder.

(a) *Specifications.* Each gram of powder contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors.* See Nos. 054771 and 059051 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 3.75 grams of powder per 110 pounds (50 kilograms) of body weight in a small amount of feed, as a single daily dose, for 5 to 7 days.

(2) *Indications for use.* For control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 36135, July 6, 1993, as amended at 64 FR 68289, Dec. 7, 1999; 79 FR 28834, May 20, 2014; 79 FR 64116, Oct. 28, 2014]

§ 520.2640 Tylosin.

(a) *Specifications.* Each container of soluble powder contains tylosin tartrate equivalent to either 100 or 256 grams tylosin base.

(b) *Sponsors*—(1) No. 058198 for use as in paragraph (e) of this section.

(2) Nos. 016592 and 061623 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

(c) *Related tolerances.* See § 556.740 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Chickens*—(i) *Amounts and indications for use.* (A) Administer 2 grams per gallon (528 parts per million (ppm)) for 1 to 5 days as an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *M. gallisepticum* at time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(B) Administer 851 to 1,419 mg/gallon (225 to 375 ppm) for 5 days for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.

(ii) *Limitations.* Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

(ii) *Indications for use.* For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum.*

(iii) *Limitations.* Do not use in layers producing eggs for human consumption. Do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

(ii) *Indications for use.* (A) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* when followed immediately by tylosin phosphate medicated feed; and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* when followed immediately by tylosin phosphate medicated feed.

(B) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae.*

(iii) *Limitations.* Do not administer within 48 hours of slaughter. As indicated in paragraph (d)(3)(ii)(A) of this section, follow with tylosin phosphate medicated feed as in § 558.625(f)(1)(vi)(*c*) of this chapter.

(4) *Honey bees*—(i) *Amount.* Mix 200 milligrams tylosin in 20 grams confectioners'/powdered sugar. Use immediately. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997; 68 FR 24879, May 9, 2003; 70 FR 69439, Nov. 16, 2005; 73 FR 76946, Dec. 18, 2008; 75 FR 76259, Dec. 8, 2010; 76 FR 59024, Sept. 23, 2011; 77 FR 29217, May 17, 2012; 79 FR 37620, July 2, 2014; 79 FR 53136, Sept. 8, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 34278, June 16, 2015; 81 FR 48702, July 26, 2016]

§ 520.2645 Tylvalosin.

(a) *Specifications.* Granules containing 62.5 percent tylvalosin (w/w) as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 50 parts per million (ppm) tylvalosin continuously in drinking water for 5 consecutive days.

(2) *Indications for use.* For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*, *Haemophilus parasuis*, *Pasteurella multocida*, and *Streptococcus suis* in groups of swine in buildings experiencing an outbreak of SRD.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 55415, Sept. 10, 2012, as amended at 83 FR 13635, Mar. 30, 2018]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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522.863 Ethylisobutrazine.
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522.900 Euthanasia solution.
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522.955 Florfenicol.
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522.960 Flumethasone injectable dosage forms.
522.960a Flumethasone suspension.
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522.970 Flunixin.
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522.1010 Furosemide.
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522.1020 Gelatin.
522.1044 Gentamicin.
522.1055 Gleptoferron.
522.1066 Glycopyrrolate.
522.1077 Gonadorelin.
522.1079 Serum gonadotropin and chorionic gonadotropin.
522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.
522.1085 Guaifenesin powder for injection.
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522.1125 Hemoglobin glutamer-200 (bovine).
522.1145 Hyaluronate.
522.1150 Hydrochlorothiazide.
522.1155 Imidocarb powder for injection.
522.1156 Imidocarb solution.
522.1160 Insulin.
522.1182 Iron injection.
522.1185 Isoflupredone.
522.1192 Ivermectin.
522.1193 Ivermectin and clorsulon.
522.1204 Kanamycin.
522.1222 Ketamine.
522.1223 Ketamine, promazine, and aminopentamide.
522.1225 Ketoprofen.
522.1242 Levamisole.
522.1260 Lincomycin.
522.1289 Lufenuron.
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522.1315 Maropitant.
522.1335 Medetomidine.
522.1350 Melatonin implant.
522.1362 Melarsomine powder for injection.
522.1367 Meloxicam.
522.1372 Mepivacaine.
522.1380 Methocarbamol.
522.1410 Methylprednisolone.
522.1450 Moxidectin solution.
522.1451 Moxidectin microspheres for injection.
522.1452 Nalorphine.
522.1465 Naltrexone.
522.1468 Naproxen for injection.
522.1484 Neomycin.
522.1503 Neostigmine.
522.1610 Oleate sodium.
522.1620 Orgotein for injection.
522.1660 Oxytetracycline injectable dosage forms.
522.1660a Oxytetracycline solution, 200 milligrams/milliliter.
522.1660b Oxytetracycline solution, 300 milligrams/milliliter.
522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
522.1662a Oxytetracycline hydrochloride injection.
522.1662b Oxytetracycline hydrochloride with lidocaine injection.
522.1662 Oxytetracycline and flunixin.
522.1680 Oxytocin.
522.1684 Pegbovigrastim.
522.1696 Penicillin G procaine injectable dosage forms.
522.1696a Penicillin G benzathine and penicillin G procaine suspension.
522.1696b Penicillin G procaine aqueous suspension.
522.1696c Penicillin G procaine in oil.
522.1698 Pentazocine.
522.1704 Pentobarbital.
522.1720 Phenylbutazone.
522.1820 Pituitary luteinizing hormone powder for injection.
522.1850 Polysulfated glycosaminoglycan.
522.1862 Pralidoxime powder for injection.
522.1870 Praziquantel.
522.1881 Prednisolone acetate.
522.1883 Prednisolone sodium phosphate.
522.1884 Prednisolone sodium succinate.
522.1885 Prednisolone tertiary butylacetate.
522.1890 Sterile prednisone suspension.
522.1920 Prochlorperazine and isopropamide.
522.1940 Progesterone and estradiol benzoate.
522.1962 Promazine.
522.2002 Propiopromazine.
522.2005 Propofol.
522.2012 Prostalene.
522.2063 Pyrilamine.
522.2075 Robenacoxib.
522.2076 Romifidine.
522.2100 Selenium and vitamin E.
522.2112 Sometribove zinc suspension.
522.2120 Spectinomycin dihydrochloride injection.
522.2121 Spectinomycin sulfate.
522.2150 Stanozolol.
522.2200 Sulfachlorpyridazine.
522.2220 Sulfadimethoxine.
522.2240 Sulfaethoxypyridazine.
522.2260 Sulfamethazine.
522.2340 Sulfomyxin.
522.2404 Thialbarbitone sodium for injection.
522.2424 Thiamylal.
522.2444 Thiopental injectable dosage forms.
522.2444a Thiopental powder for injection.
522.2444b Thiopental and pentobarbital powder for injection.
522.2460 Tildipirosin.
522.2470 Tiletamine and zolazepam for injection.
522.2471 Tilmicosin.

522.2473 Tiludronate.
522.2474 Tolazoline.
522.2476 Trenbolone acetate.
522.2477 Trenbolone acetate and estradiol.
522.2478 Trenbolone acetate and estradiol benzoate.
522.2483 Triamcinolone.
522.2582 Triflupromazine.
522.2610 Trimethoprim and sulfadiazine.
522.2615 Tripelennamine.
522.2630 Tulathromycin.
522.2640 Tylosin.
522.2662 Xylazine.
522.2670 Yohimbine.
522.2680 Zeranol.
522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See Nos. 000010 and 000859 in § 510.600(c) of this chapter:

(c) *Conditions of use in dogs, cats, and horses*—(1) *Amount.* Dogs: 0.25 to 0.5 mg per pound (/lb) of body weight; Cats: 0.5 to 1.0 mg/lb of body weight; Horses: 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* For use as a tranquilizer and as a preanesthetic agent.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10167, Mar. 5, 2010; 78 FR 17597, Mar. 22, 2013; 79 FR 16182, Mar. 25, 2014]

§ 522.52 Alfaxalone.

(a) *Specifications.* Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) *Sponsor.* See No. 049480 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats and dogs*—(1) *Amount*—(i) *Cats*—(A) *Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kilogram (kg) for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) *Dogs*—(A) *Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or 0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) *Indications for use.* For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Alfaxalone is a Class IV controlled substance.

[77 FR 64717, Oct. 23, 2012, as amended at 79 FR 64116, Oct. 28, 2014]

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17338, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16183, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.62 Aminopentamide.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligram (mg) aminopentamide hydrogen sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by subcutaneous or intramuscular injection every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg; For animals weighing 11 to 20 lbs: 0.2 mg; For animals weighing 21 to 50 lbs: 0.3 mg; For animals weighing 51 to 100 lbs: 0.4 mg; For animals weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use, dosage may be continued by oral administration of tablets.

(2) *Indications for use.* For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.82 Aminopropazine.

(a) *Specifications.* Each milliliter of solution contains aminopropazine fumarate equivalent to 25 milligrams (mg) aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

(ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* Administer 0.25 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

(ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in colic spasms.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.84 Beta-aminopropionitrile.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains 0.7 milligrams (mg) beta-aminopropionitrile fumarate.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 7 mg by intralesional injection every other day for five treatments beginning about 30 days after initial injury.

(2) *Indications for use in horses.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in horses where there is sonographic evidence of fiber tearing.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.88 Amoxicillin.

(a) *Specifications*—(1) Each vial contains 3 grams (g) of amoxicillin trihydrate. Each milliliter of constituted suspension contains 100 or 250 milligrams (mg) amoxicillin trihydrate for use as in paragraph (d)(1) of this section.

(2) Each vial contains 25 g of amoxicillin trihydrate. Each milliliter of constituted suspension contains 250 mg amoxicillin trihydrate for use as in paragraph (d)(2) of this section.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.38 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Administer 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use*—(A) *Dogs.* For treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis;* genitourinary infections (cystitis) due to *S. aureus, Streptococcus* spp., *E. coli,* and *P.*

mirabilis; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., and *P. mirabilis;* soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(B) *Cats*. For treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis;* genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount*. Administer 3 to 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use*. For treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida*, *P. hemolytica*, *Haemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum*.

(iii) *Limitations*. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.90 Ampicillin injectable dosage forms.

[79 FR 16183, Mar. 25, 2014]

§ 522.90a Ampicillin trihydrate suspension.

(a) *Specifications*. (1) Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams (mg) of ampicillin.

(2) Each milliliter contains ampicillin trihydrate equivalent to 150 mg of ampicillin.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraphs (d)(1), (d)(2), (d)(3)(i)(A), (d)(3)(ii)(A), (d)(3)(iii), and (d)(4) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraphs (d)(3)(i)(B), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. For enteritis: 3 mg per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 mg per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(ii) *Indications for use*. For treatment of bacterial enteritis in calves caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(iii) *Limitations*. Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. 3 mg per pound of body weight by intramuscular injection, once or twice daily, for up to 3 days.

(ii) *Indications for use*. Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(iii) *Limitations*. Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs*—(i) *Amount*—(A) 3 to 6 mg per pound of body weight by intramuscular injection, once or twice daily. Usual treatment is 3 to 5 days.

(B) 3 to 5 mg of ampicillin per pound of body weight, once a day for up to 4 days.

(ii) *Indications for use*—(A) Treatment of respiratory tract infections due to *E. coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli*, *Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(B) Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*, when caused by susceptible organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Cats*—(i) *Amount.* 5 to 10 mg per pound of body weight by intramuscular or subcutaneous injection, once or twice daily. Usual treatment is 3 to 5 days.

(ii) *Indications for use.* Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.90b Ampicillin trihydrate powder for injection.

(a) *Specifications.* Each milliliter of aqueous suspension constituted from ampicillin trihydrate powder contains 200, 250, or 400 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 000010 and 010515 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 3 mg/pound (lb) of body weight twice daily by subcutaneous or intramuscular injection.

(ii) *Indications for use.* For treatment of strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 2 to 5 mg/lb of body weight once daily by intramuscular injection.

(ii) *Indications for use.* For treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, and *Escherichia coli*.

(iii) *Limitations.* Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and for 144 hours (6 days) after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993; 63 FR 41420, Aug. 4, 1998; 75 FR 10167, Mar. 5, 2010; 76 FR 17338, Mar. 29, 2011; 76 FR 53051, Aug. 25, 2011; 82 FR 21690, May 10, 2017]

§ 522.90c Ampicillin sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 010515 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*: 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) *Indications for use.* For the treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Streptococcus* spp. (including *S. equi*), *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 45158, Aug. 13, 2007, as amended at 79 FR 16184, Mar. 25, 2014]

§ 522.144 Arsenamide.

(a) *Specifications.* Each milliliter of solution contains 10.0 milligrams arsenamide sodium.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 milliliter (mL) per pound of body weight (1.0 mL for every 10 pounds) by intravenous injection twice a day for 2 days.

(2) *Indications for use.* For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16184, Mar. 25, 2014]

§ 522.147 Atipamezole.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams atipamezole hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Inject intramuscularly the same volume as that of dexmedetomidine or medetomidine used.

(2) *Indications for use.* For reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride or medetomidine hydrochloride.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 48830, Sept. 17, 1996, as amended at 64 FR 71640, Dec. 22, 1999; 72 FR 264, Jan. 4, 2007]

§ 522.150 Azaperone.

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) azaperone.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 mg per kilogram (1 mg per pound) by deep intramuscular injection.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 65689, Dec. 11, 2009, as amended at 77 FR 46613, Aug. 6, 2012; 81 FR 48702, July 26, 2016]

§ 522.161 Betamethasone.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Betamethasone acetate equivalent to 10.8 milligrams (mg) betamethasone and betamethasone disodium phosphate equivalent to 3 mg of betamethasone.

(2) Betamethasone dipropionate equivalent to 5 mg betamethasone and betamethasone sodium phosphate equivalent to 2 mg of betamethasone.

(b) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000061 for product described in paragraph (a)(1) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) No. 000061 for product described in paragraph (a)(2) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by intramuscular injection 0.25 to 0.5 milliliter (mL) per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of four injections.

(ii) *Indications for use.* As an aid in the control of pruritus associated with dermatoses.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* Administer 2.5 to 5 mL by intra-articular injection.

(ii) *Indications for use*—(A) For the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpel and fetlock joints.

(B) As an aid in the control of inflammation associated with various arthropathies.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16184, Mar. 25, 2014]

§ 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.

(a) *Specifications.* Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs.* (i) It is used as an aid in the control of pruritus associated with dermatoses.

(ii) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of 4 injections.

(2) *Horses.* (i) It is used as an aid in the control of inflammation associated with various arthropathies.

(ii) It is administered aseptically by intraarticular injection at a dosage of 2.5 to 5 milliliters per joint, depending on the severity of the condition and the joint size. Dosage may be repeated upon recurrence of clinical signs. Injection into the joint cavity should be preceded by withdrawal of synovial fluid.

(iii) Not for use in horses intended for food.

(3) *Clinical and experimental data.* It has been demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) *Restrictions.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

§ 522.167 Betamethasone sodium phosphate and betamethasone acetate.

(a) *Specifications.* Each milliliter (mL) of suspension contains 6 milligrams (mg) betamethasone (3.15 mg betamethasone sodium phosphate and 2.85 mg betamethasone acetate).

(b) *Sponsor.* See No. 010797 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1.5 mL (9 mg total betamethasone) per joint by intra-articular injection. May be administered concurrently in up to two joints per horse.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 18776, Apr. 8, 2015]

§ 522.204 Boldenone.

(a) *Specifications.* Each milliliter of solution contains 25 or 50 milligrams (mg) boldenone undecylenate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 0.5 mg per pound body weight by intramuscular injection. Treatment may be repeated at 3-week intervals.

(2) *Indications for use.* As an aid for treating debilitated horses when an improvement in weight, hair coat, or general physical condition is desired.

(3) *Limitations.* Do not administer to horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 70998, Nov. 25, 2005, as amended at 79 FR 16184, Mar. 25, 2014]

§ 522.224 Bupivacaine.

(a) *Specifications.* Each milliliter (mL) of liposomal suspension contains 13.3 milligrams (mg) bupivacaine.

(b) *Sponsor.* See No. 086026 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 5.3 mg/kg (0.4 mL/kg) by infiltration injection into the tissue layers at the time of incisional closure.

(2) *Indications for use.* For single-dose infiltration into the surgical site to provide local postoperative analgesia for cranial cruciate ligament surgery in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 67151, Sept. 30, 2016]

§ 522.230 Buprenorphine.

(a) *Specifications.* Each milliliter of solution contains 1.8 milligrams (mg) buprenorphine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 0.24 mg per kilogram (0.11 mg per pound) by subcutaneous injection once daily, for up to 3 days. Administer the first dose approximately 1 hour prior to surgery.

(2) *Indications for use.* For the control of postoperative pain associated with surgical procedures in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 53136, Sept. 8, 2014, as amended at 80 FR 18776, Apr. 8, 2015]

§ 522.234 Butamisole.

(a) *Specifications.* Each milliliter of solution contains 11 milligrams (mg) butamisole hydrochloride.

(b) *Sponsors.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 mg per pound of body weight by subcutaneous injection. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

(2) *Indications for use.* For the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16184, Mar. 25, 2014]

§ 522.246 Butorphanol.

(a) *Specifications.* Each milliliter of solution contains butorphanol (as butorphanol tartrate) in the following amounts:

(1) 0.5 milligrams (mg);

(2) 2 mg; or

(3) 10 mg

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section; for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section; and for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(2) No. 000859 for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) Nos. 000061, 000859, and 059399 for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.025 mg per pound of body weight by subcutaneous injection at intervals of 6 to 12 hours, as required. If necessary, increase dose to a maximum of 0.05 mg per pound of body weight. Treatment should not normally be required for longer than 7 days.

(ii) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(2) *Cats*—(i) *Amount.* Administer 0.2 mg per pound of body weight by subcutaneous injection. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days.

(ii) *Indications for use.* For the relief of pain in cats caused by major or

minor trauma, or pain associated with surgical procedures.

(3) *Horses*—(i) *Amount.* Administer 0.05 mg per pound of body weight by intravenous injection. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.

(ii) *Indications for use.* For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations.* Do not use in horses intended for human consumption.

[72 FR 27957, May 18, 2007, as amended at 73 FR 31358, June 2, 2008; 74 FR 61516, Nov. 25, 2009; 75 FR 22524, Apr. 29, 2010; 77 FR 60302, Oct. 3, 2012; 78 FR 17597, Mar. 22, 2013; 79 FR 16184, Mar. 25, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 13229, Mar. 13, 2015]

§ 522.275 N-Butylscopolammonium.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) N-butylscopolammonium bromide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 0.3 mg per kilogram of body weight (0.14 mg per pound) slowly intravenously.

(2) *Indications for use.* For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 35512, June 25, 2004]

§ 522.300 Carfentanil.

(a) *Specifications.* Each milliliter of solution contains 3 milligrams (mg) carfentanil citrate.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 5 to 20 micrograms per kilogram (0.005 to 0.020 mg per kilogram) of body weight into large muscle of the neck, shoulder, back, or hindquarter.

(2) *Indications for use.* For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations.* Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[79 FR 16185, Mar. 25, 2014]

EFFECTIVE DATE NOTE: At 83 FR 13635, Mar. 30, 2018, § 522.300 was removed, effective Apr. 9, 2018.

§ 522.304 Carprofen.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) carprofen.

(b) *Sponsors.* See Nos. 016729, 026637, 054771, and 055529 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003. Redesignated at 73 FR 29685, May 22, 2008, as amended at 79 FR 74020, Dec. 15, 2014; 82 FR 43484, Sept. 18, 2017]

§ 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible

strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount.* Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida.*

[73 FR 29685, May 22, 2008, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.313 Ceftiofur injectable dosage forms.

§ 522.313a Ceftiofur crystalline free acid.

(a) *Specifications.* The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 mg ceftiofur equivalents.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use*—(1) *Swine.* The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount.* 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis.* For the control of SRD associated with *A. pleuropneumoniae, P. multocida, H. parasuis,* and *S. suis* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(2) *Cattle.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) *Indications for use*—(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni.* For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) *Limitations.* Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(3) *Horses.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004. Redesignated and amended at 71 FR 39546, July 13, 2006; 73 FR 58872, Oct. 8, 2008; 75 FR 4692, Jan. 29, 2010; 75 FR 62468, Oct. 12, 2010; 77 FR 26162, May 3, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 37620, July 2, 2014]

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella* Choleraesuis, and *Streptococcus suis*.

(iii) *Limitations.* Treated swine must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* Administer by subcutaneous or intramuscular injection as follows:

(A) For bovine respiratory disease and acute bovine interdigital necrobacillosis: 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days.

(B) For bovine respiratory disease: 2.2 mg/kg of body weight administered twice at a 48 hour interval.

(C) For acute metritis: 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

[61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998; 67 FR 45901, July 11, 2002; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 73 FR 45612, Aug. 6, 2008; 76 FR 17338, Mar. 29, 2011; 78 FR 66264, Nov. 5, 2013]

§ 522.313c Ceftiofur sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsors.* See Nos. 054771 and 068330 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle, swine, chickens, and turkeys for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (/kg)

body weight by intramuscular injection for 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis.*

(iii) *Limitations.* Treated pigs must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni.* Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment.

(3) *Sheep*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of sheep respiratory disease (sheep pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida.*

(4) *Goats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida.*

(5) *Chickens*—(i) *Amount.* 0.08 to 0.20 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *Escherichia coli* organisms susceptible to ceftiofur in day-old chicks.

(6) *Turkeys*—(i) *Amount.* 0.17 to 0.5 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur in day-old poults.

(7) *Horses*—(i) *Amount.* 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site.

(ii) *Indications for use.* For treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus.*

(iii) *Limitations.* Do not use in horses intended for human consumption.

(8) *Dogs*—(i) *Amount.* 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

(ii) *Indications for use.* For treatment of canine urinary tract infections associated with *E. coli* and *Proteus mirabilis.*

[53 FR 5369, Feb. 24, 1988, as amended at 55 FR 13768, Apr. 12, 1990; 56 FR 12119, Mar. 22, 1991; 57 FR 41862, Sept. 14, 1992; 59 FR 41666, Aug. 15, 1994; 59 FR 54518, Nov. 1, 1994; 60 FR 51719, Oct. 3, 1995; 61 FR 35130, July 5, 1996; 61 FR 66583, Dec. 18, 1996; 66 FR 21283, Apr. 30, 2001; 66 FR 32540, June 15, 2001; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 74 FR 34236, July 15, 2009; 77 FR 29218, May 17, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 21127, Apr. 15, 2014; 82 FR 12169, Mar. 1, 2017]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate.

(a) *Specifications.* Each milliliter of solution contains 42.5 milligrams (mg) of chloral hydrate, 8.86 mg of pentobarbital, and 21.2 mg of magnesium sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For general anesthesia: Administer 20 to 50 milliliters per 100 pounds of body weight by intravenous injection until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. As a sedative-relaxant: Administer at a level of one-

fourth to one-half of the anesthetic dosage level.

(2) *Indications for use.* For general anesthesia and as a sedative-relaxant in cattle and horses.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.390 Chloramphenicol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams of chloramphenicol.

(b) *Sponsor.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000; 78 FR 17597, Mar. 22, 2013; 79 FR 16185, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.454 Clodronate.

(a) *Specifications.* Each milliliter of solution contains 60 milligrams (mg) clodronate disodium.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1.8 mg per kilogram of body weight by intramuscular injection up to a maximum dose of 900 mg per horse.

(2) *Indications for use.* For the control of clinical signs associated with navicular syndrome.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 37620, July 2, 2014]

§ 522.460 Cloprostenol.

(a) *Specifications.* Each milliliter of solution contains cloprostenol sodium equivalent to:

(1) 125 micrograms (μg) of cloprostenol; or

(2) 250 μg of cloprostenol.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) of this section.

(2) Nos. 000061 and 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii), (c)(1)(iii), and (c)(2) of this section.

(c) *Conditions of use in cattle*—(1) *Amount and indications for use*—(i) Administer 375 μg by intramuscular injection to induce abortion in pregnant feedlot heifers from 1 week after mating until 4½ months of gestation.

(ii) Administer 500 μg by intramuscular injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception; for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts; and for the treatment of pyometra.

(iii) Administer 500 μg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first, for scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications.* Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) 1- to 3-day-old chickens.

(i) *Dosage.* 0.2 milligram colistin activity per chicken.

(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.480 Corticotropin.

(a) *Specifications.* Each milliliter of aqueous solution contains 40 or 80 U.S.P. (I.U.) units of repository corticotropin.

(b) *Sponsor.* See sponsors in § 510.600(c) of this chapter.

(1) No. 061623 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 026637 for use as in paragraph (c)(2) and (3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular injection.

(ii) *Indications for use.* As a diagnostic aid to test for adrenal dysfunction.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular or subcutaneous injection, to be repeated as indicated.

(ii) *Indications for use.* For stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH).

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* Administer 200 to 600 units by intramuscular or subcutaneous injection as an initial dose, followed by a dose daily or every other day of 200 to 300 units.

(ii) *Indications for use.* As a therapeutic agent for primary bovine ketosis; and for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.518 Cupric glycinate injection.

(a) *Specifications.* Each milliliter (mL) of sterile aqueous suspension contains 200 milligrams of cupric glycinate (equivalent to 60 milligrams of copper).

(b) *Sponsor.* See No. 049185 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 200 milligrams (1 mL) for calves 300 pounds and under; 400 milligrams (2 mL) for calves over 300 pounds and adult cattle.

(2) *Indications for use.* For beef calves and beef cattle for the prevention of copper deficiency, or when labeled for veterinary prescription use, for the prevention and/or treatment of copper deficiency alone or in association with molybdenum toxicity.

(3) *Limitations.* For subcutaneous use only; repeat dose in 3 months in young calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 20159, Apr. 3, 1981, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 28630, May 27, 1997]

§ 522.522 Danofloxacin.

(a) *Specifications.* Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount and indications for use.* Administer by subcutaneous injection either:

(i) 6 mg per kilogram (/kg) of body weight, repeated in 48 hours, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* and *Pasteurella multocida;* or

(ii) 8 mg/kg of body weight as a single dose for the treatment of BRD associated with *M. haemolytica* and *P. multocida* and for the control of BRD in beef cattle at high risk of developing

BRD associated with *M. haemolytica* and *P. multocida*.

(2) *Limitations*. Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 53136, Sept. 8, 2014]

§ 522.533 Deslorelin.

(a) *Specifications*—(1) Each implant contains 2.1 milligrams (mg) deslorelin acetate.

(2) Each milliliter (mL) of suspension contains 1.8 mg deslorelin acetate.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 051311 for use of product described in paragraph (a)(1) as in paragraph (c)(1) of this section.

(2) No. 051330 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount*. One implant per mare subcutaneously in the neck.

(ii) *Indications for use*. For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 mL in diameter.

(iii) *Limitations*. Do not use in horses or ponies intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer 1.8 mg (1 mL) by intramuscular injection in the neck.

(ii) *Indications for use*. For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mL in diameter.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 81456, Dec. 28, 2010, as amended at 79 FR 18158, Apr. 1, 2014]

§ 522.535 Desoxycorticosterone.

(a) *Specifications*. Each milliliter of suspension contains 25 milligrams (mg) of desoxycorticosterone pivalate.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(ii), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use*—(1) *Amount*. (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) *Indications for use*—(i) For use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's Disease).

(ii) For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 22524, Apr. 18, 2016]

§ 522.536 Detomidine.

(a) *Specification*. Each milliliter of solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required. For sedation, administer by intraveneous (IV) or intramuscular (IM) injection; for analgesia, administer by IV injection; for

both sedation and analgesia, administer by IV injection.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.540 Dexamethasone solution.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 016592, and 061623 for use as in paragraph (a)(3) of this section.

(ii) *Sponsors.* See Nos. 054925 and 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use*—(i) *Amount.* Administer 0.25 to 1 mg by intravenous injection, repeated for 3 to 5 days or until a response is noted.

(ii) *Indications for use.* For use in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 2.5 to 5.0 mg by intravenous injection.

(ii) *Indications for use.* For use in horses as a rapid adrenal glucocorticoid and/or anti-inflammatory agent.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsors.* See the following numbers in § 510.600(c) of this chapter:

(i) Nos. 016592 and 051031 for intravenous or intramuscular use of 2.0 milligrams dexamethasone injection.

(ii) No. 054771 for intravenous use of 2.0 milligrams dexamethasone injection.

(3) *Conditions of use*—(i) *Amount.* Administer by intravenous or intramuscular injection as follows:

(A) *Dogs:* 0.25 to 1 mg.

(B) *Cats:* 0.125 to 0.5 mg.

(C) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use.* For use in dogs, cats, and horses as an anti-inflammatory agent.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer by intravenous injection as follows:

(A) *Dogs:* 0.25 to 1 mg; may be repeated for 3 to 5 days.

(B) *Horses:* 2.5 to 5 mg.

(ii) *Indications for use.* For use in dogs and horses for glucocorticoid and anti-inflammatory effect.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

EFFECTIVE DATE NOTE: At 83 FR 13635, Mar. 30, 2018, § 522.540 was amended by revising paragraphs (b)(2) and (c)(2), effective Apr. 9, 2018. For the convenience of the user, the revised text is set forth as follows:

§ 522.540 Dexamethasone solution.

* * * * *

(b) * * *

(2) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

* * * * *

(c) * * *

(2) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

* * * * *

§ 522.542 Dexamethasone suspension.

(a) *Specifications.* Each milliliter of suspension contains 1 milligram (mg) of dexamethasone-21-isonicotinate.

(b) *Sponsor.* No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs: 0.25 to 1 mg; cats: 0.125 to 0.5 mg; horses: 5 to 20 mg. Dosage may be repeated.

(2) *Indications for use.* For the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains:

(1) 0.1 milligrams (mg) dexmedetomidine hydrochloride; or

(2) 0.5 mg dexmedetomidine hydrochloride.

(b) *Sponsors.* See sponsors in in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 026637 for use of product described in paragraph (a)(2) of this section;

(2) No. 052483 for use of products described in paragraph (a) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount.* (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (μg) per square meter (/m^2) of body surface area by intravenous injection or 500 μg/m^2 of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 μg/m^2 of body surface area or 375 μg/m^2 of body surface area by intramuscular injection.

(ii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 40 μg/killogram by intramuscular injection.

(ii) *Indications for use.* For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007, as amended at 72 FR 19797, Apr. 20, 2007; 72 FR 51365, Sept. 7, 2007; 75 FR 60308, Sept. 30, 2010; 78 FR 25183, Apr. 30, 2013; 78 FR 33699, June 5, 2013; 80 FR 13229, Mar. 13, 2015]

§ 522.563 Diatrizoate.

(a) *Specifications.* Each milliliter of solution contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* For excretion urography, administer 0.5 to 1.0 milliliter (mL) per pound of body weight to a maximum of 30 mL intravenously. For cystography, remove urine, administer 5 to 25 mL directly into the bladder via catheter. For urethrography, administer 1.0 to 5 mL via catheter into the urethra to provide desired contrasts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 mL directly into the heart via catheter or intraventricular puncture. For cerebral angiography, rapid injection of 3 to 10 mL via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography, rapidly inject 3 to 10 mL intravascularly into the vascular bed to be delineated. For lymphography, slowly inject 1.0 to 10 mL directly into the lymph vessel to be delineated. For arthrography, slowly inject 1.0 to 5 mL directly into the joint to be delineated. For discography, slowly inject 0.5 to 1.0 mL directly into the disc to be delineated. For sialography, slowly inject 0.5 to 1.0 mL into the duct to be delineated. For delineation of fistulous tracts, slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias, inject 0.5 to 1.0 mL per pound of body weight directly into the peritoneal cavity.

(2) *Indications for use.* For visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiography, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography; and as an aid in delineating peritoneal hernias and fistulous tracts.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsors.* See Nos. 054771 and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.200 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer 5 milligrams per pound of body weight by deep intramuscular injection every 12 hours, for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona;* in cattle due to *L. pomona;* and in swine due to *L. pomona;* and *L. grippotyphosa*.

(3) *Limitations.* Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 16187, Mar. 25, 2014]

§ 522.690 Dinoprost.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) or 12.5 mg dinoprost.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use of the 12.5 mg/mL product as in paragraph (d)(1) of this section.

(2) No. 054771 for use of the 5 mg/mL product as in paragraphs (d)(1), (2), and (3) of this section.

(3) No. 061623 for use of the 5 mg/mL product as in paragraphs (d)(2), (3), and (4) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cattle.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 25 mg as a single intramuscular or subcutaneous injection.

(ii) *Indications for use.* As a luteolytic agent; effective only in those cattle having a corpus luteum, *i.e.*, those which ovulated at least 5 days prior to treatment.

(A) For estrus synchronization in beef cows, beef heifers and replacement dairy heifers.

(B) For unobserved (silent) estrus in lactating dairy cows with a corpus luteum.

(C) For treatment of pyometra (chronic endometritis) in cattle.

(D) For abortion in beef cows, beef heifers and replacement dairy heifers.

(E) For use with gonadorelin injection as in § 522.1077 of this chapter to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.

(F) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in lactating dairy cows.

(G) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.

(2) *Horses*—(i) *Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications for use.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(3) *Swine*—(i) *Amount.* 10 mg as a single intramuscular injection.

(ii) *Indications for use.* For parturition induction in swine when injected within 3 days of normal predicted farrowing.

(4) *Cattle.* Administer product described in paragraph (b)(2) of this section as follows:

(i) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle*—(A) *Amount.* 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications.* For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle*—(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost injection as provided by No. 054771 in § 510.600(c) of this chapter may also be used concurrently with gonadorelin hydrochloride injection as in § 522.1077 and with progesterone intravaginal inserts as in § 529.1940 of this chapter.

[67 FR 41824, June 20, 2002, as amended at 79 FR 16187, Mar. 25, 2014; 79 FR 44278, July 31, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 61296, Oct. 13, 2015; 80 FR 76386, Dec. 9, 2015; 81 FR 36789, June 8, 2016]

§ 522.723 Diprenorphine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams of diprenorphine hydrochloride.

(b) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(2) *Indications for use.* The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(3) *Limitations.* For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[79 FR 16187, Mar. 25, 2014]

§ 522.770 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 054771 in § 510.600 (c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum,* and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999; 79 FR 16187, Mar. 25, 2014]

§ 522.775 Doxapram.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) doxapram hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (/lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 261, Jan. 4, 2007, as amended at 75 FR 10167, Mar. 5, 2010; 77 FR 60302, Oct. 3, 2012]

§ 522.784 Doxylamine.

(a) *Specifications.* Each milliliter contains 11.36 milligrams (mg) of doxylamine succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* Administer 25 mg per hundred pounds of body weight by intramuscular, subcutaneous, or slow intravenous injection.

(ii) *Dogs and cats:* Administer 0.5 to 1 mg per pound of body weight by

intramuscular or subcutaneous injection. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect.

(2) *Indications for use.* For use in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.800 Droperidol and fentanyl.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of droperidol and 0.4 mg of fentanyl citrate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.*

(i) For analgesia and tranquilization, administer as follows:

(A) 1 milliliter (mL) per 15 to 20 pounds (lbs) of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight; or

(B) 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight.

(ii) For general anesthesia, administer as follows:

(A) Administer 1 mL per 40 lbs of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight; or

(B) Administer 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight.

(2) *Indications for use.* As an analgesic and tranquilizer and for general anesthesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One mL per 5 pounds of body weight.

(2) *Indications for use.* For euthanasia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005, as amended at 78 FR 17597, Mar. 22, 2013; 81 FR 17608, Mar. 30, 2016]

§ 522.812 Enrofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000859 for use of products described in paragraph (a) as in paragraph (e) of this section; and

(2) No. 055529 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section, and use of product described in paragraph (a)(2) in this section as in paragraphs (e)(2), (e)(3)(i)(B), and (e)(3)(ii) of this section.

(3) No. 026637 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(c) *Related tolerance.* See § 556.226 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use*—(1) *Dogs.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a

single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount*—(A) *Single-dose therapy:* For treatment of bovine respiratory disease (BRD), administer 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds (/100 lb)) once by subcutaneous injection. For control of BRD, administer 7.5 mg/kg of body weight (3.4 mL/100 lb) once by subcutaneous injection.

(B) *Multiple-day therapy:* For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use*—(A) *Single-dose therapy:* For the treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle; for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis.*

(B) *Multiple-day therapy:* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Swine.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amounts and indications for use.* (A) Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Mycoplasma hyopneumoniae.*

(B) Administer, by subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis.*

(C) Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

(ii) *Limitations.* Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

[72 FR 10597, Mar. 9, 2007, as amended at 73 FR 17890, Apr. 2, 2008; 73 FR 21819, Apr. 23, 2008; 76 FR 22611, Apr. 22, 2011; 77 FR 55415, Sept. 10, 2012; 77 FR 76863, Dec. 31, 2012; 78 FR 19987, Apr. 3, 2013; 79 FR 37620, July 2, 2014; 80 FR 13229, Mar. 13, 2015; 80 FR 18776, Apr. 8, 2015; 80 FR 61296, Oct. 13, 2015]

§ 522.814 Eprinomectin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) eprinomectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 500.1410 and 556.227 of this chapter.

(d) *Conditions of use in cattle on pasture*—(1) *Amount.* Administer 1 mg/kilogram of body weight by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of the following internal and external parasites: Gastrointestinal roundworms (adults and fourth-stage larvae) *Bunostomum*

phlebotomum, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Trichostrongylus axei*, *Ostertagia ostertagi* (including inhibited stage); (adults) *Haemonchus placei*, *Oesophagostomum radiatum*, *O. lyrata*, *T. colubriformis;* lungworms (adults) *Dictyocaulus viviparus;* cattle grubs *Hypoderma bovis;* mites *Sarcoptes scabiei* var. *bovis*. Prevents reinfection with *C. oncophora*, *C. punctata*, and *T. axei* for 100 days following treatment; *H. placei*, *O. radiatum*, *O. lyrata*, and *O. ostertagi* for 120 days following treatment; and *B. phlebotomum* and *D. viviparus* for 150 days following treatment.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals intended for human consumption must not be slaughtered within 48 days of the last treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

[76 FR 72618, Nov. 25, 2011, as amended at 79 FR 37620, July 2, 2014]

§ 522.820 Erythromycin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.

(2) Each mL of solution contains 200 mg erythromycin base.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.230 of this chapter.

(d) *Conditions of use*—(1) *Dog*. Administer product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 3 to 5 mg per pound (/lb) body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*. For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*. Administer product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 3 to 5 mg/lb body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*. For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*. Administer products described in paragraph (a) of this section as follows:

(i) *Amount*. 4 mg/lb body weight by deep intramuscular injection once daily for up to 5 days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations*. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To avoid excess trim, do not slaughter within 21 days of last injection.

[72 FR 69142, Dec. 7, 2007, as amended at 79 FR 16187, Mar. 25, 2014]

§ 522.840 Estradiol.

(a) *Specifications*. Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with not less than 0.5 mg oxytetracycline powder.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.240 of this chapter.

(d) *Conditions of use*. For implantation in steers and heifers as follows:

(1) *Amount*. Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.

(2) *Indications for use.* For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.

(3) *Limitations.* For subcutaneous ear implantation in steers and heifers only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 67818, Nov. 22, 2004, as amended at 77 FR 31723, May 30, 2012; 81 FR 48702, July 26, 2016]

§ 522.842 Estradiol benzoate and testosterone propionate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 054771 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.

(2) No. 058198 for use as in paragraph (c) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(c) *Conditions of use.* For implantation in heifers as follows:

(1) *Amount.* (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

(ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(3) *Limitations.* For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 68252, Nov. 24, 2004, as amended at 77 FR 31723, May 30, 2012; 79 FR 16187, Mar. 25, 2014; 81 FR 48702, July 26, 2016]

§ 522.850 Estradiol valerate and norgestomet in combination.

(a) *Specifications.* The product is a two-component drug consisting of the following:

(1) An implant containing 6.0 milligrams of norgestomet.

(2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One implant and 2 milliliters of injection at time of implantation.

(2) *Indications for use.* For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.

(3) *Limitations.* Insert implant subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in cows producing milk for human consumption.

[47 FR 55477, Dec. 10, 1982, as amended at 48 FR 49656, Oct. 27, 1983; 51 FR 33592, Sept. 22, 1986; 54 FR 1165, Jan. 12, 1989]

§ 522.863 Ethylisobutrazine.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 2 to 5 mg per pound of body weight by intramuscular injection for profound tranquilization. Administer 1 to 2 mg per pound of body weight by intravenous injection to effect.

(2) *Indications for use.* For use as a tranquilizer.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.870 Etodolac.

(a) *Specifications.* Each milliliter contains 100 milligrams (mg) etodolac.

(b) *Sponsor.* See No. 000010 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 4.5 to 6.8 mg/pound (10 to 15 mg/kilogram) body weight as a single, dorsoscapular subcutaneous injection. If needed, the daily dose of etodolac tablets as in § 520.870 of this chapter may be given 24 hours after the injection.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 51365, Sept. 7, 2007, as amended at 75 FR 10167, Mar. 5, 2010]

§ 522.883 Etorphine.

(a) *Specifications.* Each milliliter of solution contains 1 milligram of etorphine hydrochloride.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Special considerations.* Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

(d) *Conditions of use*—(1) *Amount.* Administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(2) *Indications for use.* For the immobilization of wild and exotic animals.

(3) *Limitations.* Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.900 Euthanasia solution.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061, 051311, and 054925 for use of product described in paragraph (a)(1) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements: ''ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.''

(d) *Conditions of use in dogs*—(1) *Indications for use.* For humane, painless, and rapid euthanasia.

(2) *Amount.* One mL per 10 pounds of body weight.

(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 42969, July 21, 2003, as amended at 68 FR 55824, Sept. 29, 2003; 70 FR 8929, Feb. 24, 2005; 71 FR 13542, Mar. 16, 2006; 79 FR 16188, Mar. 25, 2014]

§ 522.914 Fenprostalene.

(a) *Specifications.* (1) Each milliliter of solution contains 0.5 milligram (mg) fenprostalene.

(2) Each milliliter of solution contains 0.25 mg fenprostalene.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and

for use of product described in paragraph (a)(2) as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §556.277 of this chapter.

(d) *Special considerations.* Labeling shall bear the following statements: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. It is readily absorbed through the skin and may cause abortion and/or bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(e) *Conditions of use*—(1) *Cattle*—(i) *Indications for use and amount*—(A) For feedlot heifers to induce abortion when pregnant 150 days or less, administer 1 mg (2 milliliter (mL)) subcutaneously.

(B) For beef or nonlactating dairy cattle for estrus synchronization, administer a single or two 1-mg (2-mL) doses subcutaneously, 11 to 13 days apart.

(ii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer a single injection of 0.25 mg (1 mL) subcutaneously.

(ii) *Indications for use.* For the induction of parturition in sows and gilts pregnant at least 112 days.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.930 Firocoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) firocoxib.

(b) *Sponsors.* See No. 050604 in §510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.04 mg/pound (lb) (0.09 mg/kilogram (kg)) of body weight (BW) intravenously, once daily, for up to 5 days. If further treatment is needed, firocoxib oral paste can be administered at a dosage of 0.045 mg/lb (0.1 mg/kg) of BW for up to an additional 9 days of treatment.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 59611, Sept. 28, 2010]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains:

(1) 300 milligrams (mg) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin.

(2) 300 mg florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol.

(3) 300 mg florfenicol in the inactive vehicles 2-pyrrolidone and glycerol formal.

(b) *Sponsors.* See sponsor numbers in §510.600(c) of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i); and

(2) Nos. 000061 and 000859 for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

(3) No. 055529 for use of product described in paragraph (a)(3) as in paragraph (d)(1)(ii).

(c) *Related tolerances.* See §§500.1410 and 556.283 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) 300 mg per milliliter (mL) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin:

(A) *Amount.* 40 mg/kilogram (kg) body weight as a single subcutaneous injection.

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and nonlactating dairy cattle.

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 44 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) 300 mg/mL florfenicol in the inactive vehicles n-methyl-2- pyrrolidone,

propylene glycol, and polyethylene glycol, or in 2-pyrrolidone and glycerol formal:

(A)(*1*) *Amount.* 20 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later. Alternatively, 40 mg/kg of body weight as a single subcutaneous injection may be used.

(*2*) *Indications for use.* For treatment of BRD associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(B)(*1*) *Amount.* 40 mg/kg of body weight as a single subcutaneous injection.

(*2*) *Indications for use.* For control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[73 FR 21041, Apr. 18, 2008, as amended at 74 FR 66574, Dec. 16, 2009; 79 FR 18158, Apr. 1, 2014; 79 FR 53136, Sept. 8, 2014; 80 FR 61296, Oct. 13, 2015; 80 FR 76386, Dec. 9, 2015]

§ 522.956 Florfenicol and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) florfenicol and 16.5 mg flunixin (27.37 mg flunixin meglumine).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Tolerances.* See §§ 556.283 and 556.286 of this chapter.

(d) *Conditions for use in cattle*—(1) *Amount.* 40 mg florfenicol/kg body weight (BW) and 2.2 mg flunixin/kg BW (equivalent to 2 mL/15 kg BW or 6 mL/100 lbs) once, by subcutaneous injection.

(2) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

(3) *Limitations.* Animals intended for human consumption must not be slaughtered within 38 days of treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 1275, Jan. 11, 2010, as amended at 75 FR 54018, Sept. 3, 2010; 79 FR 18158, Apr. 1, 2014]

§ 522.960 Flumethasone injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 6 to 10 mg by intra-articular injection. Dosage is limited to a single injection per week in any one synovial structure.

(2) *Indications for use.* For use in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpitis, and osselets.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.960b Flumethasone acetate solution.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) of flumethasone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs weighing up to 10 pounds (lbs): 2 mg; dogs weighing 10 to 25 lbs: 4 mg; dogs weighing over 25 lbs: 8 mg. Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 mg per animal.

(2) *Indications for use.* For use in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer 1.25 to 2.5 milligrams (mg) daily by intravenous, intramuscular, or intra-articular injection.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpitis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer 0.0625 to 0.25 mg daily by intravenous, intramuscular, or subcutaneous injection; 0.125 to 1.0 mg daily by intralesional injection, depending on the size and location of the lesion; or 0.166 to 1.0 mg daily by intra-articular injection, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cats*—(i) *Amount.* Administer 0.03125 to 0.125 mg daily by intravenous, intramuscular, or subcutaneous injection.

(ii) *Indications for use.* For use in the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 000859, 055529, 057561, and 061623 for use as in paragraph (e) of this section.

(2) See No. 054771 for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.5 mg per pound (/lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amounts and indications for use*—(A) Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.

(B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.

(ii) *Limitations.* Approved only for intravenous administration in cattle. Intramuscular administration has resulted in violative residues in the edible tissues of cattle sent to slaughter. Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Do not use in dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

(B) [Reserved]

(3) *Swine*—(i) *Amount.* Administer 2.2 mg/kg (1.0 mg/lb) of body weight as a single intramuscular injection.

(ii) *Indications for use.* For the control of pyrexia associated with swine respiratory disease.

(iii) *Limitations.* Swine must not be slaughtered for human consumption within 12 days of last treatment.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003; 69 FR 53618, Sept. 2, 2004; 69 FR 60308, Oct. 8, 2004; 70 FR 48868, Aug. 22, 2005; 70 FR 70998, Nov. 25, 2005; 71 FR 15564, Mar. 29, 2006; 71 FR 16222, Mar. 31, 2006; 73 FR 2809, Jan. 16, 2008; 73 FR 28037, May 15, 2008; 74 FR 6994, Feb. 12, 2009; 74 FR 34236, July 15, 2009; 75 FR 13225, Mar. 19, 2010; 75 FR 76260, Dec. 8, 2010; 79 FR 16189, Mar. 25, 2014; 82 FR 43484, Sept. 18, 2017]

§ 522.995 Fluprostenol.

(a) *Specifications.* Each milliliter of solution contains fluprostenol sodium equivalent to 50 micrograms (μg) of fluprostenol.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.55 μg fluprostenol per kilogram of body weight by intramuscular injection.

(2) *Indications for use.* For use in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications.* Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor.* See No. 052923 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use.* For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations.* For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*—(i) *Single pack.* Each package contains 2 vials. One vial contains 700 international units (IU) porcine-pituitary-derived follicle stimulating hormone (FSH) equivalent to 400 milligrams NIH–FSH–P1, as a dry powder. The other vial contains 20 milliliters (mL) of bacteriostatic sodium chloride injection. When constituted, each milliliter of solution contains 35 IU FSH.

(ii) *Dual pack.* Each package contains 2 vials. Each vial contains 700 international units (IU) porcine-pituitary-derived FSH equivalent to 400 milligrams NIH–FSH–P1, as a dry powder. Constitute with 20 mL bacteriostatic sodium chloride injection, using strict aseptic technique. When constituted, each milliliter of solution contains 35 IU FSH.

(2) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Administer 2.5 mL (87.5 IU) intramuscularly, twice daily at 12-hour intervals, for 4 consecutive days. In conjunction with the 6th dose, administer an approved prostaglandin product for cattle (cloprostenol sodium or dinoprost tromethamine), using the labeled dosage and administration instructions to cause luteolysis and induce estrus. See § 522.460 for use of cloprostenol sodium or § 522.690 for use of dinoprost tromethamine.

(ii) *Indications for use.* For the induction of superovulation in beef and dairy heifers and cows.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997; 76 FR 2808, Jan. 18, 2011; 79 FR 53136, Sept. 8, 2014; 79 FR 74020, Dec. 15, 2014; 82 FR 21690, May 10, 2017; 82 FR 43484, Sept. 18, 2017]

§ 522.1010 Furosemide.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 50 milligrams (mg) furosemide monoethanolamine.

(2) Each mL of solution contains 50 mg furosemide diethanolamine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section for use as in paragraph (d) of this section.

(1) No. 000010 as described in paragraph (a)(1) of this section for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 061623 as described in paragraph (a)(2) of this section for use as in paragraph (d)(2)(ii) of this section.

(3) No. 000859 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(4) No. 000061 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(iii), and (d)(3) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) Amount. 1.25 to 2.5 mg per pound (/lb) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses*—(i) *Amount.* 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(ii) *Amount.* 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For treatment of acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(iii) *Amount.* 250 to 500 mg/animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(3) *Cattle*—(i) *Amount.* 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily at 12-hour intervals, intramuscularly or intravenously.

(ii) *Indications for use.* For the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

[66 FR 47961, Sept. 17, 2001, as amended at 67 FR 18086, Apr. 15, 2002; 68 FR 59881, Oct. 20, 2003; 69 FR 17585, Apr. 5, 2004; 71 FR 39548, July 13, 2006; 74 FR 61516, Nov. 25, 2009; 76 FR 17338, Mar. 29, 2011; 78 FR 17597, Mar. 22, 2013; 79 FR 16189, Mar. 25, 2014]

§ 522.1014 Gamithromycin.

(a) *Specifications.* Each milliliter (mL) of solution contains 150 milligrams (mg) gamithromycin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.292 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 6 mg/kilogram of body weight (2 mL per 110 pounds) one time by subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 35 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[76 FR 57906, Sept. 19, 2011, as amended at 77 FR 26162, May 3, 2012]

§ 522.1020 Gelatin.

(a) *Specifications.* Each 100 milliliters contains 8 grams of gelatin in a 0.85 percent sodium chloride solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight.

(2) *Indications for use.* For use to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

§ 522.1044 Gentamicin.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 5, 50, or 100 milligrams (mg) gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000061 for use of 5 mg per milliliter (/mL) solution in swine as in paragraph (d)(4), 50 mg/mL solution in dogs and cats as in paragraph (d)(1), 50 mg/mL and 100 mg/mL solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 054628 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) Nos. 016592 and 061623 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See §556.300 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Two milligrams of gentamicin per pound of body weight, twice daily on the first day, once daily thereafter, using a 50 milligram-per-milliliter solution.

(ii) *Indications for use*—(*a*) *Dogs.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (tonsillitis, pneumonia, tracheobronchitis), skin and soft tissue (pyodermatitis, wounds, lacerations, peritonitis).

(*b*) *Cats.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (pneumonitis, pneumonia, upper respiratory tract infections), skin and soft tissue (wounds, lacerations, peritonitis), and as supportive therapy for secondary bacterial infections associated with panleucopenia.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* One milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 5 milligrams-per-milliliter.

(ii) *Indications for use.* As an aid in the prevention of early mortality due to Arizona paracolon infections susceptible to gentamicin.

(iii) *Limitations.* For 1- to 3-day old turkey poults. Administer subcutaneously in the neck. Injected poults must not be slaughtered for food for at least 9 weeks after treatment.

(3) *Chickens*—(i) *Amount.* 0.2 milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 1.0 milligram-per-milliliter.

(ii) *Indications for use.* In day-old chickens, for prevention of early mortality caused by *Escherichia coli. Salmonella typhimurium,* and *Pseudomonas aeruginosa* that are susceptible to gentamicin.

(iii) *Limitations.* For use in day-old chickens only. Administer aseptically, injecting the diluted product subcutaneously in the neck. Do not slaughter treated animals for food for at least 5 weeks after treatment.

(4) *Swine*—(i) *Amount.* 5 milligrams of gentamicin as a single intramuscular dose using 5 milligram-per-milliliter solution.

(ii) *Indications for use.* In piglets up to 3 days old for treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(iii) *Limitations.* For single intramuscular dose in pigs up to 3 days of age only. Do not slaughter treated animals for food for at least 40 days following treatment.

(5) *Dogs*—(i) *Amount.* 2 milligrams of gentamicin per pound of body weight, twice daily on the first day, then once daily.

(ii) *Indications for use.* For use in the treatment of urinary tract infections (cystitis) caused by *Proteus mirabilis, Escherichia coli,* and *Staphylococcus aureus.*

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If no improvement is seen after 3 days, treatment should be discontinued and the diagnosis reevaluated. Treatment not to exceed 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 1942, Jan. 13, 1978, as amended at 48 FR 791, Jan. 7, 1983; 51 FR 15606, Apr. 25, 1986; 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 60 FR 29985, June 7, 1995; 61 FR 24441, May 15, 1996; 62 FR 45157, Aug. 26, 1997; 63 FR 59714, Nov. 5, 1998; 63 FR 68182, Dec. 10, 1998; 65 FR 45877, July 26, 2000; 71 FR 76901, Dec. 22, 2006; 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 21127, Apr. 15, 2014; 81 FR 22524, Apr. 18, 2016]

§ 522.1055 Gleptoferron.

(a) *Specifications.* Each milliliter (mL) contains the equivalent of 200 milligrams of elemental iron as gleptoferron, a complex of ferric hydroxide and dextran glucoheptonic acid.

(b) *Sponsors.* See No. 013744 in §510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Indications for use and amounts.* (i) Prevention of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig

by intramuscular injection on or before 3 days of age.

(ii) Treatment of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection as soon as signs of deficiency appear.

(2) [Reserved]

[81 FR 59134, Aug. 29, 2016, as amended at 82 FR 11508, Feb. 24, 2017; 82 FR 21690, May 10, 2017]

§ 522.1066 Glycopyrrolate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligram glycopyrrolate.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight) by intravenous, intramuscular, or subcutaneous injection in dogs or by intramuscular injection in cats.

(2) *Indications for use.* As a preanesthetic agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 64451, Nov. 2, 2006, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16189, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.1077 Gonadorelin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;

(2) 100 µg of gonadorelin as gonadorelin acetate;

(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate; or

(4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(iv), and (d)(2) of this section.

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(ii), (d)(1)(v), and (d)(2) of this section.

(3) Nos. 050604 and 061623 for use of the 50-µg/mL product described in paragraph (a)(3) as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(4) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (d)(1)(iii), (d)(1)(vi), and (d)(2) of this section.

(c) *Special considerations.* Concurrent luteolytic drug use is approved as follows:

(1) Cloprostenol injection for use as in paragraph (d)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(2) Cloprostenol injection for use as in paragraph (d)(1)(v) of this section as provided by No. 000061 or No. 068504 in § 510.600(c) of this chapter.

(3) Dinoprost injection for use as in paragraph (d)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

(d) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in dairy cattle: Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(iii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin by intramuscular injection.

(iv) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

(v) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

(vi) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination

(FTAI) in lactating dairy cows: Administer to each cow 100 to 200 μg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to 72 hours later by 100 to 200 μg gonadorelin by intramuscular injection.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 34279, June 16, 2015, as amended at 81 FR 36789, June 8, 2016]

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

(a) *Specifications.* Each dose consists of 400 international units (I.U.) serum gonadotropin and 200 I.U. chorionic gonadotropin as a freeze-dried powder to be reconstituted with 5 milliliters of sterile aqueous diluent.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* 400 I.U. serum gonadotropin with 200 I.U. chorionic gonadotropin per 5 milliliters dose per animal.

(2) *Indications for use.* (i) *Gilts.* For induction of fertile estrus (heat) in healthy prepuberal (noncycling) gilts.

(ii) *Sows.* For induction of estrus in healthy weaned sows experiencing delayed return to estrus.

(3) *Limitations.* For subcutaneous use only.

(i) *Gilts.* For use only in gilts over 5½ months of age and weighing at least 85 kilograms (187 pounds).

(ii) *Sows.* Delayed return to estrus is most prevalent after the first litter. The effectiveness has not been established after later litters. Delayed return to estrus often occurs during periods of adverse environmental conditions, and sows mated under such conditions may farrow smaller than normal litters.

[55 FR 1405, Jan. 16, 1990, as amended at 58 FR 52222, Oct. 7, 1993; 74 FR 61516, Nov. 25, 2009]

§ 522.1081 Chorionic gonadotropin.

(a) *Specifications.* Each vial contains 5,000, 10,000 or 20,000 USP units of lyophilized powder for constitution with accompanying diluent to a 10-milliliter solution.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000402 and 054771 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B) and (d)(1)(i)(C) of this section.

(2) [Reserved]

(3) No. 000061 for use as in paragraphs (d)(1)(i)(A) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.304 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* As a single dose. Dosage may be repeated in 14 days if the animal's behavior or examination of the ovaries *per rectum* indicates retreatment.

(A) 10,000 USP units by intramuscular injection.

(B) 500 to 2,500 USP units by intrafollicular injection.

(C) 2,500 to 5,000 USP units by intravenous injection.

(ii) *Indications for use.* For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Finfish*—(i) *Amount.* 50 to 510 IU per pound of body weight for males, 67 to 1,816 IU per pound of body weight for females, by intramuscular injection. Up to three doses may be administered.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* In fish intended for human consumption, the total dose administered per fish (all injections combined) should not exceed 25,000 IU chorionic gonadotropin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 61516, Nov. 25, 2009, as amended at 76 FR 17778, Mar. 31, 2011; 77 FR 55414, Sept. 10, 2012; 79 FR 16189, Mar. 25, 2014]

EFFECTIVE DATE NOTE: At 83 FR 13635, Mar. 30, 2018, § 522.1081 was amended by removing ''Nos. 000402 and 054771'' and in its place adding ''No. 054771'', effective Apr. 9, 2018.

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligrams (mg) gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* Administer 0.4 mg (2 milliliter (mL)) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg (2 mL) should be administered at least 4 weeks after the first dose.

(2) *Indications for use.* For the temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Pigs should be slaughtered no earlier than 3 weeks and no later than 10 weeks after the second dose.

[76 FR 27889, May 13, 2011, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16189, Mar. 25, 2014]

§ 522.1085 Guaifenesin powder for injection.

(a) *Specifications.* The product is a sterile powder containing guaifenesin. A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution.

(b) *Sponsors.* See Nos. 037990 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milliliter of prepared solution per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a muscle relaxant.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

§ 522.1086 Guaifenesin solution.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of guaifenesin and 50 mg of dextrose.

(b) *Sponsors.* See Nos. 000859 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milliliter per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a skeletal muscle relaxant.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000; 79 FR 16189, Mar. 25, 2014]

§ 522.1145 Hyaluronate.

(a)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 054771 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock): 20 mg; larger joint (hock): 40 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 10 mg; larger joint (hock): 20 mg. Treatment may be repeated at weekly intervals for a total of four treatments.

(ii) *Indications for use*. Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 20 mg. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks.

(ii) *Indications for use*. For the intra-articular treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic, non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use*. For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications*. Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

(2) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(i) No. 050604 for use of products described in paragraph (e)(1) as in paragraph (e)(3) of this section.

(ii) No. 017030 for use of product described in paragraph (e)(1)(i) as in paragraph (e)(3) of this section.

(3) *Conditions of use*—(i) *Amount*. 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 060865 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 22 mg; larger joint (hock): 44 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 45124, Nov. 15, 1984, as amended at 51 FR 11438, Apr. 3, 1986; 51 FR 25032, July 10, 1986; 53 FR 19773, May 31, 1988; 53 FR 22297, June 15, 1988; 56 FR 50814, Oct. 9, 1991; 57 FR 2837, Jan. 24, 1992; 59 FR 33198, June 28, 1994; 61 FR 59003, Nov. 20, 1996; 63 FR 59216, Nov. 3, 1998; 71 FR 1689, Jan. 11, 2006; 71 FR 39204, July 12, 2006; 75 FR 1274, Jan. 11, 2010; 75 FR 10167, Mar. 5, 2010; 78 FR 73698, Dec. 9, 2013; 79 FR 16189, Mar. 25, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 34279, June 16, 2015]

§ 522.1150 Hydrochlorothiazide.

(a) *Specifications*. Each milliliter of solution contains 25 milligrams of hydrochlorothiazide.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 to 10 milliliters (125 to 250 milligrams) intravenously or intramuscularly once or twice a day. After onset of diuresis, treatment may be continued with an orally administered maintenance dose.

(2) *Indications for use.* For use in cattle as an aid in the treatment of postparturient udder edema.

(3) *Limitations.* Milk taken from dairy animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 16190, Mar. 25, 2014]

§ 522.1155 Imidocarb powder for injection.

(a) *Specifications.* The product is a sterile powder containing imidocarb dipropionate. Each milliliter of constituted solution contains 100 milligrams (mg) of imidocarb base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to licensed or full-time State, Federal, or military veterinarians.

(d) *Conditions of use in horses and zebras*—(1) *Amount.* For *Babesia caballi* infections, administer 2 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage once after 24 hours. For *Babesia equi* infections, administer 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage four times at 72-hour intervals.

(2) *Indications for use.* For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia equi.*

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1156 Imidocarb solution.

(a) *Specifications.* Each milliliter of solution contains 120 milligrams (mg) of imidocarb dipropionate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular injection. Repeat the dose after 2 weeks for a total of two treatments.

(2) *Indications for use.* For the treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1160 Insulin.

(a) *Specifications*—(1) Each milliliter (mL) of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

(2) Each mL of protamine zinc recombinant human insulin suspension contains 40 IU of insulin.

(b) *Sponsors.* See sponsors in § 510.600 of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25

percent less than the once daily dose required to attain an acceptable nadir.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*—(A) *Porcine insulin zinc.* Administer an initial dose of 1 to 2 IU by subcutaneous injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(B) *Protamine zinc recombinant human insulin.* Administer an initial dose of 0.1 to 0.3 IU/pound of body weight (0.2 to 0.7 IU/kilogram) every 12 hours. The dose should be given concurrently with or right after a meal. Re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 25827, May 10, 2004, as amended at 73 FR 21042, Apr. 18, 2008; 74 FR 61517, Nov. 25, 2009; 74 FR 66048, Dec. 14, 2009]

§ 522.1182 Iron injection.

(a) *Specifications.* See § 510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:

(i) Ferric hydroxide;

(ii) Ferric oxide; or

(iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) *Sponsors and conditions of use.* It is used in young piglets by sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000859 and 042552 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection. Dosage may be repeated in approximately 10 days.

(2) No. 054771 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 mg at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(3) Nos. 000061 and 013744 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(4) Nos. 051311 and 054771 for use of product described in paragraph (a)(1)(ii) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

(5) No. 054771 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(6) Nos. 016592 and 058005 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection. Treatment may be repeated in 10 days.

(7) Nos. 016592 and 042552 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron (1 mL) at 1 to 3 days of age.

(ii) For treatment of anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron at the first sign of anemia.

[73 FR 12635, Mar. 10, 2008, as amended at 73 FR 14385, Mar. 18, 2008; 78 FR 17597, Mar. 22, 2013; 78 FR 44433, July 24, 2013; 79 FR 16190, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016; 81 FR 59134, Aug. 29, 2016; 82 FR 11508, Feb. 24, 2017]

§ 522.1185 Isoflupredone.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of isoflupredone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use.* For use in the treatment of bovine ketosis. For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses and swine*—(i) *Amount*—(A) *Horses.* Administer 5 to 20 mg by intramuscular injection for systemic effect or by intrasynovial injection into a joint cavity, tendon sheath, or bursa for local effect.

(B) *Swine.* The usual dose for a 300-pound animal is 5 mg by intramuscular injection.

(ii) *Indications for use.* For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1192 Ivermectin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 016592, 055529, 058005, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

(d) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Labeling shall bear the following precaution: ''This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.''

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (μg/kg) of body weight by intramuscular injection.

(ii) *Indications for use.* For the treatment and control of large strongyles

(adult) (*Strongylus vulgaris*, *S. edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (microfilariae) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*scabies*) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For control of infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations.* Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) *Swine*—(i) *Amount.* 300 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostrongylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *S. ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*H. suis*); and mites (*S. scabiei* var. *suis*).

(iii) *Limitations.* Do not treat swine within 18 days of slaughter.

(4) *American bison*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of grubs (*H. bovis*).

(iii) *Limitations.* Do not slaughter within 56 days of last treatment.

(5) *Reindeer*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations.* Do not treat reindeer within 56 days of slaughter.

(6) *Ranch-raised foxes*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

[72 FR 27735, May 17, 2007, as amended at 72 FR 62771, Nov. 7, 2007; 74 FR 9049, Mar. 2, 2009; 75 FR 26647, May 12, 2010; 76 FR 57906, Sept. 19, 2011; 78 FR 17597, Mar. 22, 2013; 81 FR 59134, Aug. 29, 2016]

§ 522.1193 Ivermectin and clorsulon.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) *Sponsors.* See Nos. 050604, 055529, and 058005 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.163 and 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Administer 1 mL (10 mg ivermectin and 100 mg clorsulon) per 50 kilograms (110 pounds) by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T.*

colubriformis, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of *D. viviparus* and *O. radiatum* for 28 days afer treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei and C. oncophora* for 14 days after treatment.

(3) *Limitations.* For No. 050604: Do not treat cattle within 21 days of slaughter. For Nos. 055529 and 058005: Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997; 64 FR 26671, May 17, 1999; 69 FR 31735, June 7, 2004; 72 FR 27734, May 17, 2007; 77 FR 64717, Oct. 23, 2012; 79 FR 64116, Oct. 28, 2014]

EDITORIAL NOTE: At 81 FR 22524, Apr. 18, 2016, § 522.1193 was amended; however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 522.1204 Kanamycin.

(a) *Specifications.* Each milliliter of solution contains 50 or 200 milligrams (mg) of kanamycin as kanamycin sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by subcutaneous or intramuscular injection 5 mg per pound of body weight per day in equally divided doses at 12-hour intervals.

(2) *Indications for use.* For the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1222 Ketamine.

(a) *Specifications.* Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) *Sponsors.* See Nos. 000859, 026637, 054628, 054771, 059399, and 063286 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cats*—(i) *Amount.* 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) *Indications for use.* For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(2) *Subhuman primates*—(i) *Amount.* 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

(ii) *Indications for use.* For restraint.

[67 FR 17283, Apr. 10, 2002, as amended at 73 FR 8192, Feb. 13, 2008. Redesignated at 79 FR 16191, Mar. 25, 2014, as amended at 80 FR 13229, Mar. 13, 2015]

§ 522.1223 Ketamine, promazine, and aminopentamide.

(a) *Specifications.* Each milliliter of solution contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity, 7.5 (mg) of promazine hydrochloride, and 0.0625 mg of aminopentamide hydrogen sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer by intramuscular injection 15 to 20 mg ketamine base per pound of body weight, depending on the effect desired.

(2) *Indications for use.* It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014]

§ 522.1225 Ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of ketoprofen.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer by intravenous injection 1.0 mg per pound of body weight once daily for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014]

§ 522.1242 Levamisole.

(a) *Specifications.* Each milliliter of solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 054771 for use of 13.65 and 18.2 percent injection.

(c) *Conditions of use*—(1) *Amount.* 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use.* (i) The 13.65 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*), and lungworms (*Dictyocaulus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) and lungworms (*Dictyocaulus*).

(3) *Limitations.* Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not administer to cattle within 7 days of slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997; 65 FR 61090, Oct. 16, 2000; 67 FR 63055, Oct. 10, 2002. Redesignated and amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1260 Lincomycin.

(a) *Specifications.* Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

(1) 25, 50, 100, or 300 milligrams (mg) lincomycin.

(2) 25, 100, or 300 mg lincomycin.

(3) 300 mg lincomycin.

(4) 100 or 300 mg lincomycin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 054771 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) Nos. 016592 and 058005 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 054771 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

(c) *Special considerations.* When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) *Conditions of use.* It is used for animals as follows:

(1) *Dogs and cats*—(i) *Amount.* 5 mg per pound (/lb) of body weight twice

daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

(ii) *Indications for use.* Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

(ii) *Indications for use.* Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) *Limitations.* Do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985; 67 FR 34388, May 14, 2002; 68 FR 51705, Aug. 28, 2003; 69 FR 11507, Mar. 11, 2004; 69 FR 47361, Aug. 5, 2004; 71 FR 51996, Sept. 1, 2006; 78 FR 17597, Mar. 22, 2013; 79 FR 16191, Mar. 25, 2014; 81 FR 59134, Aug. 29, 2016]

§ 522.1289 Lufenuron.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* 10 mg per kilogram (4.5 mg per pound) of body weight every 6 months, by subcutaneous injection.

(2) *Indications for use.* For control of flea populations in cats 6 weeks of age and older.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014, as amended at 80 FR 61297, Oct. 13, 2015]

§ 522.1290 Luprostiol.

(a) *Specifications.* Each milliliter of solution contains 7.5 milligrams (mg) luprostiol.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: *Warning:* Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use in horses*—(1) *Amount.* 7.5 mg by intramuscular injection.

(2) Indications for use. For estrus control and termination of pregnancy in mares.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[55 FR 1185, Jan. 12, 1990, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 61 FR 66582, Dec. 18, 1996; 74 FR 25146, May 27, 2009]

§ 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous or intravenous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the prevention and treatment of acute vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 1.0 mg/kg of body weight by subcutaneous or intravenous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the treatment of vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 9243, Mar. 1, 2007, as amended at 77 FR 39391, July 3, 2012; 79 FR 16191, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016]

§ 522.1335 Medetomidine.

(a) *Specifications.* Each milliliter of solution contains 1.0 milligrams of medetomidine hydrochloride.

(b) *Sponsor*. See Nos. 015914 and 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use*. As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996, as amended at 79 FR 16191, Mar. 25, 2014; 82 FR 58556, Dec. 13, 2017]

§ 522.1350 Melatonin implant.

(a) *Specifications*. The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.

(b) *Sponsor*. See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. One implant per mink.

(2) *Indications for use*. For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.

(3) *Limitations*. For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

§ 522.1362 Melarsomine powder for injection.

(a) *Specifications*. The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor*. See Nos. 050604 and 086073 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer only by deep intramuscular injection in the lumbar muscles (L_3–L_5).

(2) *Indications*. Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995, as amended at 79 FR 16191, Mar. 25, 2014; 82 FR 21690, May 10, 2017]

§ 522.1367 Meloxicam.

(a) *Specifications*. Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsors*. See Nos. 000010, 016729, 026637, and 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 68724, Dec. 10, 2003, as amended at 69 FR 69523, Nov. 30, 2004; 78 FR 5715, Jan. 28, 2013; 79 FR 74020, Dec. 15, 2014]

§ 522.1372 Mepivacaine.

(a) *Specifications*. Each milliliter (mL) of solution contains 20 milligrams mepivacaine hydrochloride.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For nerve block, 3 to 5 mL; for epidural anesthesia, 5 to 20 mL; for

intra-articular anesthesia, 10 to 15 mL; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 mL, by infiltration, 20 to 50 mL.

(2) *Indications for use.* For use as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia, and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

(3) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 39547, July 13, 2006, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1380 Methocarbamol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of methocarbamol.

(b) *Sponsor.* See No. 051031 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* Administer by intravenous injection 20 mg per pound of body weight for moderate conditions or 25 to 100 mg per pound of body weight for severe conditions (tetanus and strychnine poisoning). The total cumulative dose should not to exceed 150 mg per pound of body weight.

(ii) *Horses.* Administer by intravenous injection 2 to 10 mg per pound of body weight for moderate conditions or 10 to 25 mg per pound of body weight for severe conditions (tetanus). Additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

(2) *Indications for use.* As an adjunct for treating acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014, as amended at 82 FR 11508, Feb. 24, 2017]

§ 522.1410 Methylprednisolone.

(a) *Specifications.* Each milliliter of suspension contains 20 or 40 milligrams (mg) of methylprednisolone acetate.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 2 to 40 mg (up to 120 mg in extremely large breeds or dogs with severe involvement) by intramuscular injection or up to 20 mg by intrasynovial injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Horses*—(i) *Amount.* Administer 200 mg by intramuscular injection or 40 to 240 mg by intrasynovial injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 51 FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 76 FR 53051, Aug. 25, 2011; 78 FR 21060, Apr. 9, 2013; 79 FR 16191, Mar. 25, 2014]

§ 522.1450 Moxidectin solution.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in beef and nonlactating dairy cattle*—(1) *Amount.* Administer 0.2 mg/kg of body weight (0.2 mg/2.2 pound) as a single, subcutaneous injection.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and *O. radiatum* for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

(3) *Limitations.* Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle 20 months of age and older. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

[70 FR 36337, June 23, 2005, as amended at 71 FR 7414, Feb. 13, 2006; 76 FR 48714, Aug. 9, 2011; 82 FR 21690, May 10, 2017]

§ 522.1451 Moxidectin microspheres for injection.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs*—(1) *Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002; 79 FR 16191, Mar. 25, 2014]

§ 522.1452 Nalorphine.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of nalorphine hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use.* Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997; 79 FR 16191, Mar. 25, 2014]

§ 522.1465 Naltrexone.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose*—(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Do not use in domestic food-producing animals. Do not use

in free-ranging animals for 45 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Dosage.* Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996; 79 FR 16192, Mar. 25, 2014]

§ 522.1484 Neomycin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of neomycin sulfate (equivalent to 35 mg of neomycin base).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 5 mg per pound of body weight daily by intramuscular or intravenous injection, divided into portions administered every 6 to 8 hours for 3 to 5 days.

(2) *Indications for use.* For the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(3) *Limitations.* Not for parenteral use in food-producing animals because of prolonged residues in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16192, Mar. 25, 2014]

§ 522.1503 Neostigmine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) neostigmine methylsulfate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer to cattle and horses at a dosage level of 1 mg per (/) 100 pounds (lbs) of body weight subcutaneously. Administer to sheep at a dosage level of 1 to 1½ mg/100 lbs body weight subcutaneously. Administer to swine at a dosage level of 2 to 3 mg/100 lbs body weight intramuscularly. These doses may be repeated as indicated.

(2) *Indications for use.* For treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions.

(3) *Limitations.* Not for use in animals producing milk, since this use will result in contamination of the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 61625, Nov. 19, 1997; 79 FR 16192, Mar. 25, 2014]

§ 522.1610 Oleate sodium.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of sodium oleate.

(b) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer by parenteral injection depending on the area of response desired. An injection of 1 milliliter (mL) will produce a response of approximately 15 square centimeters. Do not inject more than 2 mL per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 mL.

(2) *Indications for use.* It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985; 79 FR 16192, Mar. 25, 2014]

§ 522.1620 Orgotein for injection.

(a) *Specifications.* Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor.* See No. 024991 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer by deep intramuscular injection at a dosage level of 5 milligrams (mg) every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(ii) *Indications for use.* It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer by subcutaneous injection 5 mg daily for 6 days, and thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(ii) *Indications for use.* It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 32583, Aug. 4, 1976; 79 FR 16192, Mar. 25, 2014]

§ 522.1660 Oxytetracycline injectable dosage forms.

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

(a) *Specifications.* Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) *Sponsors.* See Nos. 000010, 016592, 048164, 054771, 055529, 057561, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(e) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including prerumenative (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis.*

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per

injection site in adult beef and dairy cattle may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980. Redesignated and amended at 69 FR 31879, June 8, 2004]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1660a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for use as in paragraph (e)(1)(i)(D) or (e)(1)(i)(E) of this section, labeling shall also bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

(e) *Conditions of use*—(1) *Beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Histophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(B) 5 mg/lb BW/day intramuscularly, subcutaneously, or intravenously for treatment of severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*.

(ii) *Limitations.* Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four consecutive days. Do not inject more than 10 mL per site in adult cattle, reducing the volume according to age and body size to 1 to 2 mL in small calves. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration may

result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 73 FR 14926, Mar. 20, 2008]

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.; Hemophilis spp.; Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresi*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor.* See 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(*a*) *Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(*b*) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Haemophilus spp.*,

and *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresi*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus spp.* and *Streptococcus spp.* If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale.*

(*c*) *Limitations.* For 50-milligram-per-milliliter solution, administer intramuscularly or intravenously; for 100-milligram-per-milliliter solution, administer intramuscularly only. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 0.5 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 18 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine—*(*a*) *Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(*b*) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona.* Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(*c*) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter.

(c)(1) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle and nonlactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Haemophilus spp.*, *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresi*, acute metritis, and wound infections caused by staphylococcal and streptococcal organisms.

(ii) It is administered to cattle at a dosage level of 3 to 5 milligrams per pound of body weight per day. It may be administered intramuscularly or intravenously from a 50 milligram per milliliter solution. It is administered intravenously from a 100 milligram per milliliter solution. Severe foot-rot and the severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight. Treatment should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 hours, consult a veterinarian. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the amount injected at each site according to the size of the animal. For very small calves do not use more than 2 milliliters per injection site.

(iii) Not for use in lactating dairy cattle. Discontinue treatment at least 19 days prior to slaughter. When administered intramuscularly within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site and surrounding tissues.

(d)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline

hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) In beef cattle and nonlactating dairy cattle as follows:

(*a*) It is used for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Haemophilus spp.;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* leptospirosis caused by *Leptospira pomona;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms.

(*b*) Administer by intravenous or intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and severe forms of the indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended.

(*c*) If the labeling of the drug bears the statement ''Federal law restricts this drug to use by or on the order of a licensed veterinarian,'' it may include additional directions for use in beef cattle and nonlactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale*, and anthrax caused by Bacillus anthracis in which case the drug is given at 3 to 5 milligrams of oxytetracycline per pound of body weight per day for anthrax, and at 5 milligrams per pound of body weight per day for anaplasmosis.

(ii) In swine as follows:

(*a*) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona*. Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(*b*) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day to swine. Administered to sows at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing.

(iii) In poultry (broilers, turkeys, and breeding chickens) as follows:

(*a*) It is used for the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli;* fowl cholera caused by *Pasteurella multocida;* infectious sinusitis caused by *Mycoplasma gallisepticum;* and infectious synovitis caused by *Mycoplasma synoviae*.

(*b*) Administered subcutaneously to chickens 1 day to 2 weeks of age at 6.25 milligrams of oxytetracycline per bird per day diluted with 1 part of the drug to 3 parts of sterile water; to chickens 2 to 4 weeks of age using the same diluted product at 12.5 milligrams of oxytetracycline per bird; to chickens 4 to 8 weeks of age without dilution at 25 milligrams of oxytetracycline per bird; to chickens 8 weeks of age (broilers and light pullets) at 50 milligrams of oxytetracycline per bird; to adult chickens at 100 milligrams of oxytetracycline per bird.

(*c*) Administered subcutaneously to turkeys 1 day to 2 weeks of age and 2 to 4 weeks of age at the same dosage as chickens; to turkeys 4 to 6 weeks of age at 50 milligrams of oxytetracycline as the undiluted product per bird; to turkeys 6 to 9 weeks of age at 100 milligrams of oxytetracycline per bird; to turkeys 9 to 12 weeks of age at 150 milligrams of oxytetracycline per bird; to turkeys 12 weeks of age and older at 200 milligrams of oxytetracycline per bird. In light turkey breeds, no more than 25 milligrams per pound of body weight is administered. For the treatment of infectious sinusitis in turkeys, ¼ to ½ milliliter of the drug is injected directly into each swollen sinus depending upon the age of the bird and the severity of the condition. At the time that the sinuses are treated, the drug should also be administered subcutaneously to the birds according to the dosage schedule given in paragraph (d)(3)(iii)(*c*) of this section. If refilling of the sinuses occurs, the treatment may be repeated in 5 to 7 days.

(iv) Treatment of all diseases should be instituted early. Treatment should continue for 24 to 48 hours beyond the remission of disease symptoms, but not exceed a total of 4 consecutive days. If

no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(v) When injecting intramuscularly in adult livestock, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 or 2 milliliters are injected in smaller animals such as small calves and young pigs. Intravenous administration is recommended in cattle when daily dosage exceeds 50 milliliters.

(vi) Treatment must be discontinued at least 5 days prior to slaughter for chickens and turkeys and at least 22 days prior to slaughter for cattle and swine. When administered intramuscularly to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

(vii) Not for use in lactating dairy animals. Do not administer to laying hens unless the eggs are used for hatching only.

(e)(1) *Specifications.* Each milliliter of solution contains 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(*a*) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(*b*) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(*c*) *Limitations.* Administer intramuscularly. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 1 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 milliliters intramuscularly or subcutaneously per injection site in adult beef and dairy cattle may result in antibiotic residues beyond the withdrawal period. Discontinue treatment at least 15 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine*—(*a*) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, administered once, approximately 8 hours before farrowing or immediately after completion of farrowing.

(*b*) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli,* pneumonia caused by *Pasteurella multocida,* and leptospirosis caused by *Leptospira pomona.* Sows: as an aid in control of infections enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(*c*) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine, reducing the volume according to age and body size to 1 to 2 milliliters in young pigs. Discontinue treatment at least 22 days prior to slaughter.

(f) [Reserved]

(g)(1) *Specifications.* Each milliliter of sterile solution contains 100 milligrams of oxytetracycline as oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* The drug is used for the treatment of diseases due to oxytetracycline-susceptible organisms as follows:

(i) *Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(*a*) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day.

(*b*) *Indications for use.* For the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Haemophilus spp.*, or *Klebsiella spp.*

(*c*) *Limitations.* Administer by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 milligrams of oxytetracycline per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 48 hours, consult a veterinarian. Do not inject more than 10 milliliters per injection site intramuscularly in adult cattle; no more than 1 milliliter per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) *Swine*—(*a*) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(*b*) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: As an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(*c*) *Limitations.* Administer intramuscularly. If no improvement is noted within 24 hours, consult a veterinarian. Do not inject more than 5 milliliters per site. Discontinue treatment at least 20 days prior to slaughter.

(h)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsors.* See No. 054628 in § 510.600(c) of this chapter for use of 50 and 100 milligrams per milliliter solution; and Nos. 016592 and 055529 in § 510.600(c) for use of 100 milligrams per milliliter solution.

(3) *Conditions of use*—(i) *Amount.* The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use.* The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and calf diphtheria caused by *Fusobacterium necrophorum* bacterial enterities (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* wound infections, acute metrities, and traumatic injury caused by staphylococcal and streptococcal organisms.

(iii) *Limitations.* Administer 50-milligram-per-milliliter solution intramuscularly; administer 100-milligram-per-milliliter solution intravenously. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. When injecting the drug intramuscularly, do no inject more than 10 milliliters per site in adult cattle. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less, do no inject more than 2 milliliters intramuscularly per site. Discontinue treatment at least 22 days before slaughter. Not for use in lactating dairy animals.

(i)(1) *Specifications.* Each milliliter of sterile solution contains 50 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 016592 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly per pound of body weight per day.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella spp.;* foot-rot and diptheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations*. In severe forms of the indicated diseases, administer the equivalent of 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site. Discontinue treatment at least 18 days before slaughter. Not for use in lactating dairy cattle.

(j) [Reserved]

(k)(1) *Specifications*. Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount*. 3 to 5 milligrams per pound of body weight daily, 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases.

(ii) *Indications for use*. Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; foot rot and diphtheria caused by *Fusobacterium necrophorum;* bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; acute metritis and wound infections caused by staphylococcal and streptococcal organisms; if labeled for use by or on the order of a licensed veterinarian, it may be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations*. Administer by intravenous injection. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not to exceed a total of 4 consecutive days. If no improvement occurs within 24 to 48 hours, reevaluate diagnosis and therapy. Discontinue use at least 19 days prior to slaughter. Not for use in lactating dairy cattle.

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1662a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications*. The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus, Streptococcus spp.*, Bacterial pulmonary infections caused by *Brucella bronchiseptica, Streptococcus pyogenes, Staphylococcus aureus*, secondary bacterial infections caused by *Micrococcus pyogenes var. albus, Brucella bronchiseptica, Streptococcus spp.*

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered

in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983; 79 FR 16192, Mar. 25, 2014]

§ 522.1664 Oxytetracycline and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.286 and 556.500 of this chapter.

(d) *Conditions of use cattle*—(1) *Amount.* Administer once as an intramuscular or subcutaneous injection of 1 mL per 22 pounds (lb) body weight (BW) (13.6 mg oxytetracycline and 0.9 mg flunixin per lb BW) where retreatment of calves and yearlings for bacterial pneumonia is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.

(2) *Indications for use.* For the treatment of bacterial pneumonia associated with *Pasteurella* spp. and for the control of associated pyrexia in beef and nonlactating dairy cattle.

(3) *Limitations.* Discontinue treatment at least 21 days prior to slaughter of cattle. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 3489, Jan. 20, 2011, as amended at 79 FR 16192, Mar. 25, 2014]

§ 522.1680 Oxytocin.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

(b) *Sponsors.* See Nos. 054771 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cats	0.25 to 0.5	5 to 10.
Dogs	0.25 to 1.5	5 to 30.
Ewes, Sows	1.5 to 2.5	30 to 50.
Cows, Horses	5.0	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cows	0.5 to 1.0	10 to 20.
Sows	0.25 to 1.0	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1680, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 522.1684 Pegbovigrastim.

(a) *Specifications.* Each pre-filled, single-dose syringe contains 15 milligrams of pegbovigrastim.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* Administer the first dose (syringe) by subcutaneous injection 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within

a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) by subcutaneous injection within 24 hours after calving.

(2) *Indications for use.* For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 36789, June 8, 2016, as amended at 81 FR 48702, July 26, 2016]

§ 522.1696 Penicillin G procaine injectable dosage forms.

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 054771, 055529, and 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 016592, 055529, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) No. 054771 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Horses, dogs, and beef cattle*—(i) *Amount*—(A) *Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations.* Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle*—(i) *Amount.* 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Actinomyces pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*A. pyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations.* Not for use within 30 days of slaughter. For Nos. 000859, 055529, and 061623: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

[66 FR 711, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 70 FR 21947, Apr. 28, 2005; 70 FR 50182, Aug. 26, 2005; 73 FR 16754, Mar. 31, 2008; 75 FR 54017, Sept. 3, 2010; 77 FR 4897, Feb. 1, 2012; 78 FR 17597, Mar. 22, 2013; 79 FR 16192, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016]

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 016592, 054771, and 055529 for use as in paragraph (d) of this section.

(2) No. 061623 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use.* Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount.* 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000859, 054771, 055529, and 061623: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use.* Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix rhusiopathiae*; and horses for strangles caused by *Streptococcus equi.*

(iii) *Limitations.* Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 054771 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 000859 and 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 68 FR 42589, July 18, 2003; 69 FR 17586, Apr. 5, 2004; 70 FR 16935, Apr. 4, 2005; 73 FR 14177, Mar. 17, 2008; 75 FR 54017, Sept. 3, 2010; 78 FR 17597, Mar. 22, 2013; 79 FR 16192, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016]

§ 522.1696c Penicillin G procaine in oil.

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Dogs and cats—10,000 units per pound of body weight once daily. Horses—3,000 units per pound of body weight once daily.

(2) *Indications for use.* Treatment of infections of dogs, cats, and horses caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(3) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 79 FR 16193, Mar. 25, 2014]

§ 522.1698 Pentazocine.

(a) *Specifications.* Each milliliter of solution contains pentazocine lactate equivalent to 30 milligrams (mg) of pentazocine base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer 0.15 mg pentazocine base per pound of body weight daily by intravenous or intramuscular injection. In cases of severe pain, a second dose is recommended by intramuscular injection 10 to 15 minutes after the initial dose at the same level.

(ii) *Indications for use.* For symptomatic relief of pain due to colic.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer 0.75 to 1.50 mg of pentazocine base per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For amelioration of pain accompanying postoperative recovery, fracture, trauma, and spinal disorders.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 31450, June 21, 1977, as amended at 42 FR 36995, July 19, 1977; 47 FR 5409, Feb. 5, 1982; 55 FR 23076, June 6, 1990; 79 FR 16193, Mar. 25, 2014]

§ 522.1704 Pentobarbital.

(a) *Specifications.* Each milliliter of solution contains 64.8 milligrams (mg) of sodium pentobarbital.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The drug is administered intravenously ''to effect''. For general surgical anesthesia, the usual dose is 11 to 13 mg per pound of body weight. For sedation,

the usual dose is approximately 2 mg per pound of body weight. For relieving convulsive seizures caused by strychnine in dogs, the injection should be administered intravenously ''to effect''. The drug may be administered intraperitoneally. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration.

(2) *Indications for use.* The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16193, Mar. 25, 2014]

§ 522.1720 Phenylbutazone.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) of phenylbutazone.

(2) Each milliliter of solution contains 200 mg of phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(2) Nos. 000061, 000859, 054771, and 061623 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(3) Nos. 054628 and 058005 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by intravenous injection 10 mg per pound of body weight daily in three divided doses, not to exceed 800 mg daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(ii) *Indications for use.* It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* Administer by intravenous injection 1 to 2 grams (g) per 1,000 pounds of body weight daily in three divided doses, not to exceed 4 g daily. Limit intravenous administration to not more than 5 successive days.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16193, Mar. 25, 2014]

§ 522.1820 Pituitary luteinizing hormone powder for injection.

(a) *Specifications.* The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Cattle and horses: 25 milligrams; swine: 5 milligrams; sheep: 2.5 milligrams; and dogs: 1.0 milligram. Preferably given by intravenous injection, it may be administered subcutaneously. Treatment may be repeated in 1 to 4 weeks, or as indicated.

(2) *Indications for use.* As an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 16193, Mar. 25, 2014]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications.* (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.

(2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials

contains 100 mg polysulfated glycosaminoglycan.

(b) *Sponsor.* See No. 010797 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Indications for use.* For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount*—(A) *Intra-articular use (carpal)*: 250 mg once a week for 5 weeks.

(B) *Intramuscular use (carpal and hock)*: 500 mg every 4 days for 28 days.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Dogs*—(i) *Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount.* 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

[72 FR 56896, Oct. 5, 2007, as amended at 74 FR 67816, Dec. 21, 2009]

§ 522.1862 Pralidoxime powder for injection.

(a) *Specifications.* Each vial contains 1 gram (g) of pralidoxime chloride powder for mixing with 20 cubic centimeters of sterile water for injection. Each milliliter of constituted solution contains 50 milligrams (mg) pralidoxime chloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 mg per pound of body weight, followed by administration of an additional 0.15 mg of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 g per horse. When administered to dogs and cats, it is 25 mg per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(2) *Indications for use.* It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16193, Mar. 25, 2014]

§ 522.1870 Praziquantel.

(a) *Specifications.* Each milliliter (mL) of solution contains 56.8 milligrams of praziquantel.

(b) *Sponsors.* See Nos. 000859 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by subcutaneous or intramuscular injection for dogs and puppies 5 pounds (lb) and under, 0.3 mL; for 6 to 10 lb, 0.5 mL; for 11 to 25 lb, 1.0 mL; if over 25 lb, 0.2 mL/5 lb body weight to a maximum of 3 mL.

(ii) *Indications for use.* For removal of canine cestodes *Dipylidium caninum, Taenia pisiformis,* and *Echinococcus granulosus,* and removal and control of canine cestode *Echinococcus multilocularis.*

(iii) *Limitations.* Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer by subcutaneous or intramuscular injection for cats and kittens under 5 lb, 0.2 mL; 5 to 10 lb, 0.4 mL; 11 lb and over, 0.6 mL maximum.

(ii) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis.*

(iii) *Limitations.* Federal law restricts the drug to use by or on the order of a licensed veterinarian.

[46 FR 10464, Feb. 3, 1981, as amended at 47 FR 6617, Feb. 16, 1982; 58 FR 42853, Aug. 12, 1993; 67 FR 79853, Dec. 31, 2002; 78 FR 17868, Mar. 25, 2013; 81 FR 67151, Sept. 30, 2016]

§ 522.1881 Prednisolone acetate.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) of prednisolone acetate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The drug is administered to horses intra-articularly at a dosage level of 50 to 100 mg. The dose may be repeated when necessary. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 mg. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 mg. The dose may be repeated when necessary after 7 days for two or three doses.

(2) *Indications for use.* The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and postoperatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1883 Prednisolone sodium phosphate.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer intravenously in a dosage of 2½ to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) *Indications for use.* Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 59881, Oct. 20, 2003]

§ 522.1884 Prednisolone sodium succinate.

(a) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams (mg) of prednisolone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for products containing 10, 20, and 50 mg equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (c)(1)(i), (ii), and (iii) of this section.

(c) *Conditions of use*—(1) *Amount and indications for use*—(i) *Horses.* Administer 50 to 100 mg as an initial dose by intravenous injection over a period of one-half to 1 minute, or by intramuscular injection, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.

(ii) *Dogs.* Administer by intravenous injection at a range of 2.5 to 5 mg per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) *Dogs and cats.* Administer by intramuscular injection for treatment of inflammatory, allergic, and less severe stress conditions, where immediate effect is not required, at 1 to 5 mg ranging upward to 30 to 50 mg in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to

5 days if necessary. If permanent corticosteroid effect is required, oral therapy with prednisolone tablets may be substituted.

(2) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1885 Prednisolone tertiary butylacetate.

(a) *Specifications.* Each milliliter of suspension contains 20 milligrams (mg) of prednisolone tertiary butylacetate.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* Administer by intramuscular injection 100 to 300 mg or by intrasynovial injection at a dosage level of 50 to 100 mg. Retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.

(ii) *Dogs and cats:* Administer by intramuscular injection 1 mg per 5 pounds of body weight or intrasynovially at a dosage level of 10 to 20 mg.

(2) *Indications for use.* It is used as an anti-inflammatory agent in horses, dogs, and cats.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1890 Sterile prednisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 10 to 40 milligrams (mg) of prednisone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses.* Administer 100 to 400 mg by intramuscular injection, repeating if necessary.

(ii) *Dogs and cats.* Administer 0.25 to 1.0 mg per pound of body weight by intramuscular injection for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.

(2) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each milliliter of solution contains prochlorperazine edisylate equivalent to 4 milligrams (mg) prochlorperazine and isopropamide iodide equivalent to 0.28 mg of isopropamide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in milliliters
Up to 4	0.25
5 to 14	0.5–1
15 to 30	2–3
30 to 45	3–4
45 to 60	4–5
Over 60	6

(ii) Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(2) *Indications for use.* For use in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1940 Progesterone and estradiol benzoate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), (c)(2)(iii), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1) and (c)(2) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(c) *Conditions of use in cattle.* It is used for implantation as follows:

(1) *Suckling beef calves*—(i) *Amount*—(A) 100 milligrams (mg) progesterone and 10 mg estradiol benzoate (one implant consisting of 4 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of 5 pellets, each of 4 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds (lb) of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers*—(i) *Amount*—(A) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 9 pellets, each of 8 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For animals weighing 400 lb or more; for subcutaneous ear implantation, one dose per animal. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* Reimplant 200 mg progesterone and 20 mg estradiol benzoate on approximately day 70 following an initial implant of 100 mg progesterone and 10 mg estradiol benzoate or 200 mg progesterone and 20 mg estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 70055, Dec. 2, 2004, as amended at 77 FR 31723, May 30, 2012; 79 FR 16194, Mar. 25, 2014; 81 FR 48702, July 26, 2016]

§ 522.1962 Promazine.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

(2) No. 061623 for use as in paragraphs (c)(1)(i)(B), (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*—(A) 0.2 to 0.5 milligrams per pounds (mg/lb) body weight intramuscularly or intravenously every 4 to 6 hours.

(B) 0.2 to 0.5 mg/lb body weight intravenously as required.

(ii) *Indications for use*—(A) For use as a tranquilizer, preanesthetic, or for minor operative procedures in conjunction with local anesthesia; and as adjunctive therapy for tetanus.

(B) For use as a tranquilizer and preanesthetic.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* 1 to 2 mg/lb body weight intramuscularly or intravenously every 4 to 6 hours.

(ii) *Indications for use.* For use as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic prior to worming; or to prevent motion sickness in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18962, Mar. 27, 1981, as amended at 68 FR 59881, Oct. 20, 2003; 70 FR 50183, Aug. 26, 2005; 79 FR 16194, Mar. 25, 2014]

§ 522.2002 Propiopromazine.

(a) *Specifications.* Each milliliter of solution contains 5 or 10 milligrams (mg) propiopromazine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amounts and indications for use.* Administer 0.05 to 0.5 mg per pound of body weight by intravenous or intramuscular injection for tranquilization. Administer 0.25 mg per pound of body weight by intravenous injection as a preanesthetic.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16195, Mar. 25, 2014]

§ 522.2005 Propofol.

(a) *Specifications.* Each milliliter of emulsion contains 10 milligrams (mg) propofol.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 086064 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 054771 for use as in paragraph (c) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection according to label directions. The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use*—(i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 20269, Apr. 19, 2010, as amended at 75 FR 38700, July 6, 2010; 78 FR 17868, Mar. 25, 2013; 79 FR 16195, Mar. 25, 2014; 80 FR 18776, Apr. 8, 2015; 81 FR 36789, June 8, 2016]

§ 522.2012 Prostalene.

(a) *Specifications.* Each milliliter of solution contains 1 milligram of prostalene.

(b) *Sponsor.* No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(2) *Indications for use.* For the control of estrus in mares.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16195, Mar. 25, 2014]

§ 522.2063 Pyrilamine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of pyrilamine maleate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for uses in paragraph (c) of this section.

(1) No. 000061 for use as in paragraph (c)(1)(i), (2), and (3) of this section.

(2) No. 061623 for use as in paragraph (c)(1)(ii), (2), and (3) of this section.

(c) *Conditions of use*—(1) *Amount*—(i) Horses, 40 to 60 mg per 100 pounds (lbs) body weight; foals, 20 mg/100 lbs body weight. Administer by intramuscular, subcutaneous, or intravenous injection. Dosage may be repeated every 6 to 12 hours whenever necessary.

(ii) Horses, 40 to 60 mg/100 lbs body weight; foals, 20 mg/100 lbs body weight. Administer by slow intravenous injection. Dosage may be repeated every 6 to 12 hours if necessary.

(2) *Indications for use.* It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16195, Mar. 25, 2014]

§ 522.2075 Robenacoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) robenacoxib.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.91 mg per pound (2 mg/kilogram (kg)) by subcutaneous injection, once daily, for a maximum of 3 days. After the initial subcutaneous dose, subsequent doses can be given by subcutaneous injection or as the oral tablet in dogs weighing at least 5.5 pounds (2.5 kg) and at least 4 months of age, for a maximum of 3 total doses over 3 days, not to exceed 1 dose per day. See § 520.2075(c)(1) of this chapter.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs at least 4 months of age for a maximum of 3 days.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.91 mg per pound (2 mg/kg) by subcutaneous injection, once daily, for a maximum of 3 days.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats at least 4 months of age for a maximum of 3 days.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 61297, Oct. 13, 2015, as amended at 82 FR 12170, Mar. 1, 2017]

§ 522.2076 Romifidine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) romifidine hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 40 to 120 micrograms per kilogram of body weight (mcg/kg BW) intravenously for sedation and analgesia; 100 mcg/kg BW intravenously as a preanesthetic.

(2) *Indications for use.* For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses; and for use as a preanesthetic prior to the induction of general anesthesia in adult horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 47363, Aug. 5, 2004, as amended at 79 FR 16195, Mar. 25, 2014]

§ 522.2100 Selenium and vitamin E.

(a)(1) *Specifications.* Each milliliter of emulsion contains 5.48 milligrams (mg) sodium selenite (equivalent to 2.5 mg selenium) and 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use in horses*—(i) *Amount.* Administer 1 milliliter (mL) per (/) 100 pounds (lbs) of body weight by intravenous injection or by deep intramuscular injection in divided doses in two or more sites in the gluteal or cervical muscles. Administration may be repeated at 5 to 10 day intervals.

(ii) *Indications for use.* For the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter contains 2.19 mg of sodium selenite (equivalent to 1 mg of selenium), 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs*—(i) *Amount.* Administer by subcutaneous or intramuscular injection in divided doses in two or more sites at 1 mL/20 lbs of body weight with a minimum dosage of ¼ mL and a maximum dosage of 5 mL. The dose is repeated at 3-day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which

consists of 1 mL per 40 lbs of body weight with a minimum dosage of ¼ mL which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

(ii) *Indications for use.* As an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter contains 2.19 milligrams of selenite sodium (equivalent to 1 milligram selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age or older: 1 milliliter per 40 pounds, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds. Sows: 1 milliliter per 40 pounds. Weanling pigs: 1 milliliter per 40 pounds, minimum 1 milliliter.

(ii) *Indications for use.* Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and weanling pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use. Not for use in newborn pigs. Do not use in pregnant ewes. Calves: Discontinue use 30 days before treated calves are slaughtered for human consumption. Lambs, ewes, sows, or pigs: Discontinue use 14 days before treated lambs, ewes, sows, or pigs are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter contains 10.95 milligrams selenite sodium (equivalent to 5 milligrams selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Breeding beef cows: 1 milliliter per 200 pounds of body weight during the middle third of gestation, and 30 days before calving. Weanling calves: 1 milliliter per 200 pounds of body weight.

(ii) *Indications for use.* Weanling calves and breeding beef cows: For the prevention and treatment of selenium-tocopherol deficiency syndrome.

(iii) *Limitations.* For subcutaneous or intramuscular use. Discontinue use 30 days before treated cattle are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter contains 0.55 milligram selenite sodium (equivalent to 0.25 milligram selenium), 50 milligrams (68 U.S.P. units) vitamin E.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Newborn lambs: 1 milliliter. Lambs 2 weeks of age or older: 4 milliliters. Baby pigs: 1 milliliter (or treat the sow during the last week of pregnancy).

(ii) *Indications for use.* Lambs: for prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Baby pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use only. Discontinue use 14 days before treated animals are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 57 FR 21209, May 19, 1992; 58 FR 57556, Oct. 26, 1993; 60 FR 57833, Nov. 22, 1995; 64 FR 27916, May 24, 1999; 79 FR 16195, Mar. 25, 2014]

§ 522.2112 Sometribove zinc suspension.

(a) *Specifications.* Each single-dose syringe contains 500 milligrams (mg) sometribove zinc in a prolonged-release suspension.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Inject 500 mg every 14 days starting during the 9th or 10th week (57 to 70 days) after calving and continue until the end of lactation.

(2) *Indications for use.* To increase production of marketable milk in healthy lactating dairy cows.

(3) *Limitations.* Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass. There is no milk discard or preslaughter withdrawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

[58 FR 59947, Nov. 12, 1993, as amended at 67 FR 18085, Apr. 15, 2002; 68 FR 62006, Oct. 31, 2003; 74 FR 53164, Oct. 16, 2009; 81 FR 48702, July 26, 2016]

§ 522.2120 Spectinomycin dihydrochloride injection.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. Each milliliter of the drug contains the following amount of spectinomycin activity from spectinomycin dihydrochloride pentahydrate:

(1) 5 milligrams when used as provided in paragraph (d)(1) of this section.

(2) [Reserved]

(3) 100 milligrams when used as provided in paragraphs (d) (2), (3), and (4) of this section.

(b) *Sponsor.* In § 510.600 of this chapter, see No. 016592 for conditions of use as in paragraph (d) of this section, and see No. 054771 for conditions of use as in paragraph (d)(2) and (d)(4) of this section.

(c) *Special considerations.* The quantity of spectinomycin referred to in this section refers to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* It is administered as spectinomycin dihydrochloride pentahydrate as follows:

(1) Subcutaneously in the treatment of 1-to-3-day-old turkey poults at the rate of 1 to 2 milligrams per poult as an aid in the prevention of mortality associated with Arizona group infection.

(2) Subcutaneously in the treatment of 1-to-3-day old:

(i) Turkey poults at the rate of 5 milligrams per poult as an aid in the control of chronic respiratory disease (CRD) associated with *E. coli.*

(ii) Baby chicks at the rate of 2.5 to 5 milligrams per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae*, *S. typhimurium*, *S. infantis*, and *E. coli.*

(3) Intramuscularly in the treatment of dogs:

(i) At a dosage level of 2.5 milligrams to 5.0 milligrams per pound of body weight twice daily. Treatment may be continued for 4 days. For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Administer single injection of 0.1 milliliter (10 milligrams) subcutaneously in nape of neck of 1- to 3-day-old turkey poults as an aid in control of airsacculitis associated with *M. meleagridis* sensitive to spectinomycin.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 9273, Mar. 7, 1978; 46 FR 18964, Mar. 27, 1981; 47 FR 14149, Apr. 2, 1982; 61 FR 5507, Feb. 13, 1996; 61 FR 31028, June 19, 1996; 65 FR 45877, July 26, 2000; 66 FR 22118, May 3, 2001; 79 FR 16195, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016]

§ 522.2121 Spectinomycin sulfate.

(a) *Specifications.* Each milliliter of solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 10 to 15 mg per kilogram of body weight at 24-hour intervals for 3 to 5 consecutive days.

(2) *Indications for use.* For the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

(3) *Limitations.* Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 31178, June 6, 2007, as amended at 79 FR 16195, Mar. 25, 2014]

§ 522.2150 Stanozolol.

(a) *Specifications.* Each milliliter of suspension contains 50 milligrams (mg) of stanozolol.

(b) *Sponsor.* No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* For cats and small breeds of dogs: 25 mg. For larger dogs: 50 mg. Administer by deep intramuscular injection in the thigh at weekly intervals, for several weeks.

(ii) *Horses.* Administer 25 mg per 100 pounds of body weight by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks.

(2) *Indications for use.* For use as an anabolic steroid treatment.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16195, Mar. 25, 2014]

§ 522.2200 Sulfachlorpyridazine.

(a) *Specifications.* Each milliliter of solution contains sodium sulfachlorpyridazine equivalent to 200 milligrams (mg) sulfachlorpyridazine.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use in calves.* It is used as follows:

(1) *Amount.* Administer 30 to 45 mg per pound (/lb) of body weight in divided doses by twice daily injection for 1 to 5 days.

(2) *Indications for use.* For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(3) *Limitations.* Treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[75 FR 10167, Mar. 5, 2010]

§ 522.2220 Sulfadimethoxine.

(a) *Specifications.* Each milliliter of solution contains:

(1) 100 milligrams (mg) of sulfadimethoxine sodium.

(2) 400 mg of sulfadimethoxine sodium.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054628 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) No. 054771 for use of the product described in paragraph (a)(2) as in paragraphs (d)(2), (3), and (4) of this section.

(3) Nos. 016592, 057561, and 061623 for use of the product described in paragraph (a)(2) as in paragraph (d)(4) of this section.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by subcutaneous, intramuscular, or intravenous injection at an initial dose of 25 mg per pound of body weight followed by 12.5 mg per pound of body weight every 24 hours thereafter. Continue treatment until the animal is free from symptoms for 48 hours.

(ii) *Indications for use.* For use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* Administer by intravenous or subcutaneous

injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours.

(ii) *Indications for use.* For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by *Streptococci*, *Staphylococci*, *Escherichia*, *Salmonella*, *Klebsiella*, *Proteus*, or *Shigella* organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Horses*—(i) *Amount.* Administer by intravenous injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of respiratory disease caused by Streptococcus equi (strangles).

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Cattle*—(i) *Amount.* Administer an initial dose of 25 mg per pound of body weight by intravenous injection followed by 12.5 mg per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[79 FR 16196, Mar. 25, 2014, as amended at 81 FR 22524, Apr. 18, 2016]

§ 522.2240 Sulfaethoxypyridazine.

(a) *Specifications.* The drug is an aqueous solution of sulfaethoxypyridazine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 2.5 grams per 100 pounds of body weight per day by intravenous injection for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxypyridazine in drinking water or tablets in accordance with §§ 520.2240a(e) and 520.2240b(e) of this chapter.

(2) *Indications for use.* For treatment of respiratory infection (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(3) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

§ 522.2260 Sulfamethazine.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams (mg) sulfamethazine sodium.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Initially administer 20 mL for each 50 pounds (lb) of body weight (100 mg/lb) by intravenous injection, followed by 20 mL per 100 lb of body weight (50 mg/lb) by intravenous injection, daily thereafter. Treatment should not exceed a total of 5 consecutive days.

(2) *Indications for use.* For cattle for treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*),

acute mastitis and acute metritis (*Streptococcus* spp.) when caused by one or more pathogenic organisms sensitive to sulfamethazine.

(3) *Limitations.* Withdraw medication from cattle 10 days prior to slaughter. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 62055, Dec. 22, 1981, as amended at 67 FR 78355, Dec. 24, 2002; 75 FR 10167, Mar. 5, 2010; 76 FR 53051, Aug. 25, 2011; 81 FR 17608, Mar. 30, 2016]

§ 522.2340 Sulfomyxin.

(a) *Specifications.* Sulfomyxin for injection is sterile. It is derived from the antibiotic substance produced by the growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.700 of this chapter.

(e) *Conditions of use.* (1) It is used or intended for use in chickens and turkeys as an aid in the treatment of disease caused or complicated by *E. coli*, such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens (units)	Turkeys (units)
1 to 14	12,500	12,500
15 to 28	25,000	25,000
29 to 63	50,000	50,000
Over 63	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter; do not treat turkeys within 7 days of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

§ 522.2404 Thialbarbitone sodium for injection.

(a) *Specifications.* Thialbarbitone sodium for injection when reconstituted with sterile distilled water provides 94 milligrams of thialbarbitone sodium per milliliter of solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered as a general anesthetic in surgical procedures on dogs, cats, swine, sheep, cattle, and horses. The drug is used for procedures of relatively short duration. However, the period of anesthesia can be lengthened by slower initial injection and supplemental administration during surgery.

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a preanesthetic sedation be administered to the horse 30 minutes before the drug is administered. The drug is then injected rapidly and completely. The drug is used at the following dosage levels:

Species	Weight of animal in pounds	Dosage in milligrams per pound
Dog	Over 50	14.1
Do	30–50	18.8
Do	10–30	23.5
Do	Under 10	28.2
Cat		31.3–37.6
Horse		6.3–7.8
Cattle and swine		6.7–9.4
Calves and sheep		9.4–11.8

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

§ 522.2424 Thiamylal.

(a) *Specifications.* The drug is a sterile powder. It is reconstituted with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by intravenous injection to effect. The average single dose is:

(i) *Dogs and cats:* 8 milligrams (mg) per pound of body weight (when used

with a preanesthetic, generally one-half the normal dose).

(ii) *Swine:* 40 mg per 5 pounds (lbs) of body weight.

(iii) *Horses:* Light anesthesia, 1 gram per 500 lbs to 1,100 lbs of body weight; deep anethesia, 1 gram per 300 lbs of body weight (40 mg/12 lbs of body weight).

(iv) *Cattle:* Short duration, 20 mg/5 lbs of body weight; longer duration, 40 mg/7 lbs of body weight.

(2) *Indications for use.* It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

§ 522.2444 Thiopental injectable dosage forms.

§ 522.2444a Thiopental powder for injection.

(a) *Specifications.* The drug contains sodium thiopental powder for constitution with sterile water for injection.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection as follows:

(i) 6 to 9 milligrams (mg) per pound of body weight for brief anesthesia (6 to 10 minutes).

(ii) 10 to 12 mg per pound of body weight for anesthesia of 15 to 25 minutes duration.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

§ 522.2444b Thiopental and pentobarbital powder for injection.

(a) *Specifications.* Each gram of powder contains 750 milligrams (mg) of sodium thiopental and 250 mg of sodium pentobarbital powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For total anesthesia, it is given at approximately 10 to 12 mg per pound of body weight over a period of 3.5 to 5 minutes. When preanesthetic medication is used, wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually ½ to ⅔ the normal amount is adequate.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014]

§ 522.2460 Tildipirosin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 180 milligrams (mg) tildipirosin.

(2) [Reserved]

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.733 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 4 mg/kg of bodyweight one time by subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and nonlactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 21 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 39391, July 3, 2012]

§ 522.2470 Tiletamine and zolazepam for injection.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains tiletamine hydrochloride equivalent to 50 milligrams (mg) of tiletamine base and zolazepam hydrochloride equivalent to 50 mg of zolazepam base.

(b) *Sponsors.* See Nos. 026637, 051311, and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Expressed as milligrams of the drug combination:

(i) *Healthy dogs.* An initial intramuscular dosage of 3 to 4.5 milligrams per pound (mg/lb) of body weight for diagnostic purposes; 4.5 to 6 mg/lb of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg/lb of body weight. The maximum total safe dose is 13.6 mg/lb of body weight.

(ii) *Healthy cats.* An initial intramuscular dosage of 4.4 to 5.4 mg/lb of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg/lb of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb of body weight.

(2) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes average) requiring mild to moderate analgesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014, as amended at 80 FR 34279, June 16, 2015; 82 FR 58556, Dec. 13, 2017]

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Special considerations.* (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 to 20 milligrams per kilograms (mg/kg) of body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*.

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 42 days of last treatment.

(2) *Sheep*—(i) *Amount.* 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia* (*P.*) *haemolytica*.

(iii) *Limitations.* Do not slaughter within 28 days of last treatment.

[67 FR 72367, Dec. 5, 2002, as amended at 75 FR 9334, Mar. 2, 2010; 81 FR 48703, July 26, 2016]

§ 522.2473 Tiludronate.

(a) *Specifications.* Each vial of powder contains 500 milligrams (mg) tiludronate disodium. Each milliliter

of constituted solution contains 20 mg tiludronate disodium.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer a single dose of 1 mg per kilogram (0.45 mg/pound) of body weight by intravenous infusion.

(2) *Indication for use.* For the control of clinical signs associated with navicular syndrome.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 18159, Apr. 1, 2014, as amended at 82 FR 21691, May 10, 2017]

§ 522.2474 Tolazoline.

(a) *Specifications.* Each milliliter of solution contains tolazoline hydrochloride equivalent to 100 milligrams (mg) of base activity.

(b) *Sponsor.* See No. 059399 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer slowly by intravenous injection 4 mg per kilogram of body weight or 1.8 mg per pound (4 milliliters (mL) per 100 kilograms or 4 mL per 220 pounds).

(2) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014, as amended at 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015]

§ 522.2476 Trenbolone acetate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 058198 for use as in paragraph (c) of this section.

(2) No. 000061 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(b) *Related tolerances.* See § 556.739 of this chapter.

(c) *Conditions of use*—(1) *Steers fed in confinement for slaughter*—(i) *Amount.* Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount.* Use last 63 days prior to slaughter.

(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[66 FR 47961, Sept. 17, 2001, as amended at 69 FR 70056, Dec. 2, 2004; 74 FR 61517, Nov. 25, 2009; 81 FR 48703, July 26, 2016]

§ 522.2477 Trenbolone acetate and estradiol.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 058198 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(E), (d)(1)(i)(F), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section.

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(G), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), (d)(3)(iii), (d)(4), and (d)(5) of this section.

(3) No. 054771 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(c) [Reserved]

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*—(i) *Amount.* (A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(E) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(G) 200 milligram (mg) trenbolone acetate and 40 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount.* (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(B) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 8 pellets, each of 7 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraphs (d)(2)(ii)(A) of this section.

(C) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(D) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(E) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(F) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—(i) *Amount.* (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(4) *Beef steers and heifers fed in confinement for slaughter*—(i) *Amount.* Each extended- and delayed-release implant contains 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Do not use in calves to be processed for veal. A withdrawal period has not been established for this product in pre-ruminating calves. Effectiveness and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (beef steers and heifers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

(5) *Beef heifers fed in confinement for slaughter*—(i) *Amount.* Each extended-release implant contains 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 6 coated and 4 uncoated pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol).

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Do not use in calves to be processed for veal. A withdrawal period has not been established for this product in pre-ruminating calves. Effectiveness and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (beef heifers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

[60 FR 4376, Jan. 23, 1995]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.2477, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications*—(1) Each implant consists of:

(i) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(2) Each extended release implant consists of:

(i) 8 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 6 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter.* (i) For an implant as described in paragraph (a)(1)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

(A) *Amount.* 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) For an implant as described in paragraph (a)(1)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

(A) *Amount.* 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture steers and heifers (slaughter, stocker, and feeder)*—(i) For an implant as described in paragraph (a)(2)(ii) of this section:

(A) *Amount.* 150 mg trenbolone acetate and 21 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) [Reserved]

[67 FR 78972, Dec. 27, 2002, as amended at 69 FR 67818, Nov. 22, 2004; 79 FR 16197, Mar. 25, 2014; 79 FR 64116, Oct. 28, 2014]

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

(b) *Sponsors.* See Nos. 000010 and 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*—(A) *Intramuscular or subcutaneous.* For inflammatory, arthritic, or allergic disorders, administer 0.05 to 0.1 mg per pound (/lb) of body weight as a single injection. For dermatologic disorders, administer 0.1 mg per pound (/lb) of body weight as a single injection. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.

(B) *Intralesional.* Administer 1.2 to 1.8 mg, divided in several injections around the lesion, spaced 0.5 to 2.5 centimeters apart, depending on lesion size. At any one site, the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(C) *Intra-articular and intrasynovial.* Administer 1 to 3 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders, and the management and treatment of acute arthritis and allergic and dermatologic disorders.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*—(A) *Intramuscular or subcutaneous.* Administer 0.01 to 0.02 mg/lb of body weight as a single injection. Usual dose is 12 to 20 mg.

(B) *Intra-articular and intrasynovial.* Administer 6 to 18 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10167, Mar. 5, 2010, as amended at 78 FR 21060, Apr. 9, 2013; 80 FR 34279, June 16, 2015]

§ 522.2582 Trifluprom azine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of trifluprom azine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs.* Administer by intravenous injection at a dosage of 0.5 to 1 mg per pound of body weight daily, or by intramuscular injection at a dosage of 1 to 2 mg per pound of body weight daily.

(ii) *Cats.* Administer by intramuscular injection at a dosage of 2 to 4 mg per pound of body weight daily.

(iii) *Horses.* Administer by intravenous or intramuscular injection at a dosage of 10 to 15 mg per 100 pounds of body weight daily to a maximum dose of 100 mg.

(2) *Indications for use.* For use in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014]

§ 522.2610 Trimethoprim and sulfadiazine.

(a) *Specifications.* Each milliliter (mL) contains:

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) Dogs—(i) *Amount.* 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use.* For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to Streptococcus zooepidemicus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

(ii) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 30803, May 31, 2006, as amended at 79 FR 16197, Mar. 25, 2014]

§ 522.2615 Tripelennamine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of tripelennamine hydrochloride.

(b) *Sponsors.* See Nos. 016592 and 051031 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* Administer 0.5 mg per pound of body weight by intravenous or intramuscular injection.

(ii) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations.* Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997; 78 FR 17597, Mar. 22, 2013; 79 FR 16198, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016; 82 FR 11508, Feb. 24, 2017]

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains:
(1) 100 milligrams (mg) tulathromycin
(2) 25 mg tulathromycin
(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section:
(1) Product described as in paragraph (a)(1) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.
(2) Product described as in paragraph (a)(2) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.
(c) *Related tolerances.* See § 556.745 of this chapter.
(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.
(ii) *Indications for use*—(A) *Beef and non-lactating dairy cattle.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis.* For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis.* For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii.*
(B) *Suckling calves, dairy calves, and veal calves.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis.*
(iii) *Limitations.* (A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
(B) Calves intended for human consumption must not be slaughtered within 22 days from the last treatment. Not for use in ruminating cattle. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
(2) *Swine*—(i) *Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.
(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.
(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009; 78 FR 63872, Oct. 25, 2013; 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015; 81 FR 67151, Sept. 30, 2016]

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter (mL) of solution contains 50 or 200 milligrams (mg) of tylosin activity (as tylosin base).
(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:
(1) No. 000986 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.
(2) Nos. 000010 and 061623 for use of a 200-mg/mL solution as in paragraphs (e)(1) and (2) of this section.
(c) *Related tolerances.* See § 556.740 of this chapter.
(d) *Special considerations.* Labeling must bear the warning statements: ''Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.''
(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 8 mg per pound (mg/lb) of body weight by intramuscular injection once daily for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes;* foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *A. pyogenes.*

(iii) *Limitations.* Do not inject more than 10 mL per site. Use a 50-mg/mL solution for calves weighing less than 200 pounds. Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves.

(2) *Swine*—(i) *Amount.* Administer 4 mg/lb of body weight by intramuscular injection twice daily for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. If tylosin medicated drinking water is used as a followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(ii) *Indications for use.* Treatment of swine arthritis caused by *Mycoplasma hyosynoviae;* swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae;* swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations.* Do not inject more than 5 mL per site. Adverse reactions, including shock and death may result from overdosage in baby pigs. It is recommended that tylosin 50-mg/mL injection be used in pigs weighing less than 25 lbs. Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product.

(3) *Dogs and cats*—(i) *Amount.* Administer 3 to 5 mg/lb of body weight by intramuscular injection at 12- to 24-hour intervals.

(ii) *Indications for use*—(A) *Dogs.* Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida.*

(B) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin-susceptible organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 67151, Sept. 30, 2016]

§ 522.2662 Xylazine.

(a) *Specifications.* Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

(1) 20 milligrams (mg) xylazine.

(2) 100 mg xylazine.

(3) 300 mg xylazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 054628 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) Nos. 000010 and 061623 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 059399 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(2) *Horses*—(i) *Amount.* 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(3) *Elk and deer*—(i) *Amount.* Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (*Cervus canadensis*): 0.25 to 0.5 mg/lb.

(B) Mule deer (*Odocoileus hemionus*), sika deer (*Cervus nippon*), and whitetailed deer (*Odocoileus virginianus*): 1 to 2 mg/lb.

(C) Fallow deer (*Dama dama*): 2 to 4 mg/lb.

(ii) *Indications for use.* (A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of fractious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following injury or surgery, and as a preanesthetic to local anesthetic. At the recommended dosages, can be used in conjunction with local anesthetics, such as procaine or lidocaine.

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

[68 FR 26206, May 15, 2003, as amended at 75 FR 10167, Mar. 5, 2010, 78 FR 21060, Apr. 9, 2013; 79 FR 16198, Mar. 25, 2014; 79 FR 21127, Apr. 15, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015]

§ 522.2670 Yohimbine.

(a) *Specifications.* Each milliliter (mL) of solution contains 2 or 5 milligrams (mg) of yohimbine (as hydrochloride).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 059399 for use of in 2 mg/mL solution as in paragraph (c)(1) of this section.

(2) No. 053923 for use of in 5 mg/mL solution as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.05 mg per pound (0.11 mg per kilogram) of body weight by intravenous injection.

(ii) *Indications for use.* To reverse the effects of xylazine in dogs.

(iii) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Deer and elk*—(i) *Amount.* Administer 0.2 to 0.3 mg per kilogram of body weight by intravenous injection.

(ii) *Indications for use.* A s an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 74020, Dec. 15, 2014, as amended at 80 FR 13230, Mar. 13, 2015]

§ 522.2680 Zeranol.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.760 of this chapter.

(d) *Conditions of use*—(1) *Beef cattle*—(i) *Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use*—(A) For increased rate of weight gain and improved feed conversion in weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers.

(B) For increased rate of weight gain in suckling calves.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1

month of age or after weaning in heifers intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Feedlot lambs*—(i) *Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[59 FR 19639, Apr. 25, 1994; 60 FR 26360, May 17, 1995, as amended at 62 FR 61625, Nov. 19, 1997; 64 FR 46840, Aug. 27, 1999; 67 FR 6867, Feb. 14, 2002; 70 FR 6764, Feb. 9, 2005]

§ 522.2690 Zinc gluconate.

(a) *Specifications.* Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) *Sponsor.* See No. 076175 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) *Indications for use.* Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26995, May 19, 2003, as amended at 76 FR 79064, Dec. 21, 2011]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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524.2350 Tolnaftate cream.
524.2482 Triamcinolone spray.
524.2483 Triamcinolone cream.
524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

§ 524.86 Amitraz.

(a) *Specifications.* Amitraz liquid contains 19.9 percent amitraz in an organic solvent.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For dogs for the treatment of generalized demodicosis (*Demodex canis*).

(2) *Amount.* One 10.6 milliliter bottle per 2 gallons of warm water (250 parts per million) for each treatment, for a total of 3 to 6 treatments, 14 days apart.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 18589, Apr. 30, 1982, as amended at 79 FR 10967, Feb. 27, 2014]

§ 524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains:

(1) 500 units bacitracin, 3.5 milligrams (mg) neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate; or

(2) 400 units bacitracin zinc, 5 mg neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(2) Nos. 000061, 043264, and 059399 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014; 80 FR 61297, Oct. 13, 2015]

§ 524.155 Bacitracin, neomycin, polymyxin B, and hydrocortisone ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 400 units of bacitracin zinc, 5 milligrams (mg) of neomycin sulfate (equivalent to 3.5 mg of neomycin sulfate), 10,000 units of polymyxin B sulfate, and10 mg of hydrocortisone.

(b) *Sponsors.* See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997; 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014]

§ 524.390 Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol.

(b) *Sponsors.* See Nos. 043264 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply every 3 hours around the clock for 48 hours, after which night instillations may be omitted.

(2) *Indications for use.* For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the use of this drug in food-producing animals.

[77 FR 4897, Feb. 1, 2012, as amended at 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014]

§ 524.402 Chlorhexidine.

(a) *Specifications.* Each gram of ointment contains 10 milligrams chlorhexidine acetate.

(b) *Sponsors.* See Nos. 054771 and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs, cats, and horses*—(1) *Indications for use.* For use as a topical antiseptic ointment for surface wounds.

(2) *Limitations.* Do not use in horses intended for human consumption.

[72 FR 265, Jan. 4, 2007, as amended at 79 FR 10967, Feb. 27, 2014]

§ 524.450 Clotrimazole.

(a) *Specifications.* Each gram of cream contains 10 milligrams of clotrimazole.

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply ¼-inch ribbon of cream per square inch of lesion once daily for 2 to 4 weeks.

(2) *Indications of use.* For the treatment of fungal infections of dogs and cats caused by *Microsporum canis* and *Trichophyton mentagrophytes.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 48128, July 18, 1980, as amended at 79 FR 10967, Feb. 27, 2014]

§ 524.463 Copper naphthenate.

(a) *Amount.* The drug is a 37.5 percent solution of copper naphthenate.

(b) *Sponsors.* See Nos. 017135, 054771, and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply daily to affected hooves until fully healed.

(2) *Indications for use.* As an aid in treating horses and ponies for thrush caused by organisms susceptible to copper naphthenate.

(3) *Limitations.* Use on horses and ponies only. Avoid contact around eyes. Do not contaminate feed. Do not use in horses intended for human consumption.

[47 FR 4250, Jan. 29, 1982, as amended at 68 FR 55825, Sept. 29, 2003; 71 FR 38074, July 5, 2006; 79 FR 10967, Feb. 27, 2014]

§ 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a ¼-inch strip of ointment directly on the cornea or into the conjunctival sac of the affected eye(s) every 12 hours.

(2) *Indications for use.* For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 48651, Sept. 20, 1995, as amended at 62 FR 48940, Sept. 18, 1997; 79 FR 10967, Feb. 27, 2014]

§ 524.590 Diclofenac.

(a) *Specifications.* Each gram of cream contains 10 milligrams diclofenac sodium.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply a 5-inch (5″) ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use in horses.* For the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 40767, July 7, 2004, as amended at 74 FR 26782, June 4, 2009; 74 FR 47436, Sept. 16, 2009]

§ 524.660 Dimethyl sulfoxide.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 90 percent dimethyl sulfoxide and 10 percent water.

(2) Each milliliter (mL) of gel product contains 90 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and dogs*—(1) *Amount*—(i) *Horses.* Apply topically two to three times daily in an amount not to exceed 100 mL per day. Total duration of therapy should not exceed 30 days.

(ii) *Dogs.* Apply topically three to four times daily in an amount not to exceed 20 mL per day. Total duration of therapy should not exceed 14 days.

(2) *Indications for use.* To reduce acute swelling due to trauma.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10967, Feb. 27, 2014]

§ 524.770 Doramectin.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) doramectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount*. Administer topically as a single dose 0.5 mg (1 mL) per kilogram (1 mL per 22 pounds) body weight.

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *Ostertagia ostertagi* (inhibited fourth-stage larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia pectinata* (adults), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris spp.* (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Solenopotes capillatus*; biting lice: *Bovicola (Damalinia) bovis*; mange mites: *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*; and to control infections and to protect from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Oesophagostomum radiatum* for 28 days; and with *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment; and to control infestations and to protect from reinfestation with *Linognathus vituli* for 42 days and with *Bovicola (Damalinia) bovis* for 77 days after treatment.

(3) *Limitations*. Do not slaughter cattle within 45 days of latest treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 48392, Aug. 10, 2004, as amended at 70 FR 43046, July 26, 2005; 79 FR 10967, Feb. 27, 2014]

§ 524.775 Emodepside and praziquantel.

(a) *Specifications*. Each milliliter of solution contains 21.4 milligrams (mg) emodepside and 85.7 mg praziquantel.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. The recommended minimum dose is 1.36 mg/pound (lb) (3 mg/kilogram (kg)) emodepside and 5.45 mg/lb (12 mg/kg) praziquantel applied as a single topical dose.

(2) *Indications for use*. For the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 42291, Aug. 2, 2007]

§ 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.

(a) *Specifications*. Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—Dogs*—(1) *Amount*. 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[65 FR 66620, Nov. 7, 2000, as amended at 79 FR 10967, Feb. 27, 2014]

§ 524.814 Eprinomectin.

(a) *Specifications*. Each milliliter (mL) contains 5 milligrams (mg) of eprinomectin.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.227 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) applied topically along backbone from withers to tailhead.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. viviparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

(3) *Limitations.* A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

[76 FR 72619, Nov. 25, 2011]

§ 524.900 Famphur.

(a) *Specifications.* The drug is in liquid form containing 13.2 percent famphur.

(b) *Sponsor.* See Nos. 000061 and 051311 in § 510.600(c) of this chapter.

(c) *Special considerations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Related tolerances.* See § 556.273 of this chapter.

(e) *Conditions of use*—(1) *Amount.* Apply 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, from the shoulder to the tail head as a single treatment. Apply as soon as possible after heel fly activity ceases.

(2) *Indications for use in beef and nonlactating dairy cattle.* For control of cattle grubs and to reduce cattle lice infestations.

(3) *Limitations.* Do not slaughter within 35 days after treatment. Do not use on lactating dairy cows or dry dairy cows within 21 days of freshening, calves less than 3 months old, animals stressed from castration, overexcitement or dehorning, sick or convalescent animals. Animals may become dehydrated and under stress following shipment. Do not treat until they are in good condition. Brahman and Brahman crossbreeds are less tolerant of cholinesterase-inhibiting insecticides than other breeds. Do not treat Brahman bulls. Swine should be eliminated from area where runoff occurs.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 34352, Aug. 30, 1984; 57 FR 7652, Mar. 4, 1992; 59 FR 28769, June 3, 1994; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997; 69 FR 41427, July 9, 2004; 79 FR 10968, Feb. 27, 2014]

§ 524.916 Fentanyl.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) fentanyl.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1.2 mg/lb (2.7 mg/kg) applied topically to the dorsal scapular area 2 to 4 hours prior to surgery.

(ii) *Indications for use.* For the control of postoperative pain associated with surgical procedures in dogs.

(iii) *Limitations.* Fentanyl is a Class II controlled substance. Observe all ''black-box warnings'' on product labeling. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012, as amended at 79 FR 44433, July 24, 2013; 81 FR 48703, July 26, 2016]

§ 524.920 Fenthion.

(a) *Specifications.* (1) The drug is a liquid containing:

(i) 3 percent of fenthion; or

(ii) 20 percent fenthion.

(2) The drug is a solution containing either 5.6 or 13.8 percent fenthion. Each concentration is available in 2 volumes

which are contained in single-dose applicators.

(b) *Sponsor*. See sponsors in § 510.600(c) of this chapter:

(1) No. 000859 for use of product described in paragraph (a)(1)(i) as in paragraph (d)(1) of this section.

(2) No. 000859 for use of product described in paragraph (a)(1)(ii) as in paragraph (d)(2) of this section.

(3) No. 000859 for use of products described in paragraph (a)(2) as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See 40 CFR 180.214.

(d) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount*. It is used at the rate of one-half fluid ounce per 100 pounds of body weight applied topically on the backline of the animal. Only one application per season should be made for grub control and this will also provide initial control of lice. A second application for lice control may be made if animals become reinfested, but no sooner than 35 days after the first treatment. Proper timing of treatment is important for grub control; cattle should be treated as soon as possible after heel-fly activity ceases.

(ii) *Indications for use.* For the control of grubs and lice in beef and nonlactating cattle.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Cattle should not be slaughtered within 35 days following a single treatment. If a second application is made for lice control, cattle should not be slaughtered within 45 days of the second treatment. The drug must not be used within 28 days of freshening of dairy cattle. If freshening should occur within 28 days after treatment, do not use milk as human food for the balance of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; or sick, convalescent, or stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious infectious diseases.

(2) *Beef cattle and dairy cattle not of breeding age*—(i) *Amount.* It is administered as a single, topical application placed on the backline of animals as follows: For animals weighing 150 to 300 pounds, apply 4 milliliters (mL); for animals weighing 301 to 600 pounds, apply 8 mL; for animals weighing 601 to 900 pounds, apply 12 mL; for animals weighing 901 to 1,200 pounds, apply 16 mL; and for animal weighing over 1,200 pounds, apply 20 mL. For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. A second application is required for animals heavily infested with lice or for those which become reinfested. A second application should be made no sooner than 35 days after the first treatment.

(ii) *Indications for use.* For control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Host-parasite reactions such as bloat, salivation, staggering and paralysis may sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gullet, or while the northern cattle grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated before these stages of grub development. Consult your veterinarian, extension livestock specialist, or extension entomologist regarding the timing of treatment. If it is impossible to determine the area from which the cattle came and/or exact stage of the grubs, it is recommended that the cattle receive only a maintenance ration of low-energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gullet. Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases. Do not slaughter within 45 days of treatment.

(3) *Dogs*—(i) *Amount.* Four to 8 milligrams per kilogram of body weight. Apply the contents of the proper size,

single-dose tube directly to one spot on the dog's skin.

(ii) *Indications for use.* For flea control on dogs only.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10968, Feb. 27, 2014]

§ 524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) florfenicol, 10 mg terbinafine, and 1 mg betamethasone acetate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of bacteria (*Staphylococcus pseudintermedius*) and yeast (*Malassezia pachydermatis*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 13230, Mar. 13, 2015]

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications.* Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 15 milligrams (mg) florfenicol, 13.3 mg terbinafine, and 2 mg mometasone furoate.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dropperette (1 mL) per affected ear(s).

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 76387, Dec. 9, 2015]

§ 524.960 Flumethasone, neomycin, and polymyxin B ophthalmic solution.

(a) *Specifications.* Each milliliter of ophthalmic preparation contains 0.10 milligram flumethasone, 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 units of polymyxin B sulfate, with or without hydroxypropyl methylcellulose.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Preparation containing hydroxypropyl methylcellulose.* Dogs: 1 to 2 drops per eye, every 6 hours.

(ii) *Preparation without hydroxyproply methylcellulose.* Dogs and cats: 2 to 3 drops per eye, every 4 hours.

(2) *Indications for use.* Treatment of the inflammation, edema, and secondary bacterial infections associated with topical ophthalmological conditions of the eye such as corneal injuries, incipient pannus, superficial keratitis, conjunctivitis, acute nongranulomatous anterior uveitis, kerato- conjunctivitis, and blepharitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 16012, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10968, Feb. 27, 2013]

§ 524.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) flunixin (equivalent to 83 mg flunixin meglumine).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Apply only once at a dose of 3.3 mg flunixin per kg body weight (1.5 mg/lb; 3 mL per 100 lbs) topically in a narrow strip along the dorsal midline from the withers to the tailhead.

(2) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease and the control of pain associated with foot rot in steers, beef heifers, beef cows, beef bulls intended for slaughter, and replacement dairy heifers under 20 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a

licensed veterinarian. Cattle must not be slaughtered for human consumption within 8 days of the last treatment. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in suckling beef calves, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

[83 FR 13635, Mar. 30, 2018]

§ 524.981 [Reserved]

§ 524.981a Fluocinolone cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount is applied to the affected area two or three times daily.

(2) *Indications for use.* For the relief of pruritis and inflammation associated with certain superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical burns and physical abrasions.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10968, Feb. 27, 2014]

§ 524.981b Fluocinolone solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount of solution is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses.

(ii) *Cats.* For the relief of pruritis and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

§ 524.981c Fluocinolone and neomycin cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide and 0.5 percent neomycin sulfate (0.35 percent neomycin base).

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—A small amount is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and nonspecific dermatoses.

(ii) *Dogs and cats.* Used in the treatment of wound infections.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

§ 524.981d Fluocinolone and dimethyl sulfoxide solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 1 to 2 milliliters into each anal sac following expression of anal sac contents.

(2) *Indications for use.* For the relief of impaction commonly present in apparently normal anal sacs, for the reversal of inflammatory changes associated with abnormal anal sacs, and to counteract the offensive odor of anal sac secretions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10969, Feb. 27, 2014]

§ 524.981e Fluocinolone and dimethyl sulfoxide otic solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 60 percent dimethyl sulfoxide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—Instill 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters.

(2) *Indications for use.* For the relief of pruritis and inflammation associated with acute and chronic otitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10969, Feb. 27, 2014]

§ 524.998 Fluralaner.

(a) *Specifications.* Each milliliter of solution contains 280 milligrams (mg) fluralaner.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(ii) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of *A. americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 18.2 mg/lb (40 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *D. variabilis* ticks.

(ii) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*) and the treatment and control of *I. scapularis* (black-legged tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater; for the treatment and control of *D. variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 67152, Sept. 30, 2016, as amended at 82 FR 43485, Sept. 18, 2017]

§ 524.1005 Furazolidone powder.

(a) *Specifications.* The product contains either 4 or 10 percent furazolidone in inert dispersing agent and propellant.

(b) *Sponsors.* (1) See No. 051031 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(2) See No. 017135 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

(c) *Conditions of use*—(1) *Amount.* Hold container about 6 to 12 inches from the eye or affected area and apply only enough powder to impart a light yellow color.

(2) *Indications of use*—(i) *Dogs.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and pyogenic dermatitis.

(ii) *Horses.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and following firing (heat or electrocautery).

(iii) [Reserved]

(iv) *Horses and ponies.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* sensitive to furazolidone.

(3) *Limitations.* For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug

once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Do not use in horses intended for human consumption.

[45 FR 49543, July 25, 1980, as amended at 50 FR 30153, July 24, 1985; 56 FR 50653, Oct. 8, 1991; 57 FR 31314, July 15, 1992; 60 FR 55659, Nov. 2, 1995; 65 FR 41588, July 6, 2000; 79 FR 10969, Feb. 27, 2014; 82 FR 11508, Feb. 24, 2017]

§ 524.1044 Gentamicin ophthalmic and topical dosage forms.

§ 524.1044a Gentamicin ophthalmic solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) *Sponsors.* See Nos. 000061 and 059399 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

(2) *Indications for use.* For the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 18776, Apr. 8, 2015]

§ 524.1044b Gentamicin and betamethasone otic solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amounts and indications for use*—(i) For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006]

§ 524.1044c Gentamicin ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) *Sponsors.* See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(2) *Indications for use.* For treatment of conjunctivitis caused by susceptible bacteria.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 47363, Aug. 5, 2004, as amended at 77 FR 64717, Oct. 23, 2012]

§ 524.1044d Gentamicin and betamethasone ointment.

(a) *Specifications.* Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*—(i) *Otitis externa.* Instill 3 to 8 drops into the ear canal twice daily for 7 days.

(ii) *Infected superficial lesions.* Apply to cover the treatment area twice daily for 7 to 14 days.

(2) *Indications for use.* For the treatment of acute and chronic otitis externa and infected superficial lesions caused by bacteria sensitive to gentamicin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 26378, June 18, 1982, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044e Gentamicin spray.

(a) *Specification.* Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 1.07 milligrams of gentamicin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* Hold the sprayer upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pump once. Treat once daily for up to 3 days.

(2) *Indications for use.* For the treatment of pinkeye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis.*

(3) *Limitations.* Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce similar signs. If conditions persists or increases, discontinue use and consult a veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended 52 FR 7833, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

§ 524.1044f Gentamicin and betamethasone spray.

(a) *Specifications.* Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) *Sponsors.* See Nos. 000061, 054925, 058005, 058829, and 065531 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use.* For the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 72 FR 5929, Feb. 8, 2007; 74 FR 22822, May 15, 2009; 77 FR 3598, Jan. 25, 2012]

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

(a) *Specifications.* Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram (g) tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 054925 for use of 7.5- or 15-g tubes; 10-, 15-, 25-, or 215-g bottles.

(3) No. 069043 for use of 10-, 20-, 40-, or 215-g bottles.

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill ointment twice daily into the ear canal for 7 consecutive days.

(i) From 7.5- or 15-g tubes; 10-, 12.5-, 15-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 20-, 40-, or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 38973, July 21, 1993, as amended at 63 FR 31932, June 11, 1998; 68 FR 42970, July 21, 2003; 70 FR 8291, Feb. 18, 2005; 71 FR 13542, Mar. 16, 2006; 71 FR 16481, Apr. 3, 2006; 71 FR 38261, July 6, 2006; 71 FR 56867, Sept. 28, 2006; 78 FR 17597, Mar. 22, 2013; 79 FR 10969, Feb. 27, 2014; 81 FR 17608, Mar. 30, 2016]

§ 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

(a) *Specifications.* Each gram of suspension contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate or mometasone furoate anhydrous, USP, equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

(2) *Indications for use.* For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 15370, Mar. 31, 2003; 70 FR 36338, June 23, 2005; 79 FR 10969, Feb. 27, 2014; 81 FR 59134, Aug. 29, 2016]

§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) *Specifications.* Each milliliter (mL) of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) of gentamicin base and 1 mg betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use.* For treatment of external eye infections and inflammation.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 54492, Sept. 8, 2010, as amended at 80 FR 13230, Mar. 13, 2015]

§ 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 1.11 milligrams (mg) hydrocortisone aceponate, 17.4 mg miconazole nitrate, and 1.5 mg gentamicin (as gentamicin sulfate).

(b) *Sponsor.* See No.051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill 1.0 mL in the affected ear once daily for 5 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 78150, Dec. 16, 2011, as amended at 83 FR 13635, Mar. 30, 2018]

§ 524.1140 Imidacloprid and ivermectin.

(a) *Specifications.* The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100 milligrams (mg) imidacloprid and 800 micrograms (µg) ivermectin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of Use in Dogs*—(1) *Amount.* The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 µg/lb (80 µg/kg) of ivermectin, topically once a month.

(2) *Indications for Use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 78685, Dec. 26, 2002]

§ 524.1146 Imidacloprid and moxidectin.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) imidacloprid and 25 mg moxidectin for use as in paragraph (d)(1) of this section.

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraphs (d)(2) and (d)(3) of this section.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use*—(A) For the prevention of heartworm disease caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(B) For treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*.

(2) *Cats*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(3) *Ferrets*—(i) *Amount*. Topically apply 9.0 mg/lb body weight (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

[72 FR 10597, Mar. 9, 2007, as amended at 78 FR 73698, Dec. 9, 2013]

§ 524.1193 Ivermectin topical solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 5 milligrams of ivermectin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 050604, 055529, 058829, 061623 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 016592, 054925, and 058005 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount*. One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenoptes capillatus*; and horn flies *Haematobia irritans*.

(ii) It controls infections and prevents reinfection with *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *C. punctata*, and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *O. ostertagi*, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) *Limitations.* Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

[55 FR 50551, Dec. 7, 1990, as amended at 62 FR 38908, July 21, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 44385, Aug. 19, 1998; 66 FR 13236, Mar. 5, 2001; 66 FR 63165, Dec. 5, 2001; 68 FR 3817, Jan. 27, 2003; 68 FR 4713, Jan. 30, 2003; 69 FR 501, Jan. 6, 2004; 69 FR 62181, Oct. 25, 2004; 71 FR 13542, Mar. 16, 2006; 72 FR 6464, Feb. 12, 2007; 74 FR 36112, July 22, 2009; 75 FR 26648, May 12, 2010; 76 FR 81807, Dec. 29, 2011; 78 FR 17597, Mar. 22, 2013; 78 FR 63872, Oct. 25, 2013; 81 FR 25328, Apr. 28, 2016; 83 FR 13635, Mar. 30, 2018]

§ 524.1195 Ivermectin otic suspension.

(a) *Specifications.* Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) *Indications for use.* For the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 7578, Jan. 24, 2001, as amended at 74 FR 26782, June 4, 2009]

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 3.5 milligrams kanamycin activity as kanamycin sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) *Indications for use.* For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10969, Feb. 27, 2014]

§ 524.1200b Kanamycin ophthalmic solution.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams kanamycin activity as kanamycin sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as frequently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) *Indications for use.* For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10970, Feb. 27, 2014]

§ 524.1204 Kanamycin, amphomycin, and hydrocortisone ointment.

(a) *Specifications.* Each gram of ointment contains 5 milligrams kanamycin activity as kanamycin sulfate, 5 milligrams of amphomycin activity as the calcium salt, and 10 milligrams of hydrocortisone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply to the affected areas of

the skin at least twice daily. In severe or widespread lesions it may be desirable to apply the ointment more than twice daily. After some improvement is observed, treatment can usually be reduced to once daily.

(2) *Indications for use.* For the treatment of acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcers, superficial wounds, and superficial abscesses associated with bacterial infections caused by organisms susceptible to one or both antibiotics.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10970, Feb. 27, 2014]

§ 524.1240 Levamisole.

(a) *Specifications.* The drug contains 200 milligrams of levamisole per milliliter of diethylene glycol monobutyl ether (DGME) solution.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use. Cattle*—(1) *Amount.* 2.5 milliliters per 110 pounds (10 milligrams of levamisole per kilogram) of body weight as a single dose topically to the back of the animal.

(2) *Indications for use.* Anthelmintic effective against stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*), and lungworms (*Dictyocaulus*).

(3) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Cattle must not be slaughtered within 9 days following last treatment. Do not administer to dairy animals of breeding age. Do not treat animals before dipping or prior to exposure to heavy rain. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before using in severely debilitated animals.

[52 FR 10887, Apr. 6, 1987, as amended at 53 FR 7504, Mar. 9, 1988; 62 FR 61626, Nov. 19, 1997; 67 FR 78355, Dec. 24, 2002; 79 FR 10970, Feb. 27, 2014]

§ 524.1376 2-Mercaptobenzothiazole solution.

(a) *Specifications.* The drug contains 1.3 percent 2-mercaptobenzothiazole in a suitable solvent.

(b) *Sponsor.* See 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply twice daily to affected area.

(2) *Indications for use.* For dogs as an aid in the treatment of hot spots (moist dermatitis) and as first aid for scrapes and abrasions.

(3) *Limitations.* Clip hair from affected area before applying. If no improvement is seen within 1 week, consult a veterinarian.

[48 FR 15618, Apr. 12, 1983, as amended at 65 FR 50913, Aug. 22, 2000; 68 FR 33381, June 4, 2003]

§ 524.1443 Miconazole.

(a) *Specifications*—(1) Each gram of cream contains miconazole nitrate equivalent to 20 milligrams miconazole base.

(2) Each gram of lotion or spray contains miconazole nitrate equivalent to 1 percent miconazole base.

(b) *Sponsors.* See § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000061 for use of cream, lotion, and spray;

(2) Nos. 054925 and 058829 for use of lotion and spray.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(2) *Indications for use.* For topical treatment of infections caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006]

§ 524.1445 Miconazole, polymixin B, and prednisolone suspension.

(a) *Specifications.* Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill five drops in the ear canal twice daily for 7 consecutive days.

(2) *Indications for use.* For the treatment of canine otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 4693, Jan. 29, 2010, as amended at 77 FR 46613, Aug. 6, 2012; 81 FR 48703, July 26, 2016]

§ 524.1446 Milbemycin otic solution.

(a) *Specifications.* Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One tube administered topically into each external ear canal.

(2) *Indications for use.* For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[65 FR 13905, Mar. 15, 2000, as amended at 66 FR 13849, Mar. 8, 2001]

§ 524.1450 Moxidectin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 5 milligrams (mg) moxidectin (0.5 percent solution).

(2) 25 mg moxidectin (2.5 percent solution).

(b) *Sponsors.* See sponsor numbers in § 510.600 of this chapter:

(1) No. 000859 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section;

(2) No. 000859 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer topically 0.5 mg per kilogram (kg) of body weight.

(ii) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus* (adult and L4)); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

(iii) *Limitations.* A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. See § 500.25 of this chapter.

(2) *Dogs*—(i) *Amount.* Administer topically a minimum of 1.1 mg per pound (lb) (2.5 mg/kg) of body weight, once monthly using the appropriate preloaded applicator tube.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*, as well as the treatment and control of intestinal hookworm (*Ancylostoma caninum* (adult, immature adult, and L4 larvae) and *Uncinaria stenocephala* (adult, immature adult, and L4 larvae)), roundworm (*Toxocara canis* (adult and L4 larvae) and *Toxascaris leonina*

(adult)), and whipworm (*Trichuris vulpis* (adult)) infections in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 lbs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 14036, Mar. 24, 1998, as amended at 65 FR 36617, June 9, 2000; 66 FR 46370, Sept. 5, 2001. Redesignated at 76 FR 48715, Aug. 9, 2011, as amended at 80 FR 53460, Sept. 4, 2015; 82 FR 21691, May 10, 2017]

§ 524.1465 Mupirocin.

(a) *Specifications.* Each gram of ointment contains 20 milligrams mupirocin.

(b) *Sponsors.* See Nos. 025463, 051672, and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply twice daily. Treatment should not exceed 30 days.

(2) *Indications for use.* For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *S. intermedius.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 18119, Apr. 11, 2007, as amended at 75 FR 79296, Dec. 20, 2010; 78 FR 52854, Aug. 27, 2013; 79 FR 10970, Feb. 27, 2014; 82 FR 11508, Feb. 24, 2017]

§ 524.1484 Neomycin ophthalmic and topical dosage forms.

§ 524.1484b Neomycin, isoflupredone, tetracaine, and myristyl-gamma-picolinium powder.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses, dogs, and cats*—(1) *Amount.* Apply to affected areas as a dusting powder.

(2) *Indications for use.* For the treatment or as adjunctive therapy of certain ear and skin conditions caused by or associated with neomycin-susceptible organisms and/or allergy; as a superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable; as a dusting powder following amputation of tails, claws, and dewclaws and following ear trimming, castrating, and such surgical procedures as ovariohysterectomies. For the treatment of acute otitis externa, acute moist dermatitis, and interdigital dermatitis in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014]

§ 524.1484c Neomycin, isoflupredone, and tetracaine ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(2) *Indications for use.* For the treatment of acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014]

§ 524.1484d Neomycin, hydrocortisone, and tetracaine otic ointment.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Instill a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily.

(2) *Indications for use.* For the treatment of ear canker and other inflammatory conditions of the external ear canal, acute otitis externa and, to a lesser degree, chronic otitis externa.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984; 79 FR 10970, Feb. 27, 2014]

§ 524.1484e Neomycin and polymyxin B ophthalmic solution.

(a) *Specifications.* Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill 1 to 2 drops per eye every 6 hours.

(2) *Indications for use.* For the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10970, Feb. 27, 2014]

§ 524.1484f Neomycin, prednisolone, and tetracaine otic suspension.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Instill 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use.* For the treatment of acute otitis externa and, to a lesser degree, chronic otitis externa; as treatment or adjunctive therapy of certain ear conditions caused by or associated with neomycin-susceptible organisms and/or allergy.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) thiabendazole, 3.2 mg neomycin (from neomycin sulfate), and 1 mg dexamethasone.

(b) *Sponsors.* See Nos. 026637 and 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (2 to 4 drops per square inch) twice daily. In treating otitis externa, instill 5 to 15 drops in the ear twice daily. Treat for up to 7 days.

(2) *Indications for use.* As an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 10971, Feb. 27, 2014; 80 FR 61297, Oct. 13, 2015]

§ 524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Rub a small amount into the affected area 1 to 3 times a day. After definite improvement, apply once daily or every other day.

(2) *Indications for use.* For the treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—dogs*—(1) *Amount.* Rub a small amount into the involved area 1 to 3 times a day. After definite improvement, it may be applied once a day or every other day.

(2) *Indications for use.* Treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations.* For use in dogs only. Shake drug thoroughly and clean lesion before using. If redness, irritation, or swelling persists or increases, discontinue use and reevaluate diagnosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484i Neomycin and hydrocortisone ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, and 5 milligrams of hydrocortisone acetate in each gram of ointment.[1]

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply 3 or 4 times daily into the conjunctival sac. With improvement, frequency may be reduced to 2 or 3 times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal 1 to 3 times daily.

(2) *Indications for use.* For the treatment of infections, allergic and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 40456, Sept. 12, 1978, as amended at 79 FR 10971, Feb. 27, 2014]

§ 524.1484j Neomycin and prednisolone ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate equivalent to 3.5 milligrams neomycin base.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition remains under control. Treatment may require from a few days to several weeks.

(2) *Indications for use.* For use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye, such as those associated with allergic reactions or gross irritants.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10971, Feb. 27, 2014]

§ 524.1484k Neomycin and prednisolone suspension.

(a) *Specifications.* Each milliliter of suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams

of neomycin sulfate equivalent to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* For beginning treatment of acute ocular inflammations place 1 or 2 drops in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, reduce the dosage to 1 drop 2 to 4 times daily. For otitis externa, place 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use.* For the treatment of treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10971, Feb. 27, 2014]

§ 524.1580 Nitrofurazone topical dosage forms.

§ 524.1580a Nitrofurazone ointment.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) See Nos. 054628, 054925, 058005, 059051, and 061623 for use on dogs, cats, or horses.

(2) See No. 017135 for use on dogs and horses.

(3) See Nos. 017153 and 058829 for use on horses.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain on the lesion for at least 24 hours. Use of a bandage is optional.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.

(3) *Limitations.* For use only on dogs, cats, and horses. Do not use on horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[46 FR 43402, June 27, 1980. Redesignated at 79 FR 10971, Feb. 27, 2014]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 524.1580a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 524.1580b Nitrofurazone soluble powder.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor.* See Nos. 054628 and 059051 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.

(3) *Limitations.* In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian. For use only on dogs, cats, and horses (not for food use).

[45 FR 43402, June 27, 1980, as amended at 47 FR 43368, Oct. 1, 1982; 48 FR 28984, June 24, 1983; 53 FR 40728, Oct. 18, 1988; 54 FR 30542, July 21, 1989; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997; 76 FR 17778, Mar. 31, 2011; 78 FR 21060, Apr. 9, 2013. Redesignated at 79 FR 10971, Feb. 27, 2014, as amended at 79 FR 64117, Oct. 28, 2014]

§ 524.1580c Nitrofurazone and butacaine ointment.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) *Sponsor.* See No. 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For prevention or treatment of surface bacterial infections of ears, wounds, burns, and cutaneous ulcers of dogs, cats, and horses.

(2) *Limitations.* Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The

dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[49 FR 9417, Mar. 13, 1984, as amended at 71 FR 13542, Mar. 16, 2006. Redesignated at 79 FR 10971, Feb. 27, 2014; 79 FR 10971, Feb. 27, 2014]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thiostrepton; and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsors.* For petrolatum base ointments see Nos. 000856, 025463, 054771, and 054925 in § 510.600(c) of this chapter. For vanishing cream base ointments see Nos. 025463, 054771, and 054925.

(c) *Conditions of use*—(1) *Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 29770, July 11, 1978; 50 FR 41490, Oct. 11, 1985; 53 FR 39257, Oct. 6, 1988; 54 FR 5431, Feb. 3, 1989; 54 FR 48090, Nov. 21, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 61 FR 63712, Dec. 2, 1996; 64 FR 42831, Aug. 6, 1999; 67 FR 67521, Nov. 6, 2002; 68 FR 55201, Sept. 23, 2003; 70 FR 50183, Aug. 26, 2005; 71 FR 13542, Mar. 16, 2006; 79 FR 10972, Feb. 27, 2014]

§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thiostrepton, and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Apply 1 drop of ointment to the affected eye(s) 2 or 3 times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For infectious kerato-conjunctivitis (pinkeye).

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985; 79 FR 10972, Feb. 27, 2014]

§ 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.

(a) *Specifications.* Each gram of suspension contains 10 milligrams (mg)

orbifloxacin, mometasone furoate monohydrate equivalent to 1 mg mometasone furoate, and 1 mg posaconazole.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. For dogs weighing less than 30 lbs. instill 4 drops once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops into the ear canal. Therapy should continue for 7 consecutive days.

(2) *Indications for use*. For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 16346, Apr. 1, 2010]

§ 524.1662 Oxytetracycline ophthalmic and topical dosage forms.

§ 524.1662a Oxytetracycline and hydrocortisone spray.

(a) *Specifications*. Each 3-ounce unit of oxytetracycline hydrochloride and hydrocortisone spray contains 300 milligrams of oxytetracycline hydrochloride and 100 milligrams of hydrocortisone with an inert freon propellant such that a 1-second spray treatment will deliver approximately 2.5 milligrams of oxytetracycline hydrochloride and 0.8 milligram of hydrocortisone.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds. Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon after the initial favorable response has been obtained.

(2) *Indications for use*. For the relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions; for the prevention of bacterial infections in superficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus.

(3) *Limitations*. Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10972, Feb. 27, 2014]

§ 524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.

(a) *Specifications*. Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer topically to the eye two to four times daily.

(2) *Indications for use*. For the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms including ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

(3) *Limitations*. Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10972, Feb. 27, 2014]

§ 524.1742 *N*-(Mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) emulsifiable liquid.

(a) *Specifications.* The emulsifiable liquid contains 11.6 percent *N*-(mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Methods of application.* Methods of application to control the following conditions on beef cattle:

To control/method of use	Dilution rate (gal. drug: gal. of water)
Grubs:	
Dip	1:60
Pour-on	1:2
Spray	1:49
Lice:	
Dip	1:60
Pour-on	1:2 or 1:5
Spray	1:49 or 1:100
Hornflies:	
Dip	1:60
Spray	1:49 or 1:100
Cattle Ticks:	
Dip	1:60 or 1:240
Spray	1:49
Southern cattle ticks:	
Dip	1:60 or 1:240
Spray	1:49
Scabies mites:.	
Dip	1:60
Lone Star Ticks:	
Dip	1:60
Spray	1:49 or 1:100

(i) *Dip vat procedure.* (*a*) Prior to charging vat, empty old contents and thoroughly clean the vat. Dip vats should be calibrated to maintain an accurate dilution. Add water, then drug to the vat according to the dilution rate indicated in the table. Add super phosphate at a rate of 100 pounds per 1,000 gallons of vat solution. Super phosphate is added to control the pH of the solution and ensure vat stability. Super phosphate is usually available at most fertilizer dealers as 0–45–0 or 0–46–0. Stir the dip thoroughly, preferably with a compressed air device; however, any form of thorough mixing is adequate. Re-stir vat contents prior to each use. During the dipping operation, each time the dip's volume is reduced by ⅛ to ¼ of its initial volume, replenish with water and add the drug at a rate of 1 gallon for each 50 or 200 gallons water added—depending on dilution rate 1:60 or 1:240. Also add super phosphate as necessary to maintain pH between 4.5 and 6.5. Stir well and resume dipping. Repeat replenishment process as necessary. For evaportion, add additional water accordingly. For added water due to rainfall, merely replenish dip with the product according to directions. If overflow occurs, either analyze for drug concentration and adjust accordingly or dispose of vat contents and recharge. Check pH after each addition of water or super phosphate to assure proper pH controls.

(*b*) *Dip maintenance.* (*1*) With use of dip vat tester, dipping may continue as long as the drug concentration is maintained between 0.15 and 0.25 percent, and the dip is not too foul for satisfactory use as indicated by foul odor or excessive darkening (i.e., color changes from beige to very dark brown).

(*2*) Without use of dip vat tester, vat should be emptied, cleaned, and recharged each time one of the following occurs: When the dip has been charged for 120 days; when the dip becomes too foul for satisfactory use, within the 120-day limit; if the number of animals dipped equals twice the number of gallons of the initial dip volume, within the 120-day limit.

(ii) *Spray method.* To prepare the spray, mix drug with water according to table and stir thoroughly. Apply the fresh mixture as a high-pressure spray, taking care to wet the skin, not just the hair. Apply to the point of ''runoff,'' about 1 gallon of diluted spray per adult animal. Lesser amounts will permit runoff for younger animals.

(iii) *Pour-on method.* Dilute the drug with water according to table by slowly adding water to the product while stirring. Apply 1 ounce of the diluted mixture per 100 pounds of body weight (to a maximum of 8 ounces per head) down the center line of the back.

(2) *Timing of applications for cattle grub control.* For optimum cattle grub control, it is important to treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal, as the rapid kill of large numbers of larvae in these tissues may cause toxic side effects, such as bloat, salivation, staggering, and paralysis.

(3) *Treatment regimens.* (i) Control of scabies mites requires two treatments, 10 to 14 days apart.

(ii) Control of Lone Star Ticks and hornflies requires two treatments, 7 days apart.

(4) *Warnings.* The drug is a cholinesterase inhibitor. Do not use this drug on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not apply within 21 days of slaughter. For use on beef cattle only. Do not treat sick, convalescent, or stressed cattle, or calves less than 3 months old except in Federal or State eradication programs where immediate treatment of all animals in an infested herd is mandatory. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty animals. Do not dip animals when overheated. Repeat treatment as necessary but not more often than every 7 to 10 days. Treatment for lice, ticks, hornflies, and scabies mites may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Treatment for lice, ticks, and scabies mites may be made any time 7 to 10 days following treatment for grubs. Do not treat grubs when the grub larvae are in the gullet or spinal canal. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear rubber gloves, goggles, and protective clothing. In case of skin contact, wash immediately with soap and water; for eyes, flush with water. Wash all contaminated clothing with soap and hot water before re-use.

(d) *Related tolerances.* See 40 CFR 180.261.

[40 FR 13873, Mar. 27, 1975, as amended at 46 FR 27914, May 22, 1981; 48 FR 39607, Sept. 1, 1983; 54 FR 51021, Dec. 12, 1989; 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997; 63 FR 5255, Feb. 2, 1998]

§ 524.1982 Proparacaine ophthalmic solution.

(a) *Specifications.* The drug is an aqueous solution containing 0.5 percent proparacaine hydrochloride, 2.45 percent glycerin as a stabilizer, and 0.2 percent chlorobutanol (choral derivative) and 1:10,000 benzalkonium chloride as preservatives.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*(1) *Amount.* It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to ten drops in the ear; for nasal use, instill five to ten drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(2) *Indications for use.* For use as a topical ophthalmic anesthetic. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected; as an aid in the removal of foreign bodies from the nose and ear canal; as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(3) *Limitations.* Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

(d) *Conditions of use.* (1) The drug is indicated for use as a topical ophthalmic anesthetic in animals. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in

minor surgery, and prior to catheterization.

(2) It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985; 79 FR 10972, Feb. 27, 2014]

§ 524.2098 Selamectin.

(a) *Specifications*. Each milliliter contains 60 or 120 milligrams of selamectin.

(b) *Sponsor*. See 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 2.7 milligrams of selamectin, topically, per pound (6 milligrams per kilogram) of body weight.

(2) *Indications for use*. Kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and control of tick (*Dermacentor variabilis*) infestations in dogs. Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. For dogs 6 weeks of age and older, and cats 8 weeks of age and older.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 37401, July 12, 1999, as amended at 64 FR 48707, Sept. 8, 1999; 65 FR 45282, July 21, 2000; 74 FR 19878, Apr. 30, 2009; 79 FR 10972, Feb. 27, 2014]

§ 524.2101 Selenium disulfide suspension.

(a) *Specifications*. The product contains 0.9-percent weight in weight (w/w) selenium disulfide (1-percent weight in volume (w/v)).

(b) *Sponsors*. See Nos. 000061, 017135, and 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use on dogs*—(1) *Indications for use*. For use as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and nonspecific dermatoses.

(2) *Amount*. One to 2 ounces per application.

(3) *Limitations*. Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if rash or irritation develops, discontinue use and consult a veterinarian.

[47 FR 53351, Nov. 26, 1982, as amended at 48 FR 32762, July 19, 1983; 54 FR 36962, Sept. 6, 1989; 56 FR 9623, Mar. 7, 1991; 58 FR 41025, Aug. 2, 1993; 63 FR 26981, May 15, 1998; 70 FR 50183, Aug. 26, 2005]

§ 524.2350 Tolnaftate cream.

(a) *Specifications*. The drug contains 1 percent tolnaftate in an anhydrous cream base.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Apply a small amount of the cream to the affected areas once or twice a day for 2 to 4 weeks.

(2) *Indications for use*. For the treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypseum*.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10972, Feb. 27, 2014]

§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 4916, Jan. 31, 2003, as amended at 78 FR 17868, Mar. 25, 2013]

§ 524.2483 Triamcinolone cream.

(a) *Specifications.* The vanishing cream contains 0.1 percent triamcinolone acetonide.

(b) *Sponsor.* See Nos. 000010 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Rub into affected areas two to four times daily for 4 to 10 days.

(2) *Indications for use.* For topical treatment of allergic dermatitis and summer eczema.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13542, Mar. 16, 2006, as amended at 73 FR 79318, Dec. 29, 2008. Redesignated and amended at 75 FR 10168, Mar. 5, 2010; 77 FR 60302, Oct. 3, 2012]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a) *Specifications*—(1) Each gram of liquid or aerosol contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Each gram of liquid or aerosol contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) in this section:

(1) No. 051079 for use of product described in paragraph (a)(1).

(2) No. 017135 for use of product described in paragraph (a)(2).

(c) *Conditions of use*—(1) *Amount.* Apply directly to the wound site.

(2) *Indications for use.* As an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate, and organic debris.

[79 FR 10973, Feb. 27, 2014]

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

526.88 Amoxicillin trihydrate for intramammary infusion.
526.313 Ceftiofur.
526.363 Cephapirin benzathine.
526.365 Cephapirin sodium.
526.464 Cloxacillin intramammary dosage forms.
526.464a Cloxacillin benzathine.
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526.820 Erythromycin.
526.1130 Hetacillin infusion.
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526.1696a Penicillin G procaine.
526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).
526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).
526.1696d Penicillin G procaine-novobiocin for intramammary infusion.
526.1810 Pirlimycin.

AUTHORITY: 21 U.S.C. 360b.

§ 526.88 Amoxicillin trihydrate for intramammary infusion.

(a) *Specifications.* Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use—Lactating cows*—(1) *Amount.* One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

(2) *Indications for use.* For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Straphylococcus aureus* (penicillin sensitive).

(3) *Limitations.* Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.313 Ceftiofur.

(a) *Specifications.* Each single-use, 10-milliliter syringe of ceftiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg ceftiofur equivalents.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use in cattle*—(1) *Lactating cows*—(i) *Amount.* Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use.* For use in lactating dairy cattle:

(A) For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae,* and *Escherichia coli;* and

(B) For the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *S. dysgalactiae.*

(iii) *Limitations.* Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

(2) *Dry cows*—(i) *Amount.* Infuse 500 mg per affected quarter at the time of dry off.

(ii) *Indications for use.* For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis.*

(iii) *Limitations.* Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. Following label use, no preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005. Redesignated and amended at 71 FR 39545, July 13, 2006; 79 FR 10973, Feb. 27, 2013; 79 FR 18159, Apr. 1, 2014; 80 FR 34279, June 16, 2015]

§ 526.363 Cephapirin benzathine.

(a) *Specifications.* Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Infuse the contents of one syringe into each quarter.

(2) *Indications for use.* Use in dry cows for treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*, including penicillin-resistant strains.

(3) *Limitations.* Infuse each quarter following last milking, but no later than 30 days before calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. For use in dry cows only.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988; 73 FR 12262, Mar. 7, 2008; 75 FR 10168, Mar. 5, 2010; 76 FR 17338, Mar. 29, 2011]

§ 526.365 Cephapirin sodium.

(a) *Specifications.* Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanut-oil gel.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse one dose into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

(2) *Indications for use.* For the treatment of mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus* including strains resistant to penicillin.

(3) *Limitations.* If improvement is not noted within 48 hours after treatment, consult your veterinarian. Milk that has been taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988. Redesignated at 63 FR 8349, Feb. 19, 1998; 65 FR 20733, Apr. 18, 2000; 73 FR 3181, Jan. 17, 2008; 75 FR 10168, Mar. 5, 2010]

§ 526.464 Cloxacillin intramammary dosage forms.

§ 526.464a Cloxacillin benzathine.

(a) *Specifications.* Each dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer aseptically into each quarter immediately after last milking.

(2) *Indications for use.* For the treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Animals infused with this product must not be slaughtered for food use for 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 75 FR 10168, Mar. 5, 2010; 75 FR 71017, Nov. 22, 2010; 79 FR 10973, Feb. 27, 2014]

§ 526.464b Cloxacillin benzathine for intramammary infusion, sterile.

(a) *Specifications.* Each 6 milliliter dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(1) *Amount.* 6 milliliters per infected quarter aseptically immediately after last milking at the time of drying-off of the cow.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococus agalactiae* in dairy cows at the time of drying-off of the cow.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for human food. Animals infused with this product must not be slaughtered for food from the time of infusion until 72 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(1) *Amount.* One dose per infected quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in nonlactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus.*

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.464c Cloxacillin sodium for intramammary infusion, sterile.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent to 20.0 milligrams of cloxacillin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use. Lactating cows*—(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus,* nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (four milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.820 Erythromycin.

(a) *Specifications.* (1) Each 6-milliliter, single-dose, disposable syringe contains 300 milligrams of erythromycin (as the base), 0.45 milligram of butylated hydroxyanisole, and 0.45 milligram of butylated hydroxytoluene.

(2) Each 12-milliliter, single-dose, disposable syringe contains 600 milligrams of erythromycin (as the base), 0.90 milligram of butylated hydroxyanisole, and 0.90 milligram of butylated hydroxytoluene.

(3) The vehicle is triglyceride of saturated fatty acids from coconut oil.

(4) The drug may or may not be sterile.

(b) *Sponsor.* See Nos. 054771 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) Lactating cows: After milking, cleaning, and disinfecting, infuse contents of a single 6-milliliter syringe into each infected quarter; repeat procedure at 12-hour intervals for a maximum of 3 consecutive infusions.

(ii) Dry cows: After milking, cleaning, and disinfecting, infuse contents of a single 12-milliliter syringe into each infected quarter at the time of drying off.

(2) *Indications for use.* Treatment of mastitis due to *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae,* and *Streptococcus uberis* in lactating or dry cows.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

[47 FR 15772, Apr. 13, 1982, as amended at 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 79 FR 10973, Feb. 27, 2014]

§ 526.1130 Hetacillin infusion.

(a) *Specifications.* Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use. Lactating cows*—(1) *Amount.* 10 milliliters of hetacillin potassium equivalent to 62.5 milligrams ampicillin into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

(2) *Indications for use.* Treating acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus aureus,* and *Escherichia coli.*

(3) *Limitations.* Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 75 FR 10168, Mar. 5, 2010]

§ 526.1590 Novobiocin infusion.

(a)(1) *Specifications.* Each 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount.* Ten milliliters (equivalent to 400 milligrams of novobiocin) infused in each quarter.

(ii) *Indications for use.* It is used in dry cows for the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae.*

(iii) *Limitations.* Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food use for 30 days following udder infusion. For udder installation for the treatment of mastitis in dry cows only.

(b)(1) *Specifications.* Each 10 milliliters of oil suspension contains the equivalent of 150 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount.* Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.

(ii) *Indications for use.* Use in lactating cows for treatment of mastitis caused by susceptible strains of *Staphylococcus aureus.*

(iii) *Limitations.* Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 10554, Mar. 14, 1978, as amended at 79 FR 10973, Feb. 27, 2014]

§ 526.1696 Penicillin intramammary dosage forms.

§ 526.1696a Penicillin G procaine.

(a) *Specifications.* Each 10-milliliter single-dose syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) *Related tolerances.* See § 556.510 of this chapter.

(c) *Sponsors.* See Nos. 010515 and 061623 in § 510.600(c) of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberus* in lactating cows.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) *Conditions of use in dry cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter at time of drying-off.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[73 FR 18442, Apr. 4, 2008, as amended at 74 FR 18990, Apr. 27, 2009]

§ 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows*—(1) *Amount.* One syringe into each quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae.*

(3) *Limitations.* Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992, as amended at 78 FR 21060, Apr. 9, 2013]

§ 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.

(b) *Sponsor.* See No. 042791 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows*—(1) *Amount.* One syringe per quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations.* Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 10965, Feb. 27, 2014]

§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) *Specifications.* For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Lactating cows*—(i) *Amount.* 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use.* Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis.*

(iii) *Limitations.* For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount.* 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use.* Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae.*

(iii) *Limitations.* For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be

slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 10973, Feb. 27, 2014]

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use.* For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis.*

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008; 79 FR 10973, Feb. 27, 2014]

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

Sec.

528.1070 Bc6 recombinant deoxyribonucleic acid construct.
528.1092 opAFP–GHc2 recombinant deoxyribonucleic acid construct.
528.2010 Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

§ 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use.* Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor.* See No. 086047 in § 510.600 of this chapter.

(c) *Limitations.* Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

[74 FR 6823, Feb. 11, 2009, as amended at 80 FR 34279, June 16, 2015]

§ 528.1092 opAFP–GHc2 recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of the α-form of the *opAFP–GHc2* recombinant deoxyribonucleic acid (rDNA) construct at the α-locus in the EO–1 α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*).

(b) *Sponsor.* See No. 086053 in § 510.600 of this chapter.

(c) *Indications for use.* Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) *Limitations.* These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

[80 FR 73104, Nov. 24, 2015]

§ 528.2010 Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of a human lysosomal acid lipase (hLAL) recombinant deoxyribonucleic acid (rDNA) gene construct located at the SYN LAL–C site in chromosome 6 in a specific, diploid line (SBC LAL–C) of hemizygous and homozygous domestic chickens (*Gallus gallus*), derived from the lineage progenitor XLL 109.

(b) *Sponsor*. See No. 069334 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Intended use*. The gene construct directs the expression of that encoding gene such that recombinant, human lysosomal acid lipase (rhLAL) protein intended for the treatment of human disease is present in SBC LAL–C chicken egg whites.

(2) *Limitations*. Food or feed from XLL 109 chickens is not permitted in the food or feed supply.

[81 FR 17608, Mar. 30, 2016]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.
529.56 Amikacin.
529.382 Chloramine-T.
529.400 Chlorhexidine tablets and suspension.
529.536 Detomidine.
529.539 Dexmedetomidine.
529.778 Doxycycline.
529.1030 Formalin.
529.1044 Gentamicin in certain other dosage forms.
529.1044a Gentamicin solution for infusion.
529.1044b Gentamicin solution for dipping eggs.
529.1115 Halothane.
529.1150 Hydrogen peroxide.
529.1186 Isoflurane.
529.1350 Meloxicam.
529.1660 Oxytetracycline.
529.1940 Progesterone intravaginal inserts.
529.2150 Sevoflurane.
529.2464 Ticarcillin.
529.2503 Tricaine methanesulfonate.
529.2620 Triptorelin.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.40 Albuterol.

(a) *Specifications*. A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals*. See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 7072, Feb. 15, 2002, as amended at 79 FR 10973, Feb. 27 , 2014]

§ 529.56 Amikacin.

(a) *Specifications*. Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors*. See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use*. For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 10973, Feb. 27, 2014]

§ 529.382 Chloramine-T.

(a) *Specifications*. Chloramine-T trihydrate powder for solution.

(b) *Sponsor*. See No. 086009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.118 of this chapter.

(d) *Conditions of use*—(1) *Freshwater-reared salmonids*—(i) *Amount*. 12 to 20 milligrams per liter (mg/L) water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use*. For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.

(2) *Walleye*—(i) *Amount.* 10 to 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare.*

(3) *Freshwater-reared warmwater finfish*—(i) *Amount.* 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared warmwater finfish due to external columnaris disease associated with *F. columnare.*

[79 FR 37621, July 2, 2014]

§ 529.400 Chlorhexidine tablets and suspension.

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet disolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.

(2) *Indications for use.* For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.

(3) *Limitations.* Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administrating solutions and suspensions. Treatment may be repeated in 48 to 72 hours.

[43 FR 10705, Feb. 23, 1979, as amended at 79 FR 10973, Feb. 27, 2014; 81 FR 67152, Sept. 30, 2016]

EDITORIAL NOTE: At 79 FR 10973, Feb. 27, 2014, § 529.400 was amended by revising the section heading, however, the section heading was not provided, therefore, the amendment could not be incorporated because of an inaccurate amendatory instruction.

§ 529.536 Detomidine.

(a) *Specifications.* Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use.* For sedation and restraint.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

§ 529.539 Dexmedetomidine.

(a) *Specifications.* Each milliliter of gel contains 0.09 milligrams (mg) dexmedetomidine (equivalent to 0.1 mg dexmedetomidine hydrochloride).

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer onto the oral mucosa between the dog's cheek and gum at a dose of 125 micrograms per square meter.

(2) *Indications for use.* For the treatment of noise aversion in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 17608, Mar. 30, 2016]

§ 529.778 Doxycycline.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(2) *Indications for use.* For treatment and control of periodontal disease.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10973, Feb. 27, 2014]

§ 529.1030 Formalin.

(a) *Specifications.* Formalin is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

(b) *Sponsors.* See Nos. 049968, 050378, and 067188 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is added to environmental water as follows:

(1) *Indications for use.* (i) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(ii) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and the monogeneans *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

(iii) All finfish eggs: For control of fungi of the family Saprolegniaceae.

(2) *Amount.* The drug concentrations required are as follows:

(i) For control of external protozoan parasites on shrimp:

Shrimp	Concentration of formalin (microliters per liter)	
	Tanks and raceways (up to 4 hours daily)	Earthen ponds (single treatment)
Penaeid Shrimp ...	50 to 100[1]	25[2]

[1] Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when tanks or raceways are heavily loaded with phytoplankton or shrimp, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.

[2] Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(ii) For control of external parasites on finfish:

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (μL/L or ppm))	Administer in earthen ponds single treatment (μL/L or ppm)
Salmon and trout:		
Above 50 °F	Up to 170	15 to 25[1 2]
Below 50 °F	Up to 250	15 to 25[1 2]
All other finfish	Up to 250	15 to 25[1 2]

[1] Use the lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

[2] Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

(iii) For control of fungi of the family Saprolegniaceae on finfish eggs: Eggs of all finfish except Acipenseriformes, 1,000 to 2,000 μL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 μL/L (ppm) for 15 minutes. A preliminary bioassay should be conducted on a small subsample of fish eggs to determine sensitivity before treating an entire group. This is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility.

(3) *Limitations.* Fish tanks and raceways may be treated daily until parasite control is achieved. Pond treatment may be repeated in 5 to 10 days if needed. However, pond treatments for *Ichthyophthirius* spp. should be made at 2-day intervals until control is achieved. Egg tanks may be treated as often as necessary to prevent growth of fungi. Do not use formalin which has been subjected to temperatures below 40 °F, or allowed to freeze. Treatments in tanks and raceways should never exceed 1 hour for fish or 4 hours for penaeid shrimp (even if they show no sign of distress), nor should it exceed 15 minutes for fish eggs. Do not apply formalin to ponds with water warmer than 27 °C (80 °F), when a heavy bloom of phytoplankton is present, or when the concentration of dissolved oxygen is less than 5 milligrams per liter.

[51 FR 11441, Apr. 3, 1986, as amended at 58 FR 59169, Nov. 8, 1993; 59 FR 60076, Nov. 22, 1994; 63 FR 38304, July 16, 1998; 68 FR 5563; Feb. 4, 2003; 72 FR 45158, Aug. 13, 2007; 76 FR 17339, Mar. 29, 2011; 79 FR 2786, Jan. 16, 2014; 82 FR 58556, Dec. 13, 2017]

§ 529.1044 Gentamicin in certain other dosage forms.

§ 529.1044a Gentamicin solution for infusion.

(a) *Specifications.* Each milliliter of solution contains 50 or 100 milligrams gentamicin sulfate.

(b) *Sponsors.* See Nos. 000061, 000859, 054628, 054771, 057561, 058005, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Infuse 2 to 2.5 grams per day for 3 to 5 days during estrus.

(2) *Indications for use.* For control of bacterial infections of the uterus (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 51727, Aug. 31, 2006, as amended at 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 10973, Feb. 27, 2014]

§ 529.1044b Gentamicin solution for dipping eggs.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in turkeys*—(1) *Amount.* The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the gentamicin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100 °F then immediately submerging them in gentamicin solution maintained at about 40 °F, keeping the eggs submerged for 10 to 15 minutes.

(2) *Indications for use.* As an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (*paracolon*), *Salmonella* Saintpaul, and *Mycoplasma meleagridis.*

(3) *Limitations.* For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

[40 FR 13881, Mar. 27, 1975, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 22889, Apr. 28, 1997; 71 FR 13543, Mar. 16, 2006; 79 FR 10973, Feb. 27, 2014]

§ 529.1115 Halothane.

(a) *Specifications.* The drug is a colorless, odorless, nonflammable, nonexplosive, heavy liquid containing 0.01 percent thymol as a preservative.

(b) *Sponsor.* See Nos. 012164 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Two to 5 percent of inhaled atmosphere for induction of anesthesia; 0.5 to 2 percent for maintenance of anesthesia.

(2) *Indications for use.* For nonfood animals for the induction and maintenance of anesthesia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 27915, May 22, 1981, as amended at 62 FR 29014, May 29, 1997; 79 FR 10973, Feb. 27, 2014]

§ 529.1150 Hydrogen peroxide.

(a) *Specifications.* Each milliliter of solution contains 396.1 milligrams (mg) hydrogen peroxide (a 35% w/w solution).

(b) *Sponsor.* See No. 050378 in § 510.600(c) of this chapter.

(c) *Conditions of use in finfish*—(1) *Amount*—(i) Freshwater-reared finfish eggs: 500 to 1,000 mg per liter (/L) of culture water for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs or 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all warmwater species of freshwater-reared finfish eggs.

(ii) Freshwater-reared salmonids: 100 mg/L for 30 minutes or 50 to 100 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

(iii) Coolwater species of freshwater-reared finfish fingerlings and adults (except northern pike & paddlefish) and channel catfish fingerlings and adults: 50 to 75 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath. Coolwater species of freshwater-reared finfish fry (except northern pike, pallid sturgeon & paddlefish) and channel catfish fry: 50 mg/L for 60 minutes once per day on alternate days for three treatments in

continuous flow water supply or as a static bath.

(2) *Indications for use.* For control of mortality in freshwater-reared finfish eggs due to saprolegniasis; for control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*; and for control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*).

(3) *Limitations.* Initial bioassay on a small number is recommended before treating the entire group. Eggs: Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider withholding treatment or using an alternate therapeutant during that sensitive time to reduce egg mortalities due to drug toxicity. Finfish: Use with caution on walleye. Preharvest withdrawal time: zero days.

[72 FR 5330, Feb. 6, 2007, as amended at 78 FR 73698, Dec. 9, 2013]

§ 529.1186 Isoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid.

(b) *Sponsors.* See Nos. 012164, 054771, 065085, and 066794 in § 510.600(c) of this chapter.

(c) *Conditions of use.* Administer by inhalation:

(1) *Amount*—(i) *Horses:* For induction of surgical anesthesia: 3 to 5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(ii) *Dogs:* For induction of surgical anesthesia: 2 to 2.5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(2) *Indications for use.* For induction and maintenance of general anesthesia in horses and dogs.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 594, Jan. 7, 1986, as amended at 54 FR 23472, June 1, 1989; 58 FR 17346, Apr. 2, 1993; 59 FR 44315, Aug. 29, 1994; 60 FR 40456, Aug. 9, 1995; 63 FR 8122, Feb. 18, 1998; 63 FR 24106, May 1, 1998; 66 FR 17510, Apr. 2, 2001; 71 FR 43967, Aug. 3, 2006; 74 FR 68530, Dec. 28, 2009; 76 FR 16533, Mar. 24, 2011; 78 FR 14669, Mar. 7, 2013; 78 FR 17868, Mar. 25, 2013; 80 FR 18776, Apr. 8, 2015; 82 FR 12170, Mar. 1, 2017]

§ 529.1350 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 mg per kilogram of body weight once daily using the metered dose pump.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 76863, Dec. 31, 2012, as amended at 80 FR 18776, Apr. 8, 2015]

§ 529.1660 Oxytetracycline.

(a) *Specifications*—(1) Each gram of powder contains 366 milligrams (mg) oxytetracycline hydrochloride.

(2) Each gram of powder contains 753 mg oxytetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(1) Nos. 054771 and 061623 for use of product in paragraph (a)(1) of this section.

(2) Nos. 054771, 061623, and 069254 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances. See* § 556.500 of this chapter.

(d) *Conditions of use in finfish*—(1) *Amount.* Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.

(2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 6557, Feb. 11, 2004, as amended at 69 FR 61999, Oct. 22, 2004; 70 FR 41140, July 18, 2005; 72 FR 26289, May 9, 2007; 76 FR 17026, Mar. 28, 2011; 79 FR 10973, Feb. 27, 2014; 81 FR 22524, Apr. 18, 2016; 81 FR 94991, Dec. 27, 2016]

§ 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains:

(1) 1.38 grams (g) progesterone in molded silicone over a nylon spine.

(2) 0.3 g progesterone in molded silicone over a flexible nylon spine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and the product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.540 of this chapter.

(d) *Special considerations.* Product labeling shall bear the following warning: ''Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations.''

(e) *Conditions of use*—(1) *Cows*—(i) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 mg dinoprost as a single intramuscular injection 1 day prior to insert removal (Day 6). When used for indications listed in paragraph (e)(1)(ii)(B) of this section, administer 25 mg dinoprost as a single intramuscular injection on the day of insert removal (Day 7).

(ii) *Indications for use*—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers; for advancement of first postpartum estrus in suckled beef cows; and for advancement of first pubertal estrus in replacement beef heifers.

(B) For synchronization of estrus in lactating dairy cows.

(C) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

(D) For induction of estrous cycles in anestrous lactating dairy cows.

(iii) *Limitations.* Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in beef cows that are fewer than 20 days postpartum. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, provided by No. 054771 in § 510.600(c) of this chapter.

(2) *Ewes*—(i) *Amount.* Administer one intravaginal insert per animal for 5 days.

(ii) *Indications for use.* For induction of estrus in ewes (sheep) during seasonal anestrus.

(iii) *Limitations.* Do not use in animals with abnormal, immature, or infected genital tracts; or in ewes that have never lambed. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use.

[74 FR 59074, Nov. 17, 2009, as amended at 75 FR 63085, Oct. 14, 2010; 79 FR 10965, 10974, Feb. 27, 2014; 79 FR 44278, July 31, 2014]

§ 529.2150 Sevoflurane.

(a) *Specifications.* Sevoflurane liquid.

(b) *Sponsors.* See Nos. 012164, 054771, and 066794 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For induction of surgical anesthesia: up to 7 percent sevoflurane. For maintenance of surgical anesthesia: 3.7 to 4 percent sevoflurane with oxygen in the absence of premedication and 3.3 to 3.6 percent in the presence of premedication.

(2) *Indications for use.* For induction and maintenance of general anesthesia in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 71640, Dec. 22, 1999, as amended at 73 FR 25508, May 7, 2008; 74 FR 10484, Mar. 11, 2009, 75 FR 1021, Jan. 8, 2010; 76 FR 16533, Mar. 24, 2011; 78 FR 17868, Mar. 25, 2013; 80 FR 18776, Apr. 8, 2015]

§ 529.2464 Ticarcillin.

(a) *Specifications.* Each vial contains ticarcillin disodium powder equivalent to 6 grams of ticarcillin for reconstitution with 25 milliliters of sterile water for injection or sterile physiological saline.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 6 grams daily by intrauterine infusion for 3 consecutive days during estrus.

(2) *Indications for use.* For the treatment of endometritis caused by beta-hemolytic streptococci.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 10974, Feb. 27, 2014]

§ 529.2503 Tricaine methanesulfonate.

(a) *Specifications.* The drug is ethyl-*m*-amino-benzoate methanesulfonate.

(b) *Sponsor.* See Nos. 050378 and 051212 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* It is used as follows:

(i) *Fish.* The drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic coldblooded animals.* The drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

[79 FR 10974, Feb. 27, 2014]

§ 529.2620 Triptorelin.

(a) *Specifications.* Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) *Sponsor.* See No. 051233 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) *Indications for use.* For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) *Limitations.* Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

[77 FR 64717, Oct. 23, 2012]

PART 530—EXTRALABEL DRUG USE IN ANIMALS

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AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

SOURCE: 61 FR 57743, Nov. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 530.1 Scope.

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.

§ 530.2 Purpose.

The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. This section implements the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103–396).

§ 530.3 Definitions.

(a) *Extralabel use* means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

(b) *FDA* means the U.S. Food and Drug Administration.

(c) The phrase *a reasonable probability that a drug's use may present a risk to the public health* means that FDA has reason to believe that use of a drug may be likely to cause a potential adverse event.

(d) The phrase *use of a drug may present a risk to the public health* means that FDA has information that indicates that use of a drug may cause an adverse event.

(e) The phrase *use of a drug presents a risk to the public health* means that FDA has evidence that demonstrates that the use of a drug has caused or likely will cause an adverse event.

(f) A *residue* means any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use.

(g) A *safe level* is a conservative estimate of a drug residue level in edible animal tissue derived from food safety data or other scientific information. Concentrations of residues in tissue below the safe level will not raise human food safety concerns. A safe level is not a safe concentration or a tolerance and does not indicate that an approval exists for the drug in that species or category of animal from which the food is derived.

(h) *Veterinarian* means a person licensed by a State or Territory to practice veterinary medicine.

(i) A *valid veterinarian-client-patient relationship* is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

§ 530.4 Advertising and promotion.

Nothing in this part shall be construed as permitting the advertising or promotion of extralabel uses in animals of approved new animal drugs or approved human drugs.

§ 530.5 Veterinary records.

(a) As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall be maintained either as individual records or, in food animal practices, on a group, herd, flock, or per-client basis. Records shall be adequate to provide the following information:

(1) The established name of the drug and its active ingredient, or if formulated from more than one ingredient, the established name of each ingredient;

(2) The condition treated;

(3) The species of the treated animal(s);

(4) The dosage administered;

(5) The duration of treatment;

(6) The numbers of animals treated; and

(7) The specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or any food which might be derived from any food animals treated.

(b) A veterinarian shall keep all required records for 2 years or as otherwise required by Federal or State law, whichever is greater.

(c) Any person who is in charge, control, or custody of such records shall, upon request of a person designated by FDA, permit such person designated by FDA to, at all reasonable times, have access to, permit copying, and verify such records.

Subpart B—Rules and Provisions for Extralabel Uses of Drugs in Animals

§ 530.10 Provision permitting extralabel use of animal drugs.

An approved new animal drug or human drug intended to be used for an extralabel purpose in an animal is not unsafe under section 512 of the act and is exempt from the labeling requirements of section 502(f) of the act if such use is:

(a) By or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and

(b) In compliance with this part.

§ 530.11 Limitations.

In addition to uses which do not comply with the provision set forth in § 530.10, the following specific extralabel uses are not permitted and result in the drug being deemed unsafe within the meaning of section 512 of the act:

(a) Extralabel use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian);

(b) Extralabel use of an approved new animal drug or human drug in or on an animal feed;

(c) Extralabel use resulting in any residue which may present a risk to the public health; and

(d) Extralabel use resulting in any residue above an established safe level, safe concentration or tolerance.

§ 530.12 Labeling.

Any human or animal drug prescribed and dispensed for extralabel use by a veterinarian or dispensed by a pharmacist on the order of a veterinarian shall bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. Such information shall include the following:

(a) The name and address of the prescribing veterinarian. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian;

(b) The established name of the drug or, if formulated from more than one active ingredient, the established name of each ingredient;

(c) Any directions for use specified by the veterinarian, including the class/species or identification of the animal or herd, flock, pen, lot, or other group of animals being treated, in which the drug is intended to be used; the dosage, frequency, and route of administration; and the duration of therapy;

(d) Any cautionary statements; and

(e) The veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal or animals.

§ 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.

(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:

(1) All relevant portions of this part have been complied with;

(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;

(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;

(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

(5) The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and

(6) All relevant State laws relating to the compounding of drugs for use in animals are followed.

(c) Guidance on the subject of compounding may be found in guidance documents issued by FDA.

Subpart C—Specific Provisions Relating to Extralabel Use of Animal and Human Drugs in Food-Producing Animals

§ 530.20 Conditions for permitted extralabel animal and human drug use in food-producing animals.

(a) The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:

(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.

(2) Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

(b) The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:

(1) Such use must be accomplished in accordance with an appropriate medical rationale; and

(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

(c) Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.

§ 530.21 Prohibitions for food-producing animals.

(a) FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

§ 530.22 Safe levels and analytical methods for food-producing animals.

(a) FDA may establish a safe level for extralabel use of an approved human drug or an approved new animal drug when the agency finds that there is a reasonable probability that an extralabel use may present a risk to the public health. FDA may:

(1) Establish a finite safe level based on residue and metabolism information from available sources;

(2) Establish a safe level based on the lowest level that can be measured by a practical analytical method; or

(3) Establish a safe level based on other appropriate scientific, technical, or regulatory criteria.

(b) FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level established under this part. If FDA requires the development of such an acceptable analytical method, the agency will publish notice of that requirement in the FEDERAL REGISTER.

(c) The extralabel use of an animal drug or human drug that results in residues exceeding a safe level established under this part is an unsafe use of such drug.

(d) If the agency establishes a safe level for a particular species or category of animals and a tolerance or safe concentration is later established through an approval for that particular species or category of animals, for that species or category of animals, the safe level is superseded by the tolerance or safe concentration for that species or category of animals.

§ 530.23 Procedure for setting and announcing safe levels.

(a) FDA may issue an order establishing a safe level for a residue of an extralabel use of an approved human drug or an approved animal drug. The agency will publish in the FEDERAL

REGISTER a notice of the order. The notice will include:

(1) A statement setting forth the agency's finding that there is a reasonable probability that extralabel use in animals of the human drug or animal drug may present a risk to the public health;

(2) A statement of the basis for that finding; and

(3) A request for public comments.

(b) A current listing of those drugs for which a safe level for extralabel drug use in food-producing animals has been established, the specific safe levels, and the availability, if any, of a specific analytical method or methods for drug residue detection will be codified in § 530.40.

§ 530.24 Procedure for announcing analytical methods for drug residue quantification.

(a) FDA may issue an order announcing a specific analytical method or methods for the quantification of extralabel use drug residues above the safe levels established under § 530.22 for extralabel use of an approved human drug or an approved animal drug. The agency will publish in the FEDERAL REGISTER a notice of the order, including the name of the specific analytical method or methods and the drug or drugs for which the method is applicable.

(b) Copies of analytical methods for the quantification of extralabel use drug residues above the safe levels established under § 530.22 will be available upon request from the Communications and Education Branch (HFV–12), Division of Program Communication and Administrative Management, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855. When an analytical method for the detection of extralabel use drug residues above the safe levels established under § 530.22 is developed, and that method is acceptable to the agency, FDA will incorporate that method by reference.

§ 530.25 Orders prohibiting extralabel uses for drugs in food-producing animals.

(a) FDA may issue an order prohibiting extralabel use of an approved new animal or human drug in food-producing animals if the agency finds, after providing an opportunity for public comment, that:

(1) An acceptable analytical method required under § 530.22 has not been developed, submitted, and found to be acceptable by FDA or that such method cannot be established; or

(2) The extralabel use in animals presents a risk to the public health.

(b) After making a determination that the analytical method required under § 530.22 has not been developed and submitted, or that such method cannot be established, or that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, FDA will publish in the FEDERAL REGISTER, with a 90-day delayed effective date, an order of prohibition for an extralabel use of a drug in food-producing animals. Such order shall state that an acceptable analytical method required under § 530.22 has not been developed, submitted, and found to be acceptable by FDA; that such method cannot be established; or that the extralabel use in animals presents a risk to the public health; and shall:

(1) Specify the nature and extent of the order of prohibition and the reasons for the prohibition;

(2) Request public comments; and

(3) Provide a period of not less than 60 days for comments.

(c) The order of prohibition will become effective 90 days after date of publication of the order unless FDA publishes a notice in the FEDERAL REGISTER prior to that date, that revokes the order of prohibition, modifies it, or extends the period of public comment.

(d) The agency may publish an order of prohibition with a shorter comment period and/or delayed effective date than specified in paragraph (b) of this section in exceptional circumstances (e.g., where there is immediate risk to the public health), provided that the order of prohibition states that the comment period and/or effective date have been abbreviated because there are exceptional circumstances, and the order of prohibition sets forth the agency's rationale for taking such action.

(e) If FDA publishes a notice in the FEDERAL REGISTER modifying an order

of prohibition, the agency will specify in the modified order of prohibition the nature and extent of the modified prohibition, the reasons for it, and the agency's response to any comments on the original order of prohibition.

(f) A current listing of drugs prohibited for extralabel use in animals will be codified in § 530.41.

(g) After the submission of appropriate information (i.e., adequate data, an acceptable method, approval of a new animal drug application for the prohibited extralabel use, or information demonstrating that the prohibition was based on incorrect data), FDA may, by publication of an appropriate notice in the FEDERAL REGISTER, remove a drug from the list of human and animal drugs prohibited for extralabel use in animals, or may modify a prohibition.

(h) FDA may prohibit extralabel use of a drug in food-producing animals without establishing a safe level.

Subpart D—Extralabel Use of Human and Animal Drugs in Animals Not Intended for Human Consumption

§ 530.30 Extralabel drug use in nonfood animals.

(a) Because extralabel use of animal and human drugs in nonfood-producing animals does not ordinarily pose a threat to the public health, extralabel use of animal and human drugs is permitted in nonfood-producing animal practice except when the public health is threatened. In addition, the provisions of § 530.20(a)(1) will apply to the use of an approved animal drug.

(b) If FDA determines that an extralabel drug use in animals not intended for human consumption presents a risk to the public health, the agency may publish in the FEDERAL REGISTER a notice prohibiting such use following the procedures in § 530.25. The prohibited extralabel drug use will be codified in § 530.41.

Subpart E—Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals

§ 530.40 Safe levels and availability of analytical methods.

(a) In accordance with § 530.22, the following safe levels for extralabel use of an approved animal drug or human drug have been established: [Reserved]

(b) In accordance with § 530.22, the following analytical methods have been accepted by FDA: [Reserved]

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

(1) Chloramphenicol;
(2) Clenbuterol;
(3) Diethylstilbestrol (DES);
(4) Dimetridazole;
(5) Ipronidazole;
(6) Other nitroimidazoles;
(7) Furazolidone.
(8) Nitrofurazone.
(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);
(10) Fluoroquinolones; and
(11) Glycopeptides.
(12) Phenylbutazone in female dairy cattle 20 months of age or older.
(13) Cephalosporins (not including cephapirin) in cattle, swine, chickens, or turkeys:
(i) For disease prevention purposes;
(ii) At unapproved doses, frequencies, durations, or routes of administration; or
(iii) If the drug is not approved for that species and production class.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved]

(c) [Reserved]

(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

(1) Adamantanes.
(2) Neuraminidase inhibitors.

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002; 68 FR 9530, Feb. 28, 2003; 68 FR 14134, Mar. 24, 2003; 71 FR 14377, Mar. 22, 2006; 77 FR 745, Jan. 6, 2012]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

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556.380 Melengestrol acetate.
556.410 Metoserpate hydrochloride.
556.420 Monensin.
556.425 Morantel tartrate.
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556.430 Neomycin.
556.440 Nequinate.
556.445 Nicarbazin.
556.460 Novobiocin.
556.470 Nystatin.
556.490 Ormetoprim.
556.495 Oxfendazole.
556.500 Oxytetracycline.
556.510 Penicillin.
556.513 Piperazine.
556.515 Pirlimycin.
556.540 Progesterone.
556.560 Pyrantel tartrate.
556.570 Ractopamine.
556.580 Robenidine hydrochloride.
556.592 Salinomycin.
556.597 Semduramicin.
556.600 Spectinomycin.
556.610 Streptomycin.
556.620 Sulfabromomethazine sodium.
556.625 Sodium sulfachloropyrazine monohydrate.
556.630 Sulfachlorpyridazine.
556.640 Sulfadimethoxine.
556.650 Sulfaethoxypyridazine.
556.660 Sulfamerazine.
556.670 Sulfamethazine.
556.685 Sulfaquinoxaline.
556.700 Sulfomyxin.
556.710 Testosterone propionate.
556.720 Tetracycline.
556.730 Thiabendazole.
556.732 Tiamulin.
556.733 Tildipirosin.
556.735 Tilmicosin.
556.739 Trenbolone.
556.740 Tylosin.
556.741 Tripelennamine.
556.745 Tulathromycin.
556.748 Tylvalosin.
556.750 Virginiamycin.
556.760 Zeranol.
556.765 Zilpaterol.
556.770 Zoalene.

AUTHORITY: 21 U.S.C. 342, 360b, 371.

SOURCE: 40 FR 13942, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 556.1 General considerations; tolerances for residues of new animal drugs in food.

(a) Tolerances established in this part are based upon residues of drugs in

edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug shall result in a conclusion either that:

(1) Finite residues will be present in the edible products—in which case a finite tolerance is required; or

(2) It is not possible to determine whether finite residues will be incurred but there is reasonable expectation that they may be present—in which case a tolerance for negligible residue is required; or

(3) The drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, has been shown to induce cancer in man or animal; however, such drug will not adversely affect the animals for which it is intended, and no residue of such drug will be found by prescribed methods of analysis in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal—in which case the accepted method of analysis shall be published or cited, if previously published and available elsewhere, in this part; or

(4) It may or may not be possible to determine whether finite residues will be incurred but there is no reasonable expectation that they may be present—in which case the establishment of a tolerance is not required; or

(5) The drug is such that it may be metabolized and/or assimilated in such form that any possible residue would be indistinguishable from normal tissue constituents—in which case the establishment of a tolerance is not required.

(b) No tolerance established pursuant to paragraph (a)(1) of this section will be set at any level higher than that reflected by the permitted use of the drug.

(c) Any tolerance required pursuant to this section will, in addition to the toxicological considerations, be conditioned on the availability of a practicable analytical method to determine the quantity of residue. Such method must be sensitive to and reliable at the established tolerance level or, in certain instances, may be sensitive at a higher level where such level is also deemed satisfactory and safe in light of the toxicity of the drug residue and of the unlikelihood of such residue's exceeding the tolerance.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

§ 556.34 Albendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of albendazole is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for albendazole 2-aminosulfone (marker residue) are:

(1) *Cattle*—(i) *Liver (target tissue)*: 0.2 parts per million (ppm).

(ii) *Muscle*: 0.05 ppm.

(2) *Sheep*—(i) *Liver (target tissue)*: 0.25 ppm.

(ii) *Muscle*: 0.05 ppm.

(3) *Goat*—(i) *Liver (target tissue*): 0.25 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See § 520.45 of this chapter.

[64 FR 1504, Jan. 11, 1999, as amended at 73 FR 11027, Feb. 29, 2008]

§ 556.36 Altrenogest.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*—(i) *Liver (the target tissue).* The tolerance for altrenogest (the marker residue) is 4 parts per billion (ppb).

(ii) *Muscle.* The tolerance for altrenogest (the marker residue) is 1 ppb.

(2) [Reserved]

[68 FR 62007, Oct. 31, 2003]

§ 556.38 Amoxicillin.

A tolerance of 0.01 part per million is established for negligible residues of amoxicillin in milk and in the uncooked edible tissues of cattle.

[49 FR 45422, Nov. 16, 1984]

§ 556.40 Ampicillin.

A tolerance of 0.01 p/m is established for negligible residues of ampicillin in the uncooked edible tissues of swine and cattle and in milk.

§ 556.50 Amprolium.

Tolerances are established as follows for residues of amprolium (1-(4-amino-2-*n*- propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride):

(a) In the edible tissues and in eggs of chickens and turkeys:

(1) 1 part per million in uncooked liver and kidney.

(2) 0.5 part per million in uncooked muscle tissue.

(3) In eggs:

(i) 8 parts per million in egg yolks.

(ii) 4 parts per million in whole eggs.

(b) In the edible tissues of calves:

(1) 2.0 parts per million in uncooked fat.

(2) 0.5 part per million in uncooked muscle tissue, liver, and kidney.

(c) In the edible tissues of pheasants:

(1) 1 part per million in uncooked liver.

(2) 0.5 part per million in uncooked muscle.

[40 FR 13942, Mar. 27, 1975, as amended at 50 FR 18472, May 1, 1985]

§ 556.52 Apramycin.

A tolerance of 0.1 part per million is established for parent apramycin (marker residue) in kidney (target tissue) of swine. The acceptable daily intake (ADI) for total residues of apramycin is 25 micrograms per kilogram of body weight per day.

[62 FR 40933, July 31, 1997]

§ 556.68 Avilamycin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of avilamycin is 1.1 milligram per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for avilamycin is not required.

(c) *Related conditions of use.* See § 558.68 of this chapter.

[80 FR 61297, Oct. 13, 2015]

§ 556.70 Bacitracin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.

(b) *Tolerances.* The tolerance for residues of bacitracin from zinc bacitracin or bacitracin methylenedisalicylate in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs is 0.5 part per million.

(c) *Related conditions of use.* See §§ 520.154a, 520.154c, 558.76, and 558.78 of this chapter.

[65 FR 70791, Nov. 28, 2000, as amended at 81 FR 17608, Mar. 30, 2016]

§ 556.100 Carbadox.

A tolerance of 30 parts per billion is established for residues of quinoxaline-2-carboxylic acid (marker residue) in liver (target tissue) of swine.

[63 FR 13337, Mar. 19, 1998]

§ 556.110 Carbomycin.

A tolerance of zero is established for residues of carbomycin in the uncooked edible tissues of chickens.

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake and acceptable single-dose intake*—(1) *Acceptable daily intake (ADI).* The ADI for total residues of ceftiofur is 30 micrograms per kilogram of body weight per day.

(2) *Acceptable single-dose intake (ASDI).* The ASDI total residues of ceftiofur is 0.830 milligrams per kilogram of body weight. The ASDI is the amount of total residues of ceftiofur that may safely be consumed in a single meal. The ASDI is used to derive the tolerance for residues of desfuroylceftiofur at the injection site.

(b) *Tolerances*—(1) *Poultry, and sheep.* A tolerance for residues of ceftiofur in edible tissue is not required.

(2) *Swine.* The tolerances for desfuroylceftiofur (marker residue) are:

(i) *Kidney (target tissue).* 0.25 parts per million (ppm).

(ii) *Liver.* 3 ppm.

(iii) *Muscle.* 2 ppm.

(3) *Cattle.* The tolerances for desfuroylceftiofur (marker residue) are:

(i) *Kidney (target tissue).* 0.4 ppm.

(ii) *Liver.* 2 ppm.

(iii) *Muscle.* 1 ppm.

(iv) *Milk.* 0.1 ppm.

[63 FR 53579, Oct. 6, 1998, as amended at 68 FR 60296, Oct. 22, 2003; 69 FR 43892, July 23, 2004; 71 FR 39546, July 13, 2006]

§ 556.115 Cephapirin.

A tolerance of 0.02 parts per million (ppm) is established for residues of cephapirin in the milk and 0.1 ppm in the uncooked edible tissues of dairy cattle.

[40 FR 57454, Dec. 10, 1975]

§ 556.118 Chloramine-T.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of chloramine-T is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Fish*—(i) *Muscle/skin (target tissue).* The tolerance for *para*-toluenesulfonamide (marker residue) is 0.90 parts per million.

(ii) [Reserved]

(2) [Reserved]

(c) *Related conditions of use.* See § 529.382 of this chapter.

[79 FR 37621, July 2, 2014]

§ 556.120 Chlorhexidine.

A tolerance of zero is established for residues of chlorhexidine in the uncooked edible tissues of calves.

§ 556.150 Chlortetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances.* (1) Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

(2) A tolerance is established for residues of chlortetracycline in eggs of 0.4 ppm.

[63 FR 52158, Sept. 30, 1998, as amended at 63 FR 57246, Oct. 27, 1998]

§ 556.160 Clopidol.

Tolerances for residues of clopidol (3,5-dichloro-2,6-dimethyl-4-pyridinol) in food are established as follows:

(a) In cereal grains, vegetables, and fruits: 0.2 part per million.

(b) In chickens and turkeys:

(1) 15 parts per million in uncooked liver and kidney.

(2) 5 parts per million in uncooked muscle.

(c) In cattle, sheep, and goats:

(1) 3 parts per million in uncooked kidney.

(2) 1.5 parts per million in uncooked liver.

(3) 0.2 part per million in uncooked muscle.

(d) In swine: 0.2 part per million in uncooked edible tissues.

(e) In milk: 0.02 part per million (negligible residue).

§ 556.163 Clorsulon.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of clorsulon is 8 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Kidney (the target tissue).* The tolerance for parent clorsulon (the marker residue) is 1.0 part per million.

(ii) *Muscle.* The tolerance for parent clorsulon (the marker residue) is 0.1 part per million.

(2) [Reserved]

[66 FR 35544, July 6, 2001]

§ 556.165 Cloxacillin.

A tolerance of 0.01 part per million is established for negligible residues of cloxacillin in the uncooked edible tissues of cattle and in milk.

[40 FR 28792, July 9, 1975]

§ 556.167 Colistimethate.

A tolerance for residues of colistimethate in the edible tissues of chickens is not required.

[63 FR 13123, Mar. 18, 1998]

§ 556.169 Danofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of danofloxacin is 2.4 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent danofloxacin (the marker residue) is 0.2 part per million (ppm).

(ii) *Muscle.* The tolerance for parent danofloxacin (the marker residue) is 0.2 ppm.

(2) [Reserved]

[67 FR 78973, Dec. 27, 2002]

§ 556.170 Decoquinate.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of decoquinate is 75 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for residues of decoquinate in the uncooked, edible tissues of chickens, cattle, and goats as follows:

(1) 1 part per million (ppm) in skeletal muscle.

(2) 2 ppm in other tissues.

[64 FR 10103, Mar. 2, 1999]

§ 556.180 Dichlorvos.

A tolerance of 0.1 part per million is established for negligible residues of dichlorvos (2,2-dichlorovinyl dimethyl phosphate) in the edible tissues of swine.

§ 556.185 Diclazuril.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of diclazuril is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Chickens*—(i) *Liver.* The tolerance for parent diclazuril (the marker residue) is 3 parts per million (ppm).

(ii) *Muscle.* The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat.* The tolerance for parent diclazuril (the marker residue) is 1 ppm.

(2) *Turkeys*—(i) *Liver.* The tolerance for parent diclazuril (the marker residue) is 3 ppm.

(ii) *Muscle.* The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat.* The tolerance for parent diclazuril (the marker residue) is 1 ppm.

[64 FR 35923, July 2, 1999. Redesignated and amended at 66 FR 62917, Dec. 4, 2001]

§ 556.200 Dihydrostreptomycin.

Tolerances are established for residues of dihydrostreptomycin in uncooked, edible tissues of cattle and swine of 2.0 parts per million (ppm) in kidney and 0.5 ppm in other tissues, and 0.125 ppm in milk.

[59 FR 41977, Aug. 16, 1994]

§ 556.225 Doramectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of doramectin is 0.75 microgram per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* A tolerance of 100 parts per billion is established for parent doramectin (marker residue) in liver (target tissue) and of 30 parts per billion for parent doramectin in muscle.

(2) *Swine.* A tolerance is established for parent doramectin (marker residue) in liver (target tissue) of 160 parts per billion.

[63 FR 68184, Dec. 10, 1998]

§ 556.226 Enrofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of enrofloxacin is 3 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for enrofloxacin are:

(1) *Cattle*—(i) *Liver (target tissue).* 0.1 part per million (ppm) desethylene ciprofloxacin (the marker residue).

(ii) [Reserved]

(2) *Swine*—(i) *Liver (target tissue).* 0.5 ppm enrofloxacin (the marker residue).

(ii) [Reserved]

(c) *Related conditions of use.* See § 522.812 of this chapter.

[73 FR 21819, Apr. 23, 2008]

§ 556.227 Eprinomectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of eprinomectin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for eprinomectin B_{1a} (marker residue) are:

(1) *Cattle*—(i) *Liver (target tissue):* 1.5 parts per million.

(ii) *Muscle:* 100 parts per billion (ppb).

(iii) *Milk:* 12 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.814 and 524.814 of this chapter.

[63 FR 59715, Nov. 5, 1998, as amended at 76 FR 72619, Nov. 25, 2011]

§ 556.230 Erythromycin.

Tolerances for residues of erythromycin in food are established as follows:

(a) 0.1 part per million in uncooked edible tissues of beef cattle and swine.

(b) Zero in milk.

(c) 0.025 part per million in uncooked eggs.

(d) 0.125 part per million (negligible residue) in uncooked edible tissues of chickens and turkeys.

[40 FR 13942, Mar. 27, 1975, as amended at 58 FR 43795, Aug. 18, 1993]

§ 556.240 Estradiol and related esters.

No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals:

(a) In uncooked edible tissues of heifers, steers, and calves:

(1) 120 parts per trillion for muscle.

(2) 480 parts per trillion for fat.

(3) 360 parts per trillion for kidney.

(4) 240 parts per trillion for liver.

(b) [Reserved]

[49 FR 13873, Apr. 9, 1984, as amended at 56 FR 67175, Dec. 30, 1991; 76 FR 16291, Mar. 23, 2011]

§ 556.260 Ethopabate.

Tolerance for residues of ethopabate converted to metaphenetidine are established in the edible tissues of chickens as follows:

(a) 1.5 parts per million in uncooked liver and kidney.

(b) 0.5 part per million in uncooked muscle.

§ 556.273 Famphur.

Tolerances are established for residues of famphur including its oxygen analog in or on meat, fat, or meat byproducts of cattle at 0.1 part per million.

[62 FR 55161, Oct. 23, 1997]

§ 556.275 Fenbendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of fenbendazole is 40 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 part per million (ppm).

(ii) *Muscle.* The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

(iii) *Milk.* The tolerance for fenbendazole sulfoxide metabolite (the marker residue in cattle milk) is 0.6 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 3.2 ppm.

(ii) *Muscle.* The tolerance for parent fenbendazole (the marker residue) is 2 ppm.

(3) *Chickens*—(i) *Liver (the target tissue).* The tolerance for fenbendazole sulfone (the marker residue) is 5.2 ppm.

(ii) [Reserved]

(4) *Turkeys*—(i) *Liver (the target tissue*). The tolerance for fenbendazole sulfone (the marker residue) is 6 ppm.

(ii) *Muscle.* The tolerance for fenbendazole sulfone (the marker residue) is 2 ppm.

(5) *Goats*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 ppm.

(ii) *Muscle.* The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

(c) *Related conditions of use.* See §§ 520.905a, 520.905c, 520.905d, 520.905e, and 558.258 of this chapter.

[65 FR 20733, Apr. 18, 2000, as amended at 65 FR 41588, July 6, 2000; 65 FR 50914, Aug. 22, 2000; 81 FR 22524, Apr. 18, 2016]

§ 556.277 Fenprostalene.

A tolerance for marker residue of fenprostalene in cattle is not needed. The safe concentrations for the total residues of fenprostalene in the uncooked edible tissues of cattle are 10 parts per billion in muscle, 20 parts per billion in liver, 30 parts per billion in kidney, 40 parts per billion in fat, and 100 parts per billion in the injection site. As used in this section ''tolerance'' refers to a concentration of a marker residue in the target tissue selected to monitor for total residues of the drug in the target animal, and ''safe concentrations'' refer to the concentrations of total residues considered safe in edible tissues.

[49 FR 26716, June 29, 1984]

§ 556.283 Florfenicol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of florfenicol is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm).

(ii) *Muscle.* The tolerance for florfenicol amine (the marker residue) is 0.3 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent florfenicol (the marker residue) is 2.5 ppm.

(ii) *Muscle.* The tolerance for parent florfenicol (the marker residue) is 0.2 ppm.

(3) *Freshwater-reared finfish (other than catfish) and salmonids.* The tolerance for florfenicol amine (the marker residue) in muscle/skin (the target tissues) is 1 ppm.

(4) *Catfish.* The tolerance for florfenicol amine (the marker residue) in muscle (the target tissues) is 1 ppm.

(c) *Related conditions of use.* See §§ 520.955, 522.955, 522.956, and 558.261 of this chapter.

[76 FR 16291, Mar. 23, 2011, as amended at 81 FR 17608, Mar. 30, 2016]

§ 556.286 Flunixin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of flunixin is 0.72 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* The tolerance for flunixin free acid (the marker residue) is:

(i) *Liver (the target tissue*). 125 parts per billion (ppb).

(ii) *Muscle.* 25 ppb.

(iii) *Milk:* 2 ppb 5-hydroxy flunixin.

(2) *Swine.* The tolerance for flunixin free acid (the marker residue) is:

(i) *Liver (the target tissue).* 30 ppb.

(ii) *Muscle.* 25 ppb.

(c) *Related conditions of use.* See §§ 522.956, 522.970, and 524.970 of this chapter.

[63 FR 38750, July 20, 1998, as amended at 69 FR 60309, Oct. 8, 2004; 70 FR 70999, Nov. 25, 2005; 76 FR 16291, Mar. 23, 2011; 83 FR 13635, Mar. 30, 2018]

§ 556.292 Gamithromycin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of gamithromycin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for gamithromycin (the marker residue) are:

(1) *Cattle*—(i) *Liver (the target tissue):* 500 parts per billion (ppb).

(ii) *Muscle.* 150 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 522.1014 of this chapter.

[76 FR 57907, Sept. 19, 2011]

§ 556.300 Gentamicin sulfate.

(a) A tolerance of 0.1 part per million is established for negligible residues of gentamicin sulfate in the uncooked edible tissues of chickens and turkeys.

(b) Tolerances are established for total residues of gentamicin in edible tissues of swine as follows: 0.1 part per million in muscle, 0.3 part per million in liver, and 0.4 part per million in fat and kidney. A microbiological determinative procedure and an HPLC confirmatory procedure for gentamicin have been developed to assay gentamicin in kidney at 0.4 ppm. Since residues of gentamicin as the parent compound and total residues are equal, the marker (parent drug) residue concentration of 0.4 ppm in kidney corresponds to 0.4 ppm of total residue.

[48 FR 791, Jan. 7, 1983, as amended at 61 FR 24441, May 15, 1996]

§ 556.304 Gonadotropin.

(a) *Acceptable daily intake (ADI).* The ADI for residues of total gonadotropins (human chorionic gonadotropin and pregnant mare serum gonadotropin) is 42.25 I.U. per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for residues of gonadotropin in uncooked edible tissues of cattle or of fish is not required.

[64 FR 48545, Sept. 7, 1999]

§ 556.308 Halofuginone hydrobromide.

The marker residue selected to monitor for total residues of halofuginone hydrobromide in broilers and turkeys is parent halofuginone hydrobromide

and the target tissue selected is liver. A tolerance is established in broilers of 0.16 part per million and in turkeys of 0.13 part per million for parent halofuginone hydrobromide in liver. These marker residue concentrations in liver correspond to total residue concentrations of 0.3 part per million in liver. The safe concentrations for total residues of halofuginone hydrobromide in the uncooked edible tissues of broilers and turkeys are 0.1 part per million in muscle, 0.3 part per million in liver, and 0.2 part per million in skin with adhering fat. As used in this section, ''tolerance'' refers to a concentration of a marker residue in the target tissue selected to monitor for total residues of the drug in the target animal, and ''safe concentrations'' refers to the concentrations of total residues considered safe in edible tissues.

[54 FR 28052, July 5, 1989, as amended at 56 FR 8711, Mar. 1, 1991; 57 FR 21209, May 19, 1992]

§ 556.310 Haloxon.

A tolerance of 0.1 part per million is established for negligible residues of haloxon (3-chloro-7-hydroxy-4-methylcoumarin bis(2-chloroethyl) phosphate) in the edible tissues of cattle.

[40 FR 13942, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980]

§ 556.330 Hygromycin B.

A tolerance of zero is established for residues of hygromycin B in or on eggs and the uncooked edible tissues of swine and poultry.

§ 556.344 Ivermectin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of ivermectin is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Liver.* A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in liver (target tissue) as follows:

(i) *Cattle.* 1.6 parts per million.

(ii) *Swine.* 20 parts per billion.

(iii) *Sheep.* 30 parts per billion.

(iv) *Reindeer.* 15 parts per billion.

(v) *American bison.* 15 parts per billion.

(2) *Muscle.* Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in muscle as follows:

(i) *Swine.* 20 parts per billion.

(ii) *Cattle.* 650 parts per billion.

(c) *Related conditions of use.* See §§ 520.1192, 520.1195, 520.1197, 522.1192, 522.1193, 524.1193, and 558.300 of this chapter.

[63 FR 54352, Oct. 9, 1998, as amended at 64 FR 26671, May 17, 1999; 79 FR 64117, Oct. 28, 2014]

§ 556.346 Laidlomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of laidlomycin is 7.5 micrograms per kilogram of body weight per day.

(b) *Tolerance.* The tolerance for parent laidlomycin (the marker residue) in the liver (the target tissue) of cattle is 0.2 part per million (ppm).

[68 FR 42590, July 18, 2003]

§ 556.347 Lasalocid.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lasalocid is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million (ppm).

(2) *Chickens*—(i) *Skin with adhering fat (the target tissue).* The tolerance for parent lasalocid (the marker residue) is 1.2 ppm.

(ii) *Liver.* The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

(3) *Turkeys*—(i) *Liver (the target tissue).* The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

(ii) *Skin with adhering fat.* The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

(4) *Rabbits.* The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 ppm.

(5) *Sheep.* The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 1.0 ppm.

[66 FR 19854, Apr. 18, 2001]

§ 556.350 Levamisole hydrochloride.

A tolerance of 0.1 part per million is established for negligible residues of

levamisole hydrochloride in the edible tissues of cattle, sheep, and swine.

§ 556.360 Lincomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

(b) *Chickens.* A tolerance for residues of lincomycin in chickens is not required.

(c) *Swine.* Tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established.

[64 FR 13342, Mar. 18, 1999]

§ 556.375 Maduramicin ammonium.

A tolerance is established for residues of maduramicin ammonium in chickens as follows:

(a) A tolerance for maduramicin ammonium (marker residue) in chickens is 0.38 parts per million in fat (target tissue). A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals.

(b) The safe concentrations for total maduramicin ammonium residues in uncooked edible chicken tissues are: 0.24 parts per million in muscle; 0.72 parts per million in liver; 0.48 parts per million in skin; and 0.48 parts per million in fat. A safe concentration refers to the total residue concentration considered safe in edible tissues.

[54 FR 5229, Feb. 2, 1989]

§ 556.380 Melengestrol acetate.

A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat of cattle.

[59 FR 41241, Aug. 11, 1994]

§ 556.410 Metoserpate hydrochloride.

A tolerance of 0.02 part per million is established for negligible residues of metoserpate hydrochloride (methyl-*o*-methyl-18-epireserpate hydrochloride) in uncooked edible tissues of chickens.

§ 556.420 Monensin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of monensin is 12.5 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for residues of monensin are:

(1) *Cattle*—(i) *Liver.* 0.10 part per million (ppm).

(ii) *Muscle, kidney, and fat.* 0.05 ppm.

(iii) *Milk.* Not required.

(2) *Goats*—(i) *Edible tissues.* 0.05 ppm.

(ii) [Reserved]

(3) *Chickens, turkeys, and quail.* A tolerance for residues of monensin in chickens, turkeys, and quail is not required.

(c) *Related conditions of use.* See §§ 520.1448 and 558.355 of this chapter.

[64 FR 5159, Feb. 3, 1999, as amended at 69 FR 68783, Nov. 26, 2004; 72 FR 56897, Oct. 5, 2007]

§ 556.425 Morantel tartrate.

A tolerance of 0.7 part per million is established for *N*-methyl-1,3-propanediamine (MAPA, marker residue) in the liver (target tissue) of cattle and goats. A tolerance for residues of morantel tartrate in milk is not required.

[59 FR 17922, Apr. 15, 1994]

§ 556.426 Moxidectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of moxidectin is 4 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Fat (the target tissue).* The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver.* The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) *Muscle.* The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(iv) *Milk.* The tolerance for parent moxidectin (the marker residue) is 40 ppb.

(2) *Sheep*—(i) *Fat (the target tissue).* The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver.* The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) *Muscle.* The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(c) *Related conditions of use.* See §§ 520.1454 and 522.1450 of this chapter.

[65 FR 36617, June 9, 2000, as amended at 65 FR 76930, Dec. 8, 2000; 70 FR 36338, June 23, 2005; 70 FR 76163, Dec. 23, 2005]

§ 556.428 Narasin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of narasin is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Chickens (abdominal fat).* The tolerance for parent narasin (the marker residue) is 480 parts per billion.

(2) [Reserved]

[66 FR 23589, May 9, 2001]

§ 556.430 Neomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of neomycin is 6 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for residues of parent neomycin in uncooked edible tissues as follows:

(1) *Cattle, swine, sheep, and goats.* 7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle.

(2) *Turkeys.* 7.2 ppm in skin with adhearing fat, 3.6 ppm in liver, and 1.2 ppm in muscle.

(3) *Milk.* A tolerance is established for residues of parent neomycin of 0.15 ppm.

[64 FR 31498, June 11, 1999]

§ 556.440 Nequinate.

A tolerance of 0.1 part per million is established for negligible residues of nequinate in the uncooked edible tissues of chickens.

§ 556.445 Nicarbazin.

A tolerance of 4 parts per million is established for residues of nicarbazin in uncooked chicken muscle, liver, skin, and kidney.

[42 FR 56729, Oct. 28, 1977]

§ 556.460 Novobiocin.

Tolerances for residues of novobiocin are established at 0.1 part per million in milk from dairy animals and 1 part per million in the uncooked edible tissues of cattle, chickens, turkeys, and ducks.

[47 FR 18590, Apr. 30, 1982]

§ 556.470 Nystatin.

A tolerance of zero is established for residues of nystatin in or on eggs and the uncooked edible tissues of swine and poultry.

§ 556.490 Ormetoprim.

(a) [Reserved]

(b) *Tolerances.* A tolerance of 0.1 part per million (ppm) is established for negligible residues of ormetoprim in uncooked edible tissues of chickens, turkeys, ducks, salmonids, catfish, and chukar partridges.

[64 FR 26672, May 17, 1999]

§ 556.495 Oxfendazole.

Cattle: A tolerance is established for total oxfendazole residues in edible cattle tissues based on a marker residue concentration of 0.8 part per million (ppm) fenbendazole in the target liver tissue. A fenbendazole concentration of 0.8 ppm in liver corresponds to a total safe concentration of oxfendazole residues of 1.7 ppm in liver. The safe concentrations of total oxfendazole residues in other uncooked edible cattle tissues are: muscle, 0.84 ppm; kidney, 2.5 ppm; and fat, 3.3 ppm. A tolerance refers to the concentration of marker residue in the target tissue selected to monitor for total drug residue in the target animal. A safe concentration is the total residue considered safe in edible tissue.

[55 FR 46943, Nov. 8, 1990]

§ 556.500 Oxytetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day.

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, finfish, and lobster.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.
(3) 12 ppm in fat and kidney.
(4) 0.3 ppm in milk.

[63 FR 57246, Oct. 27, 1998, as amended at 66 FR 46370, Sept. 5, 2001; 69 FR 6557, Feb. 11, 2004]

§ 556.510 Penicillin.

Tolerances are established for residues of penicillin and the salts of penicillin in food as follows:

(a) 0.05 part per million (negligible residue) in the uncooked edible tissues of cattle.

(b) Zero in the uncooked edible tissues of chickens, pheasants, quail, swine, and sheep; in eggs; and in milk or in any processed food in which such milk has been used.

(c) 0.01 part per million in the uncooked edible tissues of turkeys.

[40 FR 13942, Mar. 27, 1975, as amended at 43 FR 32749, July 28, 1978]

§ 556.513 Piperazine.

A tolerance of 0.1 part per million piperazine base is established for edible tissues of poultry and swine.

[64 FR 23019, Apr. 29, 1999]

§ 556.515 Pirlimycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of pirlimycin is 0.01 milligrams per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent pirlimycin (the marker residue) is 0.5 part per million (ppm).

(ii) *Muscle.* The tolerance for parent pirlimycin (the marker residue) is 0.3 ppm.

(iii) *Milk.* The tolerance for parent pirlimycin (the marker residue in cattle milk) is 0.4 ppm.

(2) [Reserved]

[65 FR 61091, Oct. 16, 2000]

§ 556.540 Progesterone.

(a) [Reserved]

(b) *Tolerances.* Residues of progesterone are not permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals:

(1) *Cattle and sheep*—(i) *Muscle:* 5 parts per billion (ppb).

(ii) *Liver:* 15 ppb.

(iii) *Kidney:* 30 ppb.

(iv) *Fat:* 30 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See §§ 522.1940 and 529.1940 of this chapter.

[76 FR 57907, Sept. 19, 2011]

§ 556.560 Pyrantel tartrate.

Tolerances are established for residues of pyrantel tartrate in edible tissues of swine as follows:

(a) 10 parts per million in liver and kidney.

(b) 1 part per million in muscle.

§ 556.570 Ractopamine.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of ractopamine hydrochloride is 1.25 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for ractopamine hydrochloride (the marker residue) is 0.09 parts per million (ppm).

(ii) *Muscle.* The tolerance for ractopamine hydrochloride (the marker residue) is 0.03 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for ractopamine hydrochloride (the marker residue) is 0.15 ppm.

(ii) *Muscle.* The tolerance for ractopamine hydrochloride (the marker residue) is 0.05 ppm.

(3) *Turkeys*—(i) *Liver (the target tissue).* The tolerance for ractopamine (the marker residue) is 0.45 ppm.

(ii) *Muscle.* The tolerance for ractopamine (the marker residue) is 0.1 ppm.

[68 FR 54659, Sept. 18, 2003, as amended at 73 FR 72715, Dec. 1, 2008]

§ 556.580 Robenidine hydrochloride.

Tolerances are established for residues of robenidine hydrochloride in edible tissues of chickens as follows:

(a) 0.2 part per million in skin and fat.

(b) 0.1 part per million (negligible residue) in edible tissues other than skin and fat.

§ 556.592 Salinomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of salinomycin is

0.005 milligram per kilogram of body weight per day.

(b) [Reserved]

[65 FR 70791, Nov. 28, 2000]

§ 556.597 Semduramicin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of semduramicin is 180 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Broiler chickens.* Tolerances are established for residues of parent semduramicin in uncooked edible tissues of 400 parts per billion (ppb) in liver and 130 ppb in muscle.

(2) [Reserved]

[64 FR 48296, Sept. 3, 1999]

§ 556.600 Spectinomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of spectinomycin is 25 micrograms per kilogram of body weight per day.

(b) *Chickens and turkeys.* A tolerance of 0.1 part per million (ppm) for negligible residues of spectinomycin in uncooked edible tissues of chickens and turkeys is established.

(c) *Cattle.* A tolerance of 4 ppm for parent spectinomycin (marker residue) in kidney (target tissue) is established. A tolerance of 0.25 ppm for parent spectinomycin in cattle muscle is established.

[63 FR 24107, May 1, 1998; 63 FR 38304, July 16, 1998]

§ 556.610 Streptomycin.

Tolerances are established for residues of streptomycin in uncooked, edible tissues of chickens, swine, and calves of 2.0 parts per million (ppm) in kidney and 0.5 ppm in other tissues.

[58 FR 47211, Sept. 8, 1993]

§ 556.620 Sulfabromomethazine sodium.

Tolerances for residues of sulfabromomethazine sodium in food are established as follows:

(a) In the uncooked edible tissues of cattle at 0.1 part per million (negligible residue).

(b) In milk at 0.01 part per million (negligible residue).

[47 FR 30244, July 13, 1982]

§ 556.625 Sodium sulfachloropyrazine monohydrate.

A tolerance of zero is established for residues of sodium sulfachloropyrazine monohydrate in the uncooked edible tissues of chickens.

§ 556.630 Sulfachlorpyridazine.

A tolerance of 0.1 part per million is established for negligible residues of sulfachlorpyridazine in uncooked edible tissues of calves and swine.

§ 556.640 Sulfadimethoxine.

(a) [Reserved]

(b) *Tolerances.* (1) A tolerance of 0.1 part per million (ppm) is established for negligible residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, cattle, ducks, salmonids, catfish, and chukar partridges.

(2) A tolerance of 0.01 ppm is established for negligible residues of sulfadimethoxine in milk.

[64 FR 26672, May 17, 1999]

§ 556.650 Sulfaethoxypyridazine.

Tolerances for residues of sulfaethoxypyridazine in food are established as follows:

(a) Zero in the uncooked edible tissues of swine and in milk.

(b) 0.1 part per million (negligible residue) in uncooked edible tissues of cattle.

§ 556.660 Sulfamerazine.

A tolerance of zero is established for residues of sulfamerazine (N^1-[4-methyl-2-pyrimidinyl]sulfanilamide) in the uncooked edible tissues of trout.

§ 556.670 Sulfamethazine.

A tolerance of 0.1 part per million is established for negligible residues of sulfamethazine in the uncooked edible tissues of chickens, turkeys, cattle, and swine.

[47 FR 25323, June 11, 1982]

§ 556.685 Sulfaquinoxaline.

A tolerance of 0.1 part per million is established for negligible residues of

sulfaquinoxaline in the uncooked edible tissues of chickens, turkeys, calves, and cattle.

[61 FR 24443, May 15, 1996]

§ 556.700 Sulfomyxin.

A tolerance of zero is established for residues of sulfomyxin (N-sulfomethylpolymyxin B sodium salt) in uncooked edible tissues from chickens and turkeys.

§ 556.710 Testosterone propionate.

No residues of testosterone, resulting from the use of testosterone propionate, are permitted in excess of the following increments above the concentrations of testosterone naturally present in untreated animals:

(a) In uncooked edible tissues of heifers:

(1) 0.64 part per billion in muscle.

(2) 2.6 parts per billion in fat.

(3) 1.9 parts per billion in kidney.

(4) 1.3 parts per billion in liver.

(b) [Reserved]

[52 FR 27683, July 23, 1987]

§ 556.720 Tetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for the sum of tetracycline residues in tissues of calves, swine, sheep, chickens, and turkeys, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

[63 FR 57246, Oct. 27, 1998]

§ 556.730 Thiabendazole.

Tolerances are established at 0.1 part per million for negligible residues of thiabendazole in uncooked edible tissues of cattle, goats, sheep, pheasants, and swine, and at 0.05 part per million for negligible residues in milk.

[40 FR 13942, Mar. 27, 1975, as amended at 49 FR 29958, July 25, 1984]

§ 556.732 Tiamulin.

A tolerance of 0.6 part per million is established for 8-*alpha*-hydroxymutilin (marker compound) in liver (target tissue) of swine.

[62 FR 12086, Mar. 14, 1997. Redesignated at 80 FR 13230, Mar. 13, 2015]

§ 556.733 Tildipirosin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of tildipirosin is 50 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for tildipirosin (the marker residue) are:

(1) *Cattle*—(i) *Liver (the target tissue):* 10 parts per million.

(ii) [Reserved]

(2) [Reserved]

(c) *Related conditions of use.* See § 522.2460 of this chapter.

[77 FR 39391, July 3, 2012, as amended at 78 FR 52854, Aug. 27, 2013]

§ 556.735 Tilmicosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tilmicosin is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 1.2 parts per million (ppm).

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 7.5 ppm.

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

(3) *Sheep*—(i) *Liver (the target tissue).* The tolerance for parent tilmicosin (the marker residue) is 1.2 ppm.

(ii) *Muscle.* The tolerance for parent tilmicosin (the marker residue) is 0.1 ppm.

[64 FR 13679, Mar. 22, 1999, as amended at 67 FR 72368, Dec. 5, 2002; 78 FR 52854, Aug. 27, 2013]

§ 556.739 Trenbolone.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of trenbolone is 0.4 microgram per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed.

[64 FR 18574, Apr. 15, 1999]

§ 556.740 Tylosin.

Tolerances are established for residues of tylosin in edible products of animals as follows:

(a) In chickens and turkeys: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(b) In cattle: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(c) In swine: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(d) In milk: 0.05 part per million (negligible residue).

(e) In eggs: 0.2 part per million (negligible residue).

§ 556.741 Tripelennamine.

A tolerance of 200 parts per billion (ppb) is established for residues of tripelennamine in uncooked edible tissues of cattle and 20 ppb in milk.

[62 FR 4164, Jan. 29, 1997]

§ 556.745 Tulathromycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tulathromycin is 15 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for CP–60,300 (the marker residue) is 5.5 parts per million (ppm).

(ii) [Reserved]

(2) *Swine*—(i) *Kidney (the target tissue).* The tolerance for CP–60,300 (the marker residue) is 15 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See § 522.2630 of this chapter.

[70 FR 39918, July 12, 2005]

§ 556.748 Tylvalosin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of tylvalosin is 47.7 micrograms per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for tylvalosin in edible tissues of swine is not required.

(c) *Related conditions of use.* See §§ 520.2645 and 558.633 of this chapter.

[77 FR 55415, Sept. 10, 2012, as amended at 81 FR 36789, June 8, 2016]

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of virginiamycin is 250 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine.* Tolerances are established for residues of virginiamycin in uncooked edible tissues of 0.4 part per million (ppm) in kidney, skin, and fat, 0.3 ppm in liver, and 0.1 ppm in muscle.

(2) *Broiler chickens and cattle.* A tolerance for residues of virginiamycin is not required.

[64 FR 48296, Sept. 3, 1999]

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for residues of zeranol in edible tissues are:

(1) *Cattle.* A tolerance is not needed.

(2) *Sheep.* 20 parts per billion.

(c) *Related conditions of use.* See § 522.2680 of this chapter.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989; 67 FR 6867, Feb. 14, 2002; 70 FR 15759, Mar. 29, 2005]

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zilpaterol is 0.083 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for zilpaterol (the marker residue) is 12 parts per billion (ppb).

(ii) *Muscle.* The tolerance for zilpaterol (the marker residue) is 10 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.665 of this chapter.

[71 FR 53005, Sept. 8, 2006, as amended at 81 FR 17608, Mar. 30, 2016]

§ 556.770 Zoalene.

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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AUTHORITY: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each major species for which they are approved or are approved for use only in minor species.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one major species for which they are approved, or are regulated on a ''no-residue'' basis or with a zero tolerance because of carcinogenic concern regardless of whether a withdrawal period is required in any species.

(2) A ''Type A medicated article'' is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(3) A ''Type B medicated feed'' is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term ''highest continuous use level'' means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(4) A ''Type C medicated feed'' is intended as the complete feed for the animal or may be fed ''top dressed'' (added on top of usual ration) on or offered ''free-choice'' (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or ''drum-run'' (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(6) A ''veterinary feed directive (VFD) drug'' is a drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed pursuant to section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian. Use of animal feed bearing or containing a VFD drug must be authorized by a lawful veterinary feed directive.

(7) A ''veterinary feed directive'' is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration.

(8) A ''medicated feed'' means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a ''distributor'' means any person who distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD.

(10) An ''animal production facility'' is a location where animals are raised for any purpose, but does not include

the specific location where medicated feed is made.

(11) An ''acknowledgment letter'' is a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee). An acknowledgment letter must be provided either in hardcopy or through electronic media and must affirm:

(i) That the distributor will not ship such VFD feed to an animal production facility that does not have a VFD,

(ii) That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and

(iii) That the distributor has complied with the distributor notification requirements of § 558.6(c)(5).

(12) A ''combination veterinary feed directive (VFD) drug'' is a combination new animal drug (as defined in § 514.4(c)(1)(i) of this chapter) intended for use in or on animal feed which is limited by an approved application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed under section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug. Use of animal feed bearing or containing a combination VFD drug must be authorized by a lawful VFD.

(13) ''Major species'' means cattle, horses, swine, chickens, turkeys, dogs, and cats.

(14) ''Minor species'' means animals, other than humans, that are not major species.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007; 80 FR 31733, June 3, 2015; 81 FR 57800, Aug. 24, 2016]

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

Drug	Assay limits percent [1] Type A	Type B maximum (200x)	Assay limits percent [1] Type B/C [2]
Amprolium with Ethopabate	94–114	22.75 g/lb (5.0%)	80–120.
Avilamycin	90–110	7.3 g/lb (1.6%)	80–110.
Bacitracin methylenedisalicylate	85–115	25.0 g/lb (5.5%)	70–130.
Bacitracin zinc	84–115	5.0 g/lb (1.1%)	70–130.
Bambermycins	90–110	800 g/ton (0.09%)	80–120/70–130.
Chlortetracycline	85–115	40.0 g/lb (8.8%)	80–115/70–130.
Coumaphos	95–115	6.0 g/lb (1.3%)	80–120.
Decoquinate	90–105	2.72 g/lb (0.6%)	80–120.
Dichlorvos	100–115	33.0 g/lb (7.3%)	90–120/80–130.
Diclazuril	90–110	182 g/t (0.02%)	85–115/70–120.
Efrotomycin	94–113	1.45 g/lb (0.32%)	80–120.
Iodinated casein	85–115	20.0 g/lb (4.4%)	75–125.
Laidlomycin propionate potassium	90–110	1 g/lb (0.22%)	90–115/85–115.
Lasalocid	95–115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin	90–115	20.0 g/lb (4.4%)	80–130.
Melengestrol acetate	90–110	10.0 g/ton (0.0011%)	70–120.

CATEGORY I—Continued

Drug	Assay limits percent [1] Type A	Type B maximum (200x)	Assay limits percent [1] Type B/C [2]
Monensin	85–115	40.0 g/lb (8.8%)	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin	90–110	7.2 g/lb (1.6%)	85–115/75–125.
Nequinate	95–112	1.83 g/lb (0.4%)	80–120.
Nystatin	85–125	5.0 g/lb (1.1%)	75–125.
Oxytetracycline	90–120	20.0 g/lb (4.4%)	75–125/65–135.
Poloxalene	90–110	54.48 g/lb (12.0%)	Liq. feed: 85–115.
Ractopamine	85–105	2.46 g/lb (0.54%)	80–110/75–125.
Salinomycin	90–110	6.0 g/lb (1.3%)	80–120.
Semduramicin (as semduramicin sodium).	90–110	2.27 g/lb (0.50%)	80–110
Semduramicin (as semduramicin sodium biomass).	90–110	2.27 g/lb (0.50%)	80–120
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Tylvalosin	90–110	3.86 g/lb	85–115.
Virginiamycin	85–115	10.0 g/lb (2.2%)	70–130.
Zoalene	92–104	11.35 g/lb (2.5%)	85–115.

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

CATEGORY II

Drug	Assay limits percent [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
Carbadox	90–110	2.5 g/lb (0.55%)	75–125.
Clopidol	94–106	11.4 g/lb (2.5%)	90–115/80–120.
Erythromycin	85–115	4.625 g/lb (1.02%)	75–125.
Famphur	100–110	5.5 g/lb (1.21%)	90–115/80–120.
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125.
Florfenicol	90–110	9.1 g/lb (2.0%)	Swine feed: 85–115 Catfish feed: 80–110. Salmonid feed: 80–110.
Halofuginone hydrobromide	90–115	272.0 g/ton (.03%)	75–125.
Hygromycin B	90–110	1,200 g/ton (0.13%)	75–125.
Ivermectin	95–105	1,180 g/ton (0.13%)	80–110.
Maduramicin ammonium	90–110	545 g/ton (.06%)	80–120.
Morantel tartrate	90–110	66.0 g/lb (14.52%)	85–115.
Neomycin	80–120	20 g/lb (4.4%)	70–125.
Oxytetracycline	80–120	20 g/lb (4.4%)	65–135.
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125.
Nicarbazin (granular)	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Narasin	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Nicarbazin (powder)	98–106	5.675 g/lb (1.25%)	85–115/80–120.
Novobiocin	85–115	17.5 g/lb (3.85%)	80–120.
Pyrantel tartrate	90–110	36 g/lb (7.9%)	75–125.
Robenidine	95–115	1.5 g/lb (0.33%)	80–120.
Sulfadimethoxine	90–110	Poultry: 5.675 g/lb Fish: 85.1 g/lb	80–115/75–125.
Ormetoprim	90–110	Poultry: 3.405 g/lb Fish: 17.0 g/lb	80–115.
Sulfamerazine	85–115	18.6 g/lb (4.0%)	85–115.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Sulfaquinoxaline	98–106	11.2 g/lb (2.5%)	85–115.
Thiabendazole	94–106	45.4 g/lb (10.0%)	>7% 85–115; <7% 90–110.
Tiamulin hydrogen fumarate	90–115	10 g/lb	90–115/70–130.
Tilmicosin	90–110	37.9 g/lb (8.35%)	85–115.
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115.

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section?* This section covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:

(2) Type C feed that is intended for the following:

(i) Further manufacture of another Type C feed, or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).

(b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medicated feed is covered by this section and by § 510.455.

(c) *What is required for new animal drugs intended for use in liquid feed?* Any new animal drug intended for use in liquid feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) or index listed under section 572 of the act. Such approvals under section 512 of the act must be:

(1) An original NADA,

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(d) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in liquid feed?* An approval under section 512 of the act for a new animal drug intended for use in liquid feed must contain the following information:

(1) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and

(2) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(3) Feed labeling with recirculation or agitation directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted?* The data must be submitted as follows:

(1) Directly in the NADA,

(2) By a sponsor, or

(3) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed?* The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include the following requirements:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of a liquid medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All liquid medicated feeds that contain a Category II drug, and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds?* Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: ''FOR USE IN _____ ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.'' The blank may be filled in with the words: ''DRY FEEDS'', ''DRINKING WATER'', or ''DRY FEEDS AND DRINKING WATER''.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for a waiver?* (1) The labeling provisions of paragraph (h) of this section may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section?* The labeling provisions of paragraph (h) of this section may be implemented without prior approval as provided for in § 514.8(c)(3) of this chapter.

[69 FR 30197, May 27, 2004, as amended at 71 FR 74785, Dec. 13, 2006; 72 FR 69131, Dec. 6, 2007]

§ 558.6 Veterinary feed directive drugs.

(a) *General requirements related to veterinary feed directive (VFD) drugs.* (1) Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

(2) A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

(3) Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request.

(6) All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.''

(b) *Responsibilities of the veterinarian issuing the VFD.* (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

(i) Be licensed to practice veterinary medicine; and

(ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in § 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter.

(2) The veterinarian must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.

(3) The veterinarian must ensure that the following information is fully and accurately included on the VFD:

(i) The veterinarian's name, address, and telephone number;

(ii) The client's name, business or home address, and telephone number;

(iii) The premises at which the animals specified in the VFD are located;

(iv) The date of VFD issuance;

(v) The expiration date of the VFD. This date must not extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD must not exceed 6 months after the date of issuance;

(vi) The name of the VFD drug(s);

(vii) The species and production class of animals to be fed the VFD feed;

(viii) The approximate number of animals to be fed the VFD feed by the expiration date of the VFD. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of VFD drug in the VFD feed and duration of use;

(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted;

(xiii) The statement: ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.'';

(xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6) of this section; and

(xv) The veterinarian's electronic or written signature.

(4) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the VFD feed:

(i) A more specific description of the location of animals (*e.g.*, by site, pen, barn, stall, tank, or other descriptor that the veterinarian deems appropriate);

(ii) The approximate age range of the animals;

(iii) The approximate weight range of the animals; and

(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

(5) For VFDs intended to authorize the use of an approved, conditionally approved, or indexed combination VFD drug that includes more than one VFD drug, the veterinarian must include the drug-specific information required in paragraphs (b)(3)(vi), (ix), (x), and (xi) of this section for each VFD drug in the combination.

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

(i) ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.''

(ii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]

(iii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in

any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.''

(7) The veterinarian must issue a written (nonverbal) VFD.

(8) The veterinarian must send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client.

(9) The veterinarian must provide a copy of the VFD to the client.

(c) *Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug.* (1) The distributor is permitted to fill a VFD only if the VFD contains all the information required in paragraph (b)(3) of this section.

(2) The distributor is permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug.

(3) The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years.

(4) In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

(5) A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes animal feed containing a VFD drug. The notification is required one time per distributor and must include the following information:

(i) The distributor's complete name and business address;

(ii) The distributor's signature or the signature of the distributor's authorized agent; and

(iii) The date the notification was signed.

(6) A distributor must also notify FDA within 30 days of any change in ownership, business name, or business address.

(7) The notifications cited in paragraphs (c)(5) and (c)(6) of this section must be submitted to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 7519 Standish Pl., Rockville, MD 20855, FAX: 240–453–6882.

(8) A distributor is permitted to distribute a VFD feed to another distributor only if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in § 558.3(b)(11), from the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor's acknowledgment letter for 2 years.

[80 FR 31733, June 3, 2015; 80 FR 35841, June 23, 2015]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) *Approvals.* Type A medicated articles: 25 percent to No. 016592 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use*—(1) *Cattle.* It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592
(ii) 113.5 to 11, 350; to provide 10 milligrams per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592

(2) *Chickens*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	.....	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously until onset of production as follows:	016592

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylenedisalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed according to subtable in item (i). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 72.6 to 113.5	.....	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella* only.	Feed continuously as the sole ration; as sole source of amprolium.	016592
(iv) 72.6 to 113.5	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella* only; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(v) 113.5	.....	1. Laying chickens: For prevention of coccidiosis.	Feed continuously as the sole ration; as the sole source of amprolium.	016592
		2. Laying chickens: For treatment of coccidiosis in moderate outbreaks.	Feed for 2 weeks.	
(vi) 113.5 to 227	.....	1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously from day-old until onset of production; as the sole source of amprolium.	016592
		2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously as the sole ration; as sole source of amprolium.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vii) 113.5 to 227	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(viii) 227	.....	Laying chickens: For treatment of coccidiosis in severe outbreaks..	Feed for 2 weeks	016592

(3) *Turkeys*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(ii) 113.5 to 227	.....	Turkeys: For prevention of coccidiosis.	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) *Pheasants*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159	.....	Growing pheasants: For the prevention of coccidiosis caused by *Eimeria colchici, E. duodenalis,* and *E. phasiani.*	Feed continuously as sole ration. Use as sole source of amprolium.	016592
(ii) [Reserved]				

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.58 Amprolium and ethopabate.

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. It is used in chicken feed as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6.	.....	Broiler chickens: As an aid in the prevention of coccidiosis.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens.	016592
(2) [Reserved].				

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(3) Amprolium 113.5 and ethopabate 36.3.	.....	Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Feed continuously as sole ration; as sole source of amprolium. Not for chickens over 16 weeks of age.	016592
(4) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	1. Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis. Bacitracin as bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(5) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for improved feed efficiency.	Feed as the sole ration from the time chickens are placed on litter until market weight. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(6) Amprolium 113.5 and ethopabate 36.6.	Bambermycins 1 to 3.	Broiler chickens: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain, improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(7)–(8) [Reserved].				
(9) Amprolium 227 and ethopabate 3.6.	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying chickens	016592

(f) Amprolium and ethopabate may also be used in combination with:

(1)–(2) [Reserved]

(3) Chlortetracycline as in § 558.128.

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.58, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.59 Apramycin.

(a) *Specifications.* Type A articles containing 75 grams apramycin (as apramycin sulfate) per pound.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use in swine—*

Apramycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 150	.....	For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli.*	Feed as the sole ration for 14 consecutive days. Withdraw 28 days before slaughter.	058198
(2) [Reserved].				

[81 FR 94995, Dec. 27, 2016]

§ 558.68 Avilamycin.

(a) Each pound of Type A medicated article contains 45.4 or 90.7 grams of avilamycin.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.68 of this chapter.

(d) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for avilamycin medicated feeds must not exceed 90 days from the date of issuance. VFDs for avilamycin shall not be refilled.

(e) *Conditions of use*. Administer in feed as follows:

(1) *Chickens*—

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.6 to 40.9		Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age.	058198
(ii) 13.6 to 40.9	Monensin 90 to 110; as provided by No. 058198 in § 510.600(c) of this chapter	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. See § 558.355(d) of this chapter for additional required labeling.	058198

(2) *Swine*—

Avilamycin in grams/ton	Combinationin grams/ton	Indications for use	Limitations	Sponsor
(i) 73		Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in pigs, do not administer to pigs 14 weeks of age or older.	058198
(ii) [Reserved].				

[80 FR 61297, Oct. 13, 2015, as amended at 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 48703, July 26, 2016; 81 FR 59134, Aug. 29, 2016; 81 FR 67152, Sept. 30, 2016; 82 FR 11509, Feb. 24, 2017]

§ 558.76 Bacitracin methylenedisalicylate.

(a) *Specifications*. (1) Type A medicated articles containing 10, 25, 30, 40, 50, 60, or 75 grams bacitracin methylenedisalicylate per pound.

(2) Type A medicated article containing 50 grams bacitracin methylenedisalicylate per pound.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use of products in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(iii), (e)(1)(v) through (xiii), and (e)(1)(xv) of this section.

(2) No. 069254 for use of products in paragraph (a)(2) of this section as in paragraphs (e)(1)(ii), (e)(1)(iv), (e)(1)(xiv), and (e)(1)(xvi) of this section.

(c) *Special considerations*. The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(d) *Related tolerances*. See § 556.70 of this chapter.

(e) *Conditions of use*. (1) It is used as follows:

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
(i) 4 to 50 g/ton		Chickens, turkeys, and pheasants: For increased rate of weight gain and improved feed efficiency.		054771
(ii) 4 to 50 g/ton		Broiler and replacement chickens, growing turkeys, and growing pheasants: For increased rate of weight gain and improved feed efficiency.		069254
(iii) 5 to 20 g/ton		Quail not over 5 weeks of age: For increased rate of weight gain and improved feed efficiency.		054771
(iv) 5 to 20 g/ton		Growing quail: For increased rate of weight gain and improved feed efficiency.	For use in quail not over 5 weeks of age.	069254
(v) 10 to 25 g/ton		Chickens: For increased egg production and improved feed efficiency for egg production.	For first 7 months of production	054771
(vi) 10 to 30 g/ton		Swine: For increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	054771
(vii) [Reserved].				
(viii) 10 to 30 g/ton		Swine: For control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 50 g/ton		Broiler chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration	054771
(x) 100 to 200 g/ton		Broiler chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/ton).	054771
(xi) 200 g/ton		Turkeys: As an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylenedisalicylate. Quail: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate.	Feed continuously as the sole ration.	054771
(xii) 250 g/ton		1. Growing/finishing swine: For control of swine dysentery *Treponema hyodysenteriae* on premises with history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition.	As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian a when results are not satisfactory.	054771

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
		2. Pregnant sows: For control of clostridial enteritis caused by *C. perfringens* in suckling piglets.	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by veterinarian when results are not satisfactory.	
(xiii) To provide 70 mg per head per day.	.....	Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	054771
(xiv) To provide 70 mg per head per day.	.....	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	069254
(xv) To provide 250 mg per head per day.	.....	Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	054771
(xvi) To provide 250 mg per head per day.	.....	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	069254

(2) Bacitracin methylenedisalicylate may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Chlortetracycline as in § 558.128.

(iv) Clopidol as in § 558.175.

(v) Decoquinate as in § 558.195.

(vi) Diclazuril as in § 558.198.

(vii) Fenbendazole as in § 588.258.

(viii) Halofuginone hydrobromide as in § 558.265.

(ix) Ivermectin as in § 558.300.

(x) Lasalocid as in § 558.311.

(xi) Monensin as in § 588.355.

(xii) Narasin as in § 558.363.

(xiii) Nicarbazin alone and with narasin as in § 558.366.

(xiv) Robenidine as in § 558.515.

(xv) Salinomycin as in § 558.550.

(xvi) Semduramicin as in § 558.555.

(xvii) Zoalene as in § 558.680.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTES 1. For FEDERAL REGISTER citations affecting § 558.76, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

2. At 80 FR 78970, Dec. 18, 2015, § 558.76 was amended by removing and reserving paragraph (d)(3)(xiii); however, the amendment could not be incorporated because the paragraph did not exist.

§ 558.78 Bacitracin zinc.

(a) *Specifications.* Type A medicated articles containing bacitracin zinc equivalent to 10, 25, 40, or 50 grams per pound bacitracin.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	.....	Chickens: for increased rate of weight gain and improved feed efficiency.	Growing chickens	054771
(ii) 4 to 50	.....	Turkeys and pheasants: for increased rate of weight gain and improved feed efficiency.	Growing turkeys and pheasants	054771
(iii) 5 to 20	.....	Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as the Type C feed to starting quail through 5 weeks of age.	054771

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(iv) 10 to 25		Laying chickens; improved feed efficiency and increased egg production.		054771
(v) 10 to 50		Swine; increased rate of weight gain and improved feed efficiency.	Growing and finishing swine	054771
(vi) 20		Growing-finishing swine; increased rate of weight gain.	In Type C feed	054771
(vii) 20 to 40		Growing-finishing swine; improved feed efficiency.	do	054771

(2) It is used in feed for growing cattle at 35 to 70 milligrams per head per day as follows:

(i) To aid in stimulating growth and improving feed efficiency.

(ii) For increased rate of weight gain and improved feed efficiency; see sponsor 054771.

(3) Bacitracin zinc may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Clopidol as in § 558.175.

(iii) Decoquinate as in § 558.195.

(iv) Lasalocid as in § 558.311.

(v) Monensin as in § 558.355.

(vi) Naracin as in § 558.363.

(vii) [Reserved]

(viii) Robenidine as in § 558.515.

(ix) Salinomycin as in § 558.550.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.95 Bambermycins.

(a) *Approvals.* See sponsors in § 510.600(c) of this chapter for use of Type A medicated articles as in paragraph (d) of this section:

(1) No. 016592: 2, 4, and 10 grams per pound for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) No. 012286: 2 grams for use as in paragraph (d)(2) of this section and 0.4 and 2 grams per pound for use as in paragraph (d)(3).

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) *Conditions of use*—(1) *Chickens.* Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Broiler chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	016592.
(ii) [Reserved].			

(2) *Turkeys.* Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Growing turkeys: For improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.
(ii) 2	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.

(3) *Swine.* Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Growing-finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.
(ii) 2 to 4	Growing-finishing swine: For increased rate of weight.	Feed continuously as the sole ration.	012286, 016592.

(4) *Cattle.*

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 4	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592.
(ii) 2 to 80	Pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.	016592.

(iii) Used as a free-choice Type C medicated loose-mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

(*a*) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6–01–080	42.50
Sodium chloride (salt)	6–04–152	20.10
Calcium carbonate (38% calcium)	6–01–069	15.24
Corn distillers dried grains w/solubles	5–28–236	9.57
Magnesium oxide	6–02–756	5.15
Vitamin and trace mineral premix *	.....	3.72
Mineral oil	.....	1.00
Yeast (primary dehydrated yeast)	7–05–533	0.75
Bambermycins Type A article (10 g/lb)	.....	0.60
Iron oxide	6–02–431	0.50
Magnesium sulfate (67%)	6–02–758	0.32
Selenium premix (270 mg/lb) *	.....	0.21
Copper sulfate	6–01–720	0.18
Potassium sulfate (0.33%)	6–06–098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(*b*) *Amount per ton.* 120 grams.

(*c*)*Indications for use.* For increased rate of weight gain.

(*d*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

(*a*) *Amount.* Feed continuously to provide 10 to 40 milligrams of bambermycins per head per day.

(*b*) *Indications for use.* For increased rate of weight gain.

(*c*) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(v) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) as follows:

(A) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6–01–080	42.50
Sodium chloride (salt)	6–04–152	20.10
Calcium carbonate (38% calcium)	6–01–069	15.45
Corn distillers dried grains w/solubles	5–28–236	9.57
Magnesium oxide	6–02–756	5.15
Vitamin and trace mineral premix*		3.72
Mineral oil		1.00
Yeast (primary dehydrated yeast)	7–05–533	0.75
Bambermycins Type A article (10 g/lb)		0.60
Iron oxide	6–02–431	0.50
Magnesium sulfate (67%)	6–02–758	0.32
Copper sulfate	6–01–720	0.18
Potassium sulfate (0.33%)	6–06–098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(B) *Amount per ton.* 120 grams.

(C) *Indications for use.* For increased rate of weight gain.

(D) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers). Feed a non-medicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(5) Bambermycins may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Clopidal as in § 558.175.

(iv) Diclazuril as in § 558.198.

(v) Halofuginone as in § 558.265.

(vi) Lasalocid as in § 558.311.

(vii) Monensin as in § 558.355.

(viii) Narasin alone or with nicarbazin as in § 558.363.

(ix) Nicarbazin as in § 558.366.

(x) Salinomycin as in § 558.550.

(xi) Zoalene as in § 558.680.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2. percent (10 grams per pound) to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.100 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) Carbadox may also be used in combination with oxytetracycline as in § 558.450.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004; 82 FR 21691, May 10, 2017]

§ 558.128 Chlortetracycline.

(a) *Specifications.* Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride, or for products intended for use in milk replacer, chlortetracycline hydrochloride.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) *Nos. 054771:* 50, 90, or 100 grams per pound (g/lb) Type A medicated article.

(2) *No. 066104:* 10, 20, 30, 50, 70, or 100 g/lb of Type A medicated article.

(3) *No. 069254:* 50, 90, or 100 g/lb of Type A medicated article.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for chlortetracycline medicated feeds must not exceed 6 months from the date of issuance. VFDs for chlortetracycline shall not be refilled.

(3) In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.''

(4) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

(5) When manufactured for use as in paragraph (e)(5)(iii) of this section, include on labeling the warning: ''Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.''

(e) *Conditions of use*—(1) *Chickens.* It is used as follows:

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 100 to 200 g/ton	.....	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. For No. 066104: Do not feed to chickens producing eggs for human consumption.	054771 066104 069254
(ii) 100 to 200 g/ton ...	Clopidol, 113.5	Broiler and replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti;* and for control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as the sole ration from the time chicks are placed in floor pens for 7 to 14 days. Do not feed to chickens over 16 weeks of age. Do not feed to chickens producing eggs for human consumption. Chlortetracycline as provided by No. 054771; clopidol as provided by No. 016592 in § 510.600(c) of this chapter.	016592

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 100 to 200 g/ton ..	Decoquinate, 27.2 ...	Chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* and for control of infectious synovitis caused by *M, synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption. Chlortetracycline and decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 100 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration. Do not use this product in feeds conta. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 200 to 400 g/ton ...	.....	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. For No. 066104: Do not feed to chickens producing eggs for human consumption.	054771 066104 069254
(vi) 200 g/ton	Amprolium, 227 and ethopabate, 3.6.	For chickens where immunity to coccidiosis is not desired: For prevention of coccidiosis; and for treatment of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline.	Use in low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption. Chlortetracycline as provided by No. 054771; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter.	054771
(vii) 200 g/ton	Decoquinate, 27.2 ...	Broilers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* and for the treatment of chronic respiratory disease (air sac infection) and the prevention of synovitis.	Feed continuously as the sole ration for no more than 8 weeks. Use in low calcium feed containing 0.8% dietary calcium. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption. Chlortetracycline and decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 200 g/ton	Robenidine 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ix) 500 g/ton		Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 days. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	054771 069254
			2. Feed for 5 days; withdraw 24 hours prior to slaughter. Do not feed to chickens producing eggs for human consumption.	054771 066104 069254
(x) 500 g/ton	Monensin, 90 to 110	Chickens: As an aid in the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline; and as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed for 5 days as the sole ration. Do not feed to laying chickens. Not to be fed continuously for more than 5 days. Do not feed to chickens over 16 weeks of age. Withdraw 24 hours before slaughter. See § 558.355(d) of this chapter. Chlortetracycline as provided by No. 054771; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	054771 069254
(xi) 500 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.	Feed continuously as sole ration for up to 5 days. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xii) 500 g/ton	Salinomycin, 40 to 60.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.	For use in low calcium feeds containing 0.8% calcium. Not approved for use with pellet binders. Not to be fed continuously for more than 5 days. Do not feed to laying chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by Nos. 054771 or 069254; salinomycin as provided by Nos. 054771 or 016592 in § 510.600(c) of this chapter.	016592 054771 069254

(2) *Turkeys.* It is used as follows:

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 200 g/ton		Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254
(ii) 400 g/ton		1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254
		2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.		054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 25 mg/lb of body weight.	.....	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254

(3) *Swine.* It is used as follows:

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 50 to 100 g/ton	.....	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline.	.....	054771 066104 069254
(ii) 400 g/ton	.....	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 days.	054771 066104 069254
(iii) 10 mg/lb of body weight.	.....	Swine: For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254 in § 510.600(c) of this chapter.	054771 066104 069254
(iv) 10 mg/lb of body weight.	Bacitracin methylenedisalicylate, 10 to 30.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days.	054771
(v) 10 mg/lb of body weight.	Bacitracin methylenedisalicylate, 10 to 30.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide 10 mg/lb of body weight. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254. Bacitracin methylenedisalicylate provided by No. 054771; chlortetracycline provided by Nos. 054771 and 069254 in § 510.600(c) of this chapter.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vi) 10 mg/lb of body weight.	Tiamulin hydrogen fumarate, 35.	For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin and for treatment of swine bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* sensitive to chlortetracycline and treatment of bacterial pneumonia caused by *P. multocida* sensitive to chlortetracycline.	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide 10 mg/lb of body weight. Feed continuously as the sole ration for 14 days. Withdraw medicated feed 2 days before slaughter. Tiamulin as provided by Nos. 058198 or 069254 in § 510.600(c) of this chapter.	058198 069254

(4) *Cattle*. It is used as follows:

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.5 mg/lb of body weight daily.	.....	Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254
(ii) 25 to 1,100 to provide 0.5 mg/lb of body weight daily.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) over 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis 0.5 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 0.5 to 2.0 mg/lb of body weight daily.	.....	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771 069254
(iv) 10 mg/lb of body weight daily.	.....	1. Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor No. 069254: zero withdrawal time. See paragraph (d)(3) of this section.	054771 066104 069254
		2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	See paragraph (d)(3) of this section.	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(v) 10 mg/lb of body weight daily.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vi) 10 mg/lb of body weight daily.	Laidlomycin, 5 to 10.	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) 500 to 2,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 500 to 1,200 to provide 10 mg/lb of body weight daily.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ix) 500 to 4,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(x) 500 to 4,000 g/ton	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046–699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal period.	054771 069254
(xi) 500 to 4,000	Decoquinate, 12.9 to 90.8.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xii) 4,000 to 20,000 g/ton ..	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(3) of this section.	054771 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xiii) 4,000 to 20,000 g/ton	Decoquinate, 90.8 to 535.7.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *E. bovis* and *E. zuernii*.	Administer as a top dress supplement or mix into the daily ration to provide 22.7 mg decoquinate per 100 lb of body weight per day and 1 g chlortetracycline per 100 lb body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xiv) 70 mg/head/day	.....	Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	See paragraph (d)(3) of this section.	054771 066104 069254
(xv) 350 mg/head/day	.....	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-hour withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal period.	054771 066104 069254
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-hour withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	054771 066104 069254
(xvi) 350 mg/head/day	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xvii) 350 mg/head/day	Laidlomycin, 5 to 10.	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xviii) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xix) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xx) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxi) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxii) 25 to 700 to provide 350 mg/head/day.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxiii) 25 to 700 to provide 350 mg/head/day.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) under 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxiv) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8.	Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Chlortetracycline and lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxv) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8.	Beef cattle weighing up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for the control of coccidiosis caused by *E. bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxvi) 500 to 4,000 to provide 10 mg/head/day.	Lasalocid, 30 to 181.8.	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously for not more than 5 days at a rate of 10 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(5) *Minor species*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.		054771 066104 069254
(ii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day, depending upon age and severity of disease, for not more than 21 days. Do not feed to ducks producing eggs for human consumption.	054771 069254
(iii) 10 mg/g of finished feed daily.	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	Feed continuously for 45 days. Each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. See paragraph (d)(5) of this section.	054771 069254

(6) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Dicalcium Phosphate	46.20	6–26–335
Sodium Chloride (Salt)	15.00	6–04–152
Magnesium Oxide	10.67	6–02–756
Cottonseed Meal	10.00	5–01–625
Trace Mineral/Vitamin Premix[1]	3.80	
Calcium Carbonate	3.50	6–01–069
Dried Cane Molasses	3.00	4–04–695
Potassium Chloride	2.00	6–03–755
Mineral Oil	2.00	8–03–123
Iron Oxide	0.50	6–02–431
Chlortetracycline Type A medicated article (90 gram/lb)	3.33	

[1] Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(ii) *Amount.* 6,000 grams per ton.

(iii) Indications for use. Beef and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 0.5 to 2.0 mg chlortetracycline per pound of body weight per day.

(v) *Sponsors.* See Nos. 054771 and 069254 in § 510.600(c) of this chapter.

[81 FR 94995, Dec. 27, 2016, as amended at 82 FR 21691, May 10, 2017; 82 FR 43485, Sept. 18, 2017; 83 FR 13636, Mar. 30, 2018]

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing:

(1) 35 grams (g) per pound (/lb) each, chlortetracycline and sulfamethazine.

(2) 40 g/lb each, chlortetracycline and sulfamethazine.

(b) *Sponsors.* See sponsors numbers in § 510.600(c) of this chapter as follow:

(1) Nos. 054771 and 069254 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 054771 and 069254 for use of product described in paragraph (a)(2) as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for chlortetracycline and sulfamethazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for chlortetracycline and sulfamethazine shall not be refilled.

(e) *Conditions of use*—(1) *Cattle.* It is used in feed for beef cattle as follows:

(i) *Amount.* 350 milligrams per head per day each, chlortetracycline and sulfamethazine.

(ii) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(iii) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter. A

withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(2) *Swine.* It is used in swine feed as follows:

(i) *Amount.* 100 g/ton each, chlortetracycline and sulfamethazine.

(ii) *Indications for use.* For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis.

(iii) *Limitations.* Feed as the sole ration. Withdraw 15 days prior to slaughter.

[79 FR 37622, July 2, 2014, as amended at 80 FR 13231, Mar. 13, 2015; 81 FR 63054, Sept. 14, 2016; 81 FR 95004, Dec. 27, 2016; 82 FR 21691, May 10, 2017]

§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.160 of this chapter.

(d) *Conditions of use.* It is used as follows:

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 113.5	.....	Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Do not feed to chickens over 16 weeks of age.	016592
(2) 113.5	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(3) 113.5	Bacitracin zinc 5 to 25.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771 016592
(4) 113.5	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age	016592
(5)–(6) [Reserved].				
(7) 227	.....	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section.	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	016592
(8) 227	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age	016592

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(9) 113.5 or 227	.....	Turkeys: As an aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi.*	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	016592

(e) Clopidol may also be used in combination with:

(1)–(2) [Reserved]

(3) Chlortetracycline as in § 558.128.

(4) Lincomycin as in § 558.325.

[68 FR 17882, Apr. 14, 2003, as amended at 72 FR 60551, Oct. 25, 2007; 74 FR 61028, Nov. 23, 2009; 79 FR 10965, 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95004, Dec. 27, 2016]

§ 558.185 Coumaphos.

(a) *Specifications.* Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000859 for use of Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

(2) No. 051311 for use of Type A medicated articles containing 1.12 percent coumaphos as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See 40 CFR 180.189.

(d) *Special considerations.* Labeling shall bear the following caution statement: ''The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.'' Also, see § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Beef and dairy cattle*—(i) *Amount.* 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) *Indications for use.* Control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Trichostrongylus* spp.).

(iii) *Limitations.* Feed in the normal grain ration to which the animals are accustomed, but not in rations containing more than 0.1 percent coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with oral drenches or with feeds containing phenothiazine.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as total feed ration for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 1463, Jan. 7, 1977; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 34729, July 3, 1996; 69 FR 70056, Dec. 2, 2004; 70 FR 32489, June 3, 2005; 75 FR 24394, May 5, 2010]

§ 558.195 Decoquinate.

(a) *Specifications.* Type A medicated article containing 6 percent decoquinate.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Special considerations.* (1) Bentonite should not be used in decoquinate feeds.

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

(3) Type C cattle feeds may be manufactured from decoquinate liquid Type B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

(e) *Conditions of use.* It is used as follows:

(1) *Chickens.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2	.....	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*..	Do not feed to laying hens producing eggs for human consumption..	054771
(ii) 27.2	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylenedisalicylate as provided by No. 054771in § 510.600(c) of this chapter..	054771
(iii) 27.2	Bacitracin zinc 10 to 50.	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(iv)–(vi) [Reserved].				

(2) *Cattle.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	.....	Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for human consumption. See paragraph (d)(3) of this section..	054771
(ii) [Reserved].				
(iii) 12.9 to 90.8 ..	Monensin 5 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for improved feed efficiency..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and §558.355(d)(8). Monensin as provided by No. 058198 in §510.600(c) of this chapter..	054771
(iv) [Reserved].				
(v) 13.6 to 27.2 ...	Monensin 5 to 30 plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for improved feed efficiency; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and §558.355(d)(8). Monensin as provided by No. 058198, and tylosin as provided by Nos. 058198 and 016592 in §510.600(c) of this chapter.	016592, 054771
(vi) 90.9 to 535.7	.....	Cattle (including ruminating and nonruminating calves and veal calves): As in paragraph (e)(2)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section..	054771
(vii) [Reserved].				

(3) *Minor species.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	.....	1. Young sheep: For the prevention of coccidiosis caused by *Eimeria ovinoidalis, E. crandallis, E. parva,* and *E. bakuensis*..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption..	054771
.....	.....	2. Young goats: For the prevention of coccidiosis caused by *E. christenseni* and *E. ninakohlyakimovae*..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption..	
(ii) 90.9 to 535.7	.....	1. Young sheep: As in item 1 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption..	054771
.....	.....	2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption..	

(4) Decoquinate may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

[67 FR 72370, Dec. 5, 2002; 68 FR 15372, Mar. 31, 2003; 69 FR 26499, May 13, 2004; 69 FR 52816, Aug. 30, 2004; 69 FR 62407, Oct. 26, 2004; 69 FR 67264, Nov. 17, 2004; 70 FR 2567, Jan. 14, 2005; 78 FR 25183, Apr. 30, 2013; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 79 FR 17860, Mar. 31, 2014; 80 FR 13231, Mar. 13, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 22525, Apr. 18, 2016; 81 FR 67152, Sept. 30, 2016; 81 FR 95004, Dec. 27, 2016]

§ 558.198 Diclazuril.

(a) *Specifications.* Type A medicated article containing 0.2 percent diclazuril.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.185 of this chapter.

(d) *Conditions of use*—(1) *Chickens.* For chickens it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 part per million (ppm)).	.....	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati*), and *E. maxima.* Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*..	Feed continuously. Not for use in hens producing eggs for human food..	016592
(ii) 0.91 (1 ppm) ..	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bacitracin methylenedisalicylate provided by 054771..	016592
(iii) 0.91 (1 ppm)	Bambermycins 1 to 2	Broiler chickens: As in item (i) of this table); for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bambermycins provided by 057926..	016592
(iv)–(v) [Reserved].				

(2) *Turkeys.* For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 ppm) ..	.....	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. gallopavonis* and *E. meleagrimitis*..	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption..	016592
(ii) 0.91 (1 ppm).	Bacitracin methylenedisalicylate 4 to 50..	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter..	016592
(iii) 0.91 (1 ppm).	Bambermycins 1 to 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592
(iv) 0.91 (1 ppm).	Bambermycins 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592

(3) Diclazuril may also be used in combination with virginiamycin as in § 558.635.

[64 FR 35923, July 2, 1999, as amended at 65 FR 50134, Aug. 17, 2000; 66 FR 47962, 47963, Sept. 17, 2001; 66 FR 62917, Dec. 4, 2001; 67 FR 34830, May 16, 2002; 67 FR 47257, July 18, 2002; 67 FR 48549, July 25, 2002; 69 FR 9947, Mar. 3, 2004; 72 FR 60552, Oct. 25, 2007; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95004, Dec. 27, 2016]

§ 558.205 Dichlorvos.

(a) *Approvals.* Type A medicated articles: 3.1 and 9.6 percent to 054628 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician

or a veterinarian. Atropine is antidotal.

(3) Labeling for Type A articles and Type B feeds must include a statement that containers or materials used in packaging such Type A articles and Type B feeds are not to be reused and all such packaging materials must be destroyed after the product has been used.

(c) *Related tolerances.* See § 556.180 of this chapter.

(d) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Dichlorvos, 348 grams (0.0384 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.

(2) *Amount per ton.* Dichlorvos, 479 grams (0.0528 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

(3) *Amount per ton.* Dichlorvos, 334–500 grams (0.0366–0.0550 percent).

(i) *Indications for use.* An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum supp.*) large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.

(ii) *Limitations.* For pregnant swine; mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 50258, Oct. 29, 1975; 48 FR 46515, Oct. 13, 1983; 51 FR 7397, Mar. 3, 1986; 51 FR 28547, Aug. 8, 1986; 52 FR 2684, Jan. 26, 1987; 62 FR 35077, June 30, 1997; 78 FR 21060, Apr. 9, 2013]

§ 558.235 Efrotomycin.

(a) *Approvals.* Type A medicated article: 14.5 grams per pound to 050604 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3.6 grams per ton.

(A) *Indications for use.* For improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(ii) *Amount.* 3.6 to 14.5 grams per ton.

(A) *Indications for use.* For increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(2) [Reserved]

[57 FR 38442, Aug. 25, 1992, as amended at 62 FR 63271, Nov. 28, 1997]

§ 558.248 Erythromycin.

(a) *Specifications.* Type A medicated articles containing 92.5 grams per pound erythromycin (as the thiocyanate salt).

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for erythromycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for erythromycin shall not be refilled.

(e) *Conditions of use*—(1) *Chickens*—

Erythromycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 92.5		Chickens: As an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 days before stress and 3 to 6 days after stress. Withdraw 24 hours before slaughter.	061623
(ii) 92.5		Chickens: As an aid in the prevention of infectious coryza.	Feed for 7 to 14 days. Withdraw 24 hours before slaughter.	061623
(iii) 185		Chickens: As an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease (CRD).	Feed for 5 to 8 days. Withdraw 48 hours before slaughter. Do not use in birds producing eggs for food.	061623

(2) *Turkeys*—

Erythromycin thiocyanate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 92.5		Turkeys: As an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 days before stress and 3 to 6 days after stress.	061623
(ii) 185		Turkeys: As an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease (CRD).	Feed for 5 to 8 days. Do not use in birds producing eggs for food.	061623

[41 FR 10999, Mar. 15, 1976, as amended at 45 FR 56799, Aug. 26, 1980; 49 FR 31281, Aug. 6, 1984; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 54 FR 12189, Mar. 24, 1989; 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 79 FR 10982, Feb. 27, 2014; 81 FR 36790, June 8, 2016; 81 FR 95004, Dec. 27, 2016]

§ 558.254 Famphur.

(a) *Approvals.* Type A medicated articles: 13.2 and 33.3 percent to 000061 in § 510.600(c) of this chapter.

(b) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Conditions of use.* It is used in the feed for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

[41 FR 11000, Mar. 15, 1976, as amended at 51 FR 7397, Mar. 3, 1986; 57 FR 7652, Mar. 4, 1992; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 558.258 Fenbendazole.

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

(b) *Approvals.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Turkeys.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million).	.....	Growing turkeys: For the removal and control of gastrointestinal worms: roundworms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	000061

(2) *Swine.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period.	.....	For the removal and control of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration	000061
(ii)–(v) [Reserved].				
(vi) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylenedisalicylate 10 to 30.	Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.	054771
(vii) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylenedisalicylate 250.	1. Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition. 2. Pregnant sows: As in paragraph (e)(2)(i) of this section; for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*.	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter. 2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.	054771

(3) *Cattle.*

Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) 5 mg/kg body weight (2.27 mg/lb)	Dairy and beef cattle: For the removal and control of: Lungworms (*Dictyocaulus viviparus*); Stomach worms: barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*); Intestinal worms: hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia oncophora* and *C. punctata*); Bankrupt worms (*Trichostrongylus colubriformis*); and Nodular worms (*Oesophagostomum radiatum*).	Feed as the sole ration or as a top dress for one day. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	000061
(ii) [Reserved]			

(iii) *Free-choice feeds*—(A) *Amount.* 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient[1]	Percent	International Feed No.
(*1*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(*2*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695
Potassium iodide	0.01	6–03–759
Fenbendazole 20% Type A article	2.10	n/a
(*3*) Free-choice, liquid Type C feed:		
Cane molasses[2]	80.902	4–13–251
Water	9.36	n/a
Urea solution, 55%	7.05	5–05–707
Phosphoric acid 75% (feed grade)	2.00	6–03–707
Xantham gum	0.20	8–15–818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1]The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (*see* 21 CFR 573.920).

[2]The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(B) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(4) *Horses.*

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), and pinworms (*Oxyuris equi*); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (*Parascaris equorum*)..	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for human consumption..	000061
(ii) [Reserved]			

(5) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (*Sus scrofa*).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(iii) Rocky mountain bighorn sheep (*Ovis c. canadensis*).	10 mg/kg/day for 3 days..	For the removal and control of *Protostrongylus* spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

(6) Fenbendazole may also be used in combination with:

(i) [Reserved]

(ii) Lincomycin as in § 558.325.

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003; 72 FR 66046, Nov. 27, 2007; 73 FR 58873, Oct. 8, 2008; 74 FR 61517, Nov. 25, 2009; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95005, Dec. 27, 2016]

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.283 of this chapter.

(d) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

(i) For swine must not exceed 90 days from the date of issuance.

(ii) For fish must not exceed 6 months from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

(4) Type A medicated articles and medicated feeds intended for use in fish shall bear the following: ''Not for use in animals intended for breeding purposes. The effects of florfenicol on reproductive performance have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy.''

(e) *Conditions of use*—(1) *Swine*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
182	For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD..	Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.

(2) *Fish*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 2,724	Catfish: For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(iii) 182 to 2,724	Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with *Flavobacterium columnare.*	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iv) 273 to 2,724	Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae.*	Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

[70 FR 70047, Nov. 21, 2005, as amended at 71 FR 70304, Dec. 4, 2006; 72 FR 19798, Apr. 20, 2007; 72 FR 65885, Nov. 26, 2007; 77 FR 32012, May 31, 2012; 79 FR 18159, Apr. 1, 2014; 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 67152, Sept. 30, 2016]

§ 558.265 Halofuginone.

(a) *Specifications.* Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.308 of this chapter.

(d) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima;* for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii)–(v) [Reserved]

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mevati*, *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vii)–(viii) [Reserved]

(2) It is used in feed for turkeys as follows:

(i) *Amount per ton.* 1.36 to 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 7 days before slaughter; do not feed to layers or water fowl; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone hydrobromide 1.36 to 2.72 grams plus bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*., and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

(iii) *Amount per ton.* 1.36 to 2.72 grams of halofuginone hydrobromide plus 2 grams of bambermycins.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide is toxic to fish and other aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an eye and skin irritant. Avoid contact with skin, eyes, and clothing.

(3) It is used in feed for replacement cage laying chickens and replacement broiler breeder chickens as follows:

(i) *Amount per ton.* 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. mivati*/*E. mitis*, and *E. brunetti*.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Withdraw 4 days before slaughter. Do not feed to laying chickens or water fowl. Halofuginone hydrobromide is toxic to fish and aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an irritant to eyes and skin. Avoid contact with skin, eyes, and clothing.

(ii) [Reserved]

(4) Halofuginone may also be used in combination with:

(i) [Reserved]

(ii) Lincomycin as in § 558.325.

(iii) Virginiamycin as in § 558.635.

[50 FR 33719, Aug. 21, 1985, as amended at 50 FR 42518, Oct. 21, 1985; 51 FR 7397, Mar. 3, 1986; 51 FR 11439, Apr. 3, 1986; 51 FR 14989, Apr. 22, 1986; 51 FR 23737, July 1, 1986; 53 FR 1018, Jan. 15, 1988; 53 FR 11065, Apr. 5, 1988; 54 FR 11519, Mar. 21, 1989; 54 FR 28052, July 5, 1989; 59 FR 51498, Oct. 12, 1994; 61 FR 21076, May 9, 1996; 61 FR 24694, May 16, 1996; 64 FR 42597, Aug. 5, 1999; 65 FR 45712, July 25, 2000; 66 FR 47962, Sept. 17, 2001; 71 FR 27956, May 15, 2006; 79 FR 10982, Feb. 27, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95005, Dec. 27, 2016]

§ 558.274 Hygromycin B.

(a) *Specifications.* Type A medicated articles containing 2.4 or 8 grams hygromycin B per pound (g/lb).

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter for as follows:

(c) *Related tolerances.* See § 556.330 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for hygromycin B medicated feeds must not exceed 6 months from the date of issuance. VFDs for hygromycin B shall not be refilled.

(e) *Conditions of use.* It is used in feed as follows:

(1) *Chickens*—

Hygromycin B grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8 to 12		Chickens: For control of infections of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Use in complete feed. Withdraw 3 days before slaughter.	058198
(ii) [Reserved]				

(2) Swine—

Hygromycin B grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12		Swine: For control of infections of large roundworms (*A. suis*), nodular worms (*O. dentatum*), and whipworms (*Trichuris suis*).	In market hogs, use in complete feed for 8 weeks during the growing period. Withdraw 15 days before slaughter.	058198
(ii) [Reserved]				

[81 FR 95005, Dec. 27, 2016]

§ 558.295 Iodinated casein.

(a) *Approvals.* See 017762 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Conditions of use*—(1) *Ducks*—(i) *Amount per ton.* 100 to 200 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feathering in growing ducks.

(2) *Dairy cows*—(i) *Amount per pound.* ½ to 1½ grams per 100 lb of body weight.

(ii) *Indications for use.* For increased milk production in dairy cows.

(iii) *Limitations.* This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration must be accompanied with increased feed intake; administration may increase heat sensitivity of the animal.

[45 FR 41631, June 20, 1980, as amended at 81 FR 67152, Sept. 30, 2016]

§ 558.300 Ivermectin.

(a) *Specifications.* Type A medicated article containing 2.72 grams ivermectin per pound (g/lb).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in swine.* It is used in feed as follows:

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(1) 1.8 (to provide 0.1 milligram per kilogram (mg/kg) of body weight per day)		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(2) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 10 to 30	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for increased rate of weight gain and improved feed efficiency.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(3) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 250	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(4)–(7) [Reserved]				
(8) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylenedisalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

(f) Ivermectin may also be used in combination with:

(1) [Reserved]

(2) Lincomycin as in § 558.325.

[72 FR 37437, July 10, 2007, as amended at 81 FR 17609, Mar. 30, 2016; 81 FR 95005, Dec. 27, 2016]

§ 558.305 Laidlomycin.

(a) *Specifications.* Type A medicated articles containing 50 grams laidlomycin propionate potassium per pound.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.346 of this chapter.

(d) *Special considerations.* (1) Laidlomycin liquid Type B feeds may be manufactured from dry laidlomycin Type A articles. The liquid Type B feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) The expiration date for the liquid Type B feed is 21 days after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 7 days after date of manufacture.

(3) Labeling for all Type B feeds (liquid and dry) and Type C feeds containing laidlomycin shall bear the following statements:

(i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.

(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

(e) *Conditions of use.* It is used in cattle being fed in confinement for slaughter as follows:

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 5		For improved feed efficiency and increased rate of weight gain..	Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day..	054771
(2) 5 to 10		For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day..	054771

(f) Laidlomycin may also be used in combination with chlortetracycline as in § 558.128.

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004; 79 FR 13545, Mar. 11, 2014; 81 FR 95005, Dec. 27, 2016]

§ 558.311 Lasalocid.

(a) *Specifications.* A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals.* Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No. 054771 for use as in paragraphs (e)(1) (i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 066104 as provided by No. 054771 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 054771 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 054771 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(5) 15 and 20 percent activity to Nos. 012286 and 017800 for use in free-choice mineral feeds for cattle as in paragraph (e)(1)(xviii) of this section.

(6) 20 percent activity as a liquid Type A article to No. 054771 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 054771 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xvi).

(8) [Reserved]

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

(c) *Related tolerance.* See § 556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable lasalocid liquid feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(iii) For Type A articles, Type B or Type C feeds (cattle): A withdrawal period has not been established for this product in preruminating calves. Do

not use in calves to be processed for veal.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(1)(xii) and (e)(1)(xviii) of this section must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.

(e)(1) *Conditions of use.* It is used as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	For broiler or fryer chickens only; feed continuously as the sole ration.	054771
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter..	016592
(iii) [Reserved].				
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) [Reserved].				
(vi) 10 (0.0011 pct) to 30 (0.0033 pct).	.....	Cattle; for improved feed efficiency	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	054771
(vii) 25 (0.0027 pct) to 30 (0.0033 pct).	.....	Cattle; for improved feed efficiency and increased rate of weight gain.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	054771
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	.....	Sheep; for the prevention of coccidiosis caused by *Eimeria ovina, E. crandallis, E. ovinoidalis* (*E. ninakohlyakimovae*), *E. parva,* and *E. intricata.*	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	054771
(ix)	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed..	054771
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xi) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin zinc 4 to 50.	Broiler chickens. For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(xii)	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day..	054771
(xiii)	.....	Cattle; for control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii.*	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.	054771
(xiv) 113 (0.0125 pct).	.....	Chukar partridges; for prevention of coccidiosis caused by *Eimeria legionensis.*	Feed continuously as sole ration up to 8 weeks of age.	054771
(xv) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*..	Feed continuously as sole ration.	054771
.....	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration.	054771
.....	Bacitracin methylenedisalicylate 4 to 50.	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(xvi)	.....	Replacement calves; for control of coccidiosis caused by *E. bovis* and *E. zuernii*..	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	054771
(xvii) 113 (0.0125 pct).	.....	Rabbits; for prevention of coccidiosis caused by *Eimeria stiedae.*	Feed continuously as sole ration up to 6½ weeks of age.	054771
(xviii) 1440	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	021930 017800
(xix) 300	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	068287
(xx)–(xxviii) [Reserved].				

(2) It is used as a free-choice mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Defluorinated phosphate (20.5% Ca, 18.5% P)	35.9	6–01–080
Sodium chloride (salt)	20.0	6–04–152
Calcium carbonate (38% Ca)	18.0	6–01–069
Cottonseed meal	10.0	5–01–621
Potassium chloride	3.0	6–03–755
Selenium premix (0.02 percent Se)[1]	3.0	
Dried cane molasses (46% sugars)	2.5	4–04–695
Magnesium sulfate	1.7	6–02–758
Vitamin premix[1]	1.4	
Magnesium oxide (58% Mg)	1.2	6–02–756
Potassium sulfate	1.2	6–06–098
Trace mineral premix[1]	1.04	
Lasalocid Type A medicated article (68 g/lb)[2]	1.06	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

(ii) *Amount.* 1,440 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Cane molasses	55.167	4–13–241
Condensed molasses fermentation solubles	24.0	
50% Urea Solution (23% N)	12.0	
Ammonium polyphosphate solution	1.0	6–08–42
Phosphoric acid (54%)	3.0	6–03–707
Xanthan gum	0.05	8–15–818
Water	4.0	
Trace mineral premix[1]	0.5	
Vitamin premix[1]	0.2	
Lasalocid Type A medicated article (90.7 g/lb)[2]	0.083	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

(ii) *Amount.* 150 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(4) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% P)	57.70	6–01–082

Ingredient	Percent	International feed No.
Salt	17.55	6–04–152
Distillers dried grains w/ solubles	5.40	5–28–236
Dried cane molasses (46% Sugars)	5.20	4–04–695
Potassium chloride	4.90	6–03–755
Trace mineral/vitamin premix[1]	3.35	
Calcium carbonate (38% Ca)	2.95	6–01–069
Mineral oil	1.05	8–03–123
Magnesium oxide (58% Mg)	1.00	6–02–756
Iron oxide (52% Fe)	0.10	6–02–431
Lasalocid Type A medicated article (68 g/lb)[2]	0.80	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

(ii) *Amount.* 1,088 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

(v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(5) Lasalocid may also be used in combination with:

(i) Chlortetracycline as in § 558.128.

(ii) Melengestrol acetate alone or in combination with tylosin as in § 558.342.

(iii) Virginiamycin as in § 558.635.

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

2. At 79 FR 13545, Mar. 11, 2014, § 558.311 was amended; however, the amendment could not be incorporated because of the inaccurate amendatory instruction.

§ 558.325 Lincomycin.

(a) *Specifications.* Type A medicated articles containing 20 or 50 grams of lincomycin (as lincomycin hydrochloride) per pound.

(b) *Sponsors.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.360 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for lincomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for lincomycin shall not be refilled.

(3) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin shall bear the following:

(i) ''CAUTION: Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.''

(ii) [Reserved]

(4) Labeling of medicated feeds containing lincomycin intended for use in swine shall bear the following:

(i) ''CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.''

(ii) ''CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined.''

(e) *Conditions of use*—(1) *Chickens*—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 2		Broilers: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin.	Feed as the sole ration. Not for use in layers, breeders, or turkeys.	054771
(ii) 2	Halofuginone 2.72	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Feed continuously as sole ration. Withdraw 4 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide as provided by No. 016592 in § 510.600 of this chapter.	016592

(2) *Swine*—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 40		For control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis.*	Feed as sole ration. For use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis).	054771
(ii) 40	Fenbendazole, 10 to 80.	For control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(iii) 40	Ivermectin, 1.8	Weaned, growing and finishing swine: For control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred; and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidney worms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(iv) 40	Pyrantel, 96	For control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(v) 40	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(vi) 40 or 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	For treatment of swine dysentery, feed 100 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed for 3 weeks or until clinical signs of the disease disappear, following with 40 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(vii) 40	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.	Feed as a single therapeutic treatment at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb and 5 lb of feed per head for animals over 200 lb. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. See paragraph (d) of this section. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(viii) 100	.....	For treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear.	054771
(ix) 100	Fenbendazole, 10 to 80.	For the treatment of swine dysentery; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061
(x) 100	Ivermectin, 1.8	Weaned, growing and finishing swine: For the treatment of swine dysentery; and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 100 g/ton lincomycin may be continued to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(xi) 100	Pyrantel, 96	For the treatment of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xii) 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xiii) 100	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.	Feed as a single therapeutic treatment. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xiv) 200	.....	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.	Feed as sole ration for 21 days	054771

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(xv) 200	Fenbendazole, 10 to 80.	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061
(xvi) 200	Ivermectin, 1.8	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 200 g/ton lincomycin may be continued for an additional 14 days to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(xvii) 200	Pyrantel, 96	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration for 21 days. Not for use in swine that weigh more than 250 pounds. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	054771

[81 FR 95005, Dec. 27, 2016, as amended at 82 FR 12170, Mar. 1, 2017; 82 FR 21691, May 10, 2017; 83 FR 13637, Mar. 30, 2018]

§ 558.340 Maduramicin.

(a) *Approvals.* Type A medicated articles: 4.54 grams per pound to 054771 in § 510.600(c) of this chapter.

(b) *Tolerances.* See § 556.375 of this chapter.

(c) *Conditions of use*—(1) *Amount.* 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

(2) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria acervulina*, *E. tenella*, *E. brunetti*, *E. maxima*, *E. necatrix*, and *E. mivati*.

(3) *Limitations.* For broiler chickens only. Feed continuously as sole ration.

Do not feed to laying hens. Withdraw 5 days before slaughter.

[54 FR 5229, Feb. 2, 1989, as amended at 54 FR 26732, June 26, 1989; 54 FR 32635, Aug. 9, 1989; 54 FR 33885, Aug. 17, 1989; 55 FR 23, Jan. 2, 1990; 55 FR 8460, Mar. 8, 1990; 55 FR 49616, Nov. 30, 1990; 59 FR 8134, Feb. 18, 1994; 61 FR 18082, Apr. 24, 1996; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 79 FR 13545, Mar. 11, 2014; 81 FR 22525, Apr. 18, 2016]

§ 558.342 Melengestrol.

(a) *Specifications.* (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 054771 for use of products described in paragraph (a) of this section.

(2) No. 058198 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.380 of this chapter.

(d) *Special considerations.* (1) Type B or C medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B or C medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable melengestrol acetate liquid Type B or C feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) *Conditions of use*—(1) *Cattle.*

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5	.....	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)..	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day..	054771, 058198
(ii) 0.5	.....	Heifers intended for breeding: For suppression of estrus (heat)..	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding..	054771, 058198

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(iii)–(ix) [Reserved].				
(x) 0.25 to 0.5	Monensin 50 to 480.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day..	054771 058198
			.....	
			Monensin provided by No. 058198 in § 510.600(c) of this chapter..	
(xi) [Reserved].				

(2) Melengestrol may also be used in combination with:

(i) Ractopamine as in § 558.500.

(ii) Tylosin as in § 558.625.

(iii) Zilpaterol as in § 558.665.

[42 FR 28535, June 3, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.342, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 054771in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982, as amended at 79 FR 13545, Mar. 11, 2014]

§ 558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing 45, 60, 90.7, or 110 grams monensin, USP, per pound.

(b) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for conditions of use as in paragraph (f) of this section:

(1) No. 058198 for use as in paragraph (f) of this section.

(2) No. 054771 for use as in paragraphs (f)(1)(xxiv) and (xxv) of this section.

(3) No. 058198 for use as in paragraphs (f)(1)(i), (iii), (iv), and (v) of this section.

(c) [Reserved]

(d) *Special considerations.* (1) Type C chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2)–(3) [Reserved]

(4) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(5) All Type A medicated articles containing monensin shall bear the following warning statement: When mixing and handling monensin Type A

medicated articles, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

(6) All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(7) Type A medicated articles containing monensin intended for use in cattle and goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following statements:

(i) Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) Do not feed to lactating goats.

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing (see paragraphs (d)(10)(i) and (d)(10)(ii) of this section).

(viii) A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(ix) You may notice the following: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin. Have a comprehensive and ongoing nutritional, reproductive, and herd health program in place when feeding monensin to dairy cows.

(x) Inadequate mixing (recirculation or agitation) of monensin liquid Type B or Type C medicated feeds has resulted in increased monensin concentration which has been fatal to cattle and could be fatal to goats.

(8) Type A medicated articles containing monensin intended for use in chickens, turkeys, and quail shall bear the following statements:

(i) Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

(ii) Must be thoroughly mixed in feeds before use.

(iii) Do not feed undiluted.

(iv) Do not feed to laying chickens.

(v) Do not feed to chickens over 16 weeks of age.

(vi) For replacement chickens intended for use as cage layers only.

(vii) Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(viii) In the absence of coccidiosis in broiler chickens the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain.

(9) Type B feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(iv), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6) and (d)(7)(i) through (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i) through (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys:* See paragraphs (d)(8)(i), (d)(8)(ii), (d)(8)(iii), and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraphs (d)(8)(i), (d)(8)(ii), and (d)(8)(iii) of this section.

(10) Type C feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section):* See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section):* See paragraphs (d)(6), (d)(7)(i), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(iii) *Goats*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), and (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i), (d)(8)(iv), (d)(8)(v), (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i) and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraph (d)(8)(i) of this section.

(11) Type B and Type C liquid feeds requiring recirculation or agitation that contain monensin and are intended for use in cattle (including dairy cows) and goats shall bear the caution statement specified in paragraph (d)(7)(x) of this section.

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Related tolerances*. See § 556.420 of this chapter.

(f) *Conditions of use*. It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton*. Monensin, 90–110 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations*. Feed continuously as the sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens.

(ii) [Reserved]

(iii) *Amount per ton*. Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(*a*) *Indications for use*. For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton*. Monensin, 90–110 grams plus bacitracin, 10 grams.

(*a*) *Indications for use*. For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 to 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*,*E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.

(vii)–(xxiii) [Reserved]

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylenedisalicylate, 4 to 50 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.

(xxv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin zinc provided by No. 054771 in § 510.600(c) of this chapter, as monensin sodium.

(xxvi)–(xxviii) [Reserved]

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 50 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 058198; bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.

(xxx)–(xxxi) [Reserved]

(2) *Turkeys*—(i) *Amount per ton.* Monensin, 54 to 90 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylenedisalicylate, 4 to 50 grams.

(*a*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl

has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylenedisalicylate, 200 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iv) [Reserved]

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for improved feed efficiency in growing turkeys.

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–40 grams.

(*a*) *Indications for use.* Improved feed efficiency.

(*b*) *Limitations.* (*1*) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased monensin concentration which has been fatal to cattle.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 058198 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the

liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) [Reserved]

(iii) *Amount per ton.* Monensin, 15 to 400 grams.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.

(iv) *Amount.* Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

(v) [Reserved]

(vi) *Amount per ton.* Monensin, 25 to 400 grams.

(*a*) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii.*

(*b*) *Limitations.* Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) *Amount per ton.* Monensin, 10 to 40 grams.

(*a*) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii.*

(*b*) *Limitations.* For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

(viii)–(ix) [Reserved]

(x) *Amount per ton.* 1,620 grams monensin, USP.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–082
Sodium chloride (salt)	24.37	6–04–152
Dried cane molasses	20.0	4–04–695

Ingredient	Percent	International feed No.
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6–02–632
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix [1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1] Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(*c*) *Limitations.* Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows and bulls has not been established.

(xi) *Amount per ton.* Monensin, 10 to 200 grams.

(*a*) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii.*

(*b*) *Limitations.* For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

(xii) [Reserved]

(xiii) *Amount per ton.* Monensin, 11 to 22 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a total mixed ration (''complete feed''). See special labeling considerations in paragraph (d) of this section.

(xiv) *Amount per ton.* Monensin, 11 to 400 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.

(4) *Replacement chickens intended for use as cage layers*—(i) *Amount per ton.* Monensin, 90 to 110 grams.

(i)(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(ii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 4 to 50 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 058198; bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 50 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 058198; bacitracin

methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.

(iv)–(vii) [Reserved]

(5) *Bobwhite quail*—(i) *Amount per ton.* Monensin, 73 grams.

(ii) *Indications for use.* For the prevention of coccidiosis in growing bobwhite quail caused by *Eimeria dispersa* and *E. Lettyae.*

(iii) *Limitations.* Feed continuously as the sole ration; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

(6) *Goats*—(i) *Amount per ton.* Monensin, 20 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae.*

(*b*) *Limitations*—(*1*) *Feed continuously.* Feed only to goats being fed in confinement. Do not feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. See special labeling considerations in paragraph (d) of this section.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 058198 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) [Reserved]

(7) *Free-choice feeds*—(i) *Amount.* 150 milligrams per pound of protein-mineral block (0.033 percent).

(*a*) [Reserved]

(*b*) *Conditions of use*—(*1*) *Indications for use.* For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) which may require supplemental feed.

(*2*) *Limitations.* Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(ii) *Amount.* 400 milligrams per pound of protein-mineral block (0.088 percent).

(*a*) *Sponsor.* See No. 067949 in § 510.600(c) of this chapter.

(*b*) *Conditions of use*—(*1*) *Indications for use.* For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(*2*) *Limitations.* Provide 80 to 200 milligrams of monensin (0.2 to 0.5 pounds of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iii) *Amount.* 175 milligrams per pound of protein-mineral block (0.038 percent).

(*a*) *Sponsor.* See No. 017800 in § 510.600(c) of this chapter.

(*b*) *Conditions of use*—(*1*) *Indications for use.* For increased rate of weight

gain in pasture cattle (slaughter, stocker, and feeder).

(*2*) *Limitations.* Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iv) *Amount.* 400 milligrams per pound of block (0.088 percent).

(*a*) *Sponsor.* See No. 051267 in § 510.600(c) of this chapter.

(*b*) *Conditions of use—(1) Indications for use.* For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(*2*) *Limitations.* Provide 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(8) Monensin may also be used in combination with:

(i) Chlortetracycline as in § 558.128.

(ii) Decoquinate as in § 558.195.

(iii) Lincomycin as in § 558.325.

(iv) Melengestrol acetate as in § 558.342.

(v) Oxytetracycline as in § 558.128.

(vi) Ractopamine alone or in combination as in § 558.500.

(vii) Tilmicosin as in § 558.618.

(viii) Tylosin as in § 558.625.

(ix) Virginiamycin as in § 558.635.

(x) Zilpaterol alone or in combination as in § 558.665.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

2. At 79 FR 13545, Mar. 11, 2014, § 558.355 was amended; however, the amendments to (f)(1)(vii)(*b*) and (f)(4)(iv)(*b*) could not be incorporated because those paragraphs did not exist.

§ 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.425 of this chapter.

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Conditions of use*—(1) *Amount.* 0.44 to 4.4 grams of morantel tartrate per pound of feed.

(2) *Indications for use*—(i) *Cattle.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(ii) *Goats.* For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus*, *Ostertagia (Teladorsagia) circumcincta*, and *Trichostrongylus axei*.

(3) *Limitations.* Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter; do not treat goats within 30 days of slaughter.

[46 FR 50950, Oct. 16, 1981, as amended at 47 FR 53352, Nov. 26, 1982; 51 FR 7399, Mar. 3, 1986; 51 FR 9005, Mar. 17, 1986; 52 FR 11642, Apr. 10, 1987; 59 FR 17922, Apr. 15, 1994; 66 FR 47963, Sept. 17, 2001]

§ 558.363 Narasin.

(a) *Approvals.* Type A medicated articles containing specified levels of narasin approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:

(1) To 058198: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) [Reserved]

(3) To 058198: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.

(4) To 016592: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambermycins, paragraph (d)(1)(iv) of this section.

(5)–(6) [Reserved]

(7) To 054771: 36, 45, 54, 72, or 90 grams per pound, with 10, 25, 40, or 50 grams per pound bacitracin zinc, paragraph (d)(1)(x) of this section.

(8) To 058198: 45.4 grams per pound for use as in paragraph (d)(2) of this section.

(b) *Tolerances.* See § 556.428 of this chapter.

(c) *Special considerations.* An expiration date of 2 months (8 weeks) is required for narasin Type C medicated swine feeds.

(d) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Narasin, 54 to 90 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.

(ii) *Amount per ton.* Narasin, 27 to 45 grams, plus nicarbazin, 27 to 45 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Withdraw 5 days before slaughter. The 2 drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 058198 in § 510.600(c) of this chapter may be used in the combination.

(iii) *Amount per ton.* Narasin, 54 to 72 grams, plus bambermycins, 1 to 2 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. May be fatal if fed to adult turkeys, horses, or other equines. Narasin as provided by No. 058198; bambermycins by No. 016592 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Narasin 54 to 72 grams, and bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati, E. necatrix,* and *E. tenella,* for increased rate of weight gain, and for improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 058198, bacitracin methylenedisalicylate by 046573 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Narasin, 54 to 72 grams and bacitracin zinc, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin as provided by 058198, bacitracin zinc by 046573 in § 510.600(c) of this chapter.

(vi) [Reserved]

(2) *Growing-finishing swine*—(i) *Amount per ton.* Narasin, 13.6 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(ii) *Amount per ton.* Narasin, 18.1 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(3) Narasin may also be used for broilers in combination with:

(i) Nicarbazin with lincomycin as in § 558.366.

(ii) Nicarbazin and bacitracin methylenedisalicylate as in § 558.366.

[51 FR 29098, Aug. 14, 1986]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.363, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

2. At 79 FR 13545, Mar. 11, 2014, § 558.363 was amended; however, the amendment could not be incorporated because of an inaccurate amendatory instruction.

§ 558.364 Neomycin sulfate.

(a) *Specifications.* Type A medicated article containing 325 grams neomycin sulfate per pound.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for neomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for neomycin shall not be refilled.

(e) *Conditions of use.* Neomycin sulfate is used as follows:

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(1) 250 to 2,250 grams per ton (g/t) of dry type C feed..	.....	Cattle, swine, sheep, and goats. For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin..	To provide 10 milligrams (mg) of neomycin sulfate per pound of body weight per day for a maximum of 14 days. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in dry feeds only. Not for use in liquid feed supplements..	054771
(2) 400 to 2,000 g/t of type C milk replacer..	.....	Do.	To provide 10 mg of neomycin sulfate per pound of body weight per day for a maximum of 14 days. Amount consumed will vary depending on animal's consumption and weight. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in milk replacers only..	054771

[64 FR 70576, Dec. 17, 1999, as amended at 65 FR 45881, July 26, 2000; 79 FR 13545, Mar. 11, 2014; 81 FR 95009, Dec. 27, 2016]

§ 558.365 Nequinate.

(a) *Approvals.* Type A medicated articles: 4 percent to No. 051311 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.440 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinate, 18.16 grams.

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2685, Jan. 26, 1987; 66 FR 45167, Aug. 28, 2001; 70 FR 32489, June 3, 2005]

§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Approvals.* See Nos. 058198, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) *Conditons of use.* It is used in chicken feed as follows:

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati.*.	Sec. 558.363(d)(1)(iii)	058198
	Narasin 27 to 45 and bacitracin methylenedisalicylate 4 to 50.	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 058198, bacitracin methylenedisalicylate by 054771.	058198
	Narasin 27 to 45 and bacitracin methylenedisalicylate 50..	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 058198, bacitracin methylenedisalicylate by No. 054771 in § 510.600(c) of this chapter..	054771

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Narasin 27 to 45 and bacitracin methylenedisalicylate 100 to 200..	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 058198, bacitracin methylenedisalicylate by No. 054771 in § 510.600(c) of this chapter..	054771
	Narasin 27 to 45, and bambermycins 1 to 2.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter. Bambermycins provided by No. 016592; nicarbazin and narasin by No. 066104 in § 510.600(c) of this chapter.	058198
90.8 to 181.6 (0.01 to 0.02 pct).	.....	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin methylenedisalicylate 30.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	066104
	Bacitracin methylenedisalicylate 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
113.5 (0.0125 pct).	.....	Chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter.	058198 060728
	Bacitracin methylenedisalicylate 30.	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	.....do	060728
	Bacitracin zinc 4 to 50..	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency..	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Discontinue medication 4 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by 066104, bacitracin zinc by 054771..	066104 054771

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bambermycins 1 to 2	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter. Nicarbazin as provided by 066104..	057926
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592

[42 FR 56729, Oct. 28, 1977; 43 FR 1942, Jan. 13, 1978, as amended at 44 FR 40887, July 13, 1979; 50 FR 13562, Apr. 5, 1985; 51 FR 7399, Mar. 3, 1986; 54 FR 1928, Jan. 18, 1989; 60 FR 29483, June 5, 1995; 61 FR 1832, Jan. 24, 1996; 61 FR 14021, Mar. 29, 1996; 61 FR 14483, Apr. 2, 1996; 62 FR 29011, May 29, 1997; 63 FR 13124, Mar. 18, 1998; 63 FR 57248, Oct. 27, 1998; 64 FR 4966, Feb. 2, 1999; 64 FR 18574, Apr. 15, 1999; 64 FR 20164, Apr. 26, 1999; 64 FR 49384, Sept. 13, 1999; 65 FR 11889, Mar. 7, 2000; 66 FR 46706, Sept. 7, 2001; 66 FR 47962, Sept. 17, 2001; 66 FR 63500, Dec. 7, 2001; 67 FR 30327, May 6, 2002; 71 FR 16224, Mar. 31, 2006; 71 FR 27957, May 15, 2006; 73 FR 15884, Mar. 26, 2008; 75 FR 7555, Feb. 22, 2010; 78 FR 23, Jan. 2, 2013; 78 FR 42007, July 15, 2013; 78 FR 52429, Aug. 23, 2013; 79 FR 10983, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 48703, July 26, 2016; 81 FR 67153, Sept. 30, 2016; 81 FR 95009, Dec. 27, 2016; 82 FR 58557, Dec. 13, 2017]

§ 558.415 Novobiocin.

(a) *Specifications.* Type A medicated article containing 25 grams of novobiocin activity per pound.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.460 of this chapter.

(d) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount.* Novobiocin, 4–5 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

(4) *Ducks*—(i) *Amount.* Novobiocin, 350 grams per ton.

(ii) *Indications for use.* Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida*, susceptible to novobiocin.

(iii) *Limitations.* Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary, repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

[40 FR 13959, Mar. 27, 1975, as amended at 45 FR 42263, June 24, 1980; 51 FR 7399, Mar. 3, 1986; 52 FR 36402, Sept. 29, 1987; 79 FR 13545, Mar. 11, 2014]

§ 558.430 Nystatin.

(a) *Specifications.* Type A medicated article containing 20 grams of nystatin activity per pound.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.470 of this chapter.

(d) *Conditions of use.* It is used for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 79 FR 13545, Mar. 11, 2014]

§ 558.450 Oxytetracycline.

(a) *Specifications.* Each pound of Type A medicated article contains:

(1) Oxytetracycline (from oxytetracycline quaternary salt) equivalent to 50 or 100 grams oxytetracycline hydrochloride; or oxytetracycline (from oxytetracycline dihydrate base) equivalent to 10, 30, 50, 100, or 200 grams oxytetracycline hydrochloride.

(2) Oxytetracycline (from oxytetracycline dihydrate base) equivalent to 50, 100, or 200 grams oxytetracycline hydrochloride; or 100 grams oxytetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 066104: Type A medicated articles as in paragraph (a)(1) of this section.

(2) No. 069254: Type A medicated articles as in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for oxytetracycline medicated feeds must not exceed 6 months from the date of issuance. VFDs for oxytetracycline shall not be refilled.

(3) In accordance with § 558.5, labeling shall bear the statement: ''For use in dry animal feed only. Not for use in liquid feed supplements.''

(e) *Conditions of use*—(1) *Chickens*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 100 to 200 g/ton.	.....	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* and control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Zero-day withdrawal period.	066104 069254
(ii) 200 g/ton	Monensin, 90 to 110	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for the control of complicated chronic respiratory disease (CRD or air sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli.*	Feed continuously as the sole ration. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 72 hours before slaughter. See § 558.355(d) of this chapter Oxytetracycline as provided by No. 066104; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(iii) 400 g/ton	.....	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Zero-day withdrawal period.	066104 069254
(iv) 400 g/ton	Robenidine, 30	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for the control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 5 days before slaughter. Oxytetracycline as provided by No. 066104; robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	066104
(v) 500 g/ton	.....	Chickens: For reduction of mortality due to air sacculitis (air sac infection) caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 5 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 24 hours before slaughter.	066104 069254

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vi) 500 g/ton	Monensin, 90 to 100	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and as an aid in the reduction of mortality due to air-sacculitis (air sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.	Feed for 5 days as the sole ration. Treat at first clinical signs of the disease. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 72 hours before slaughter. See § 558.355(d) of this chapter. Oxytetracycline as provided by No. 066104; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(vii) 500 g/ton	Salinomycin, 40 to 60.	Chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and as an aid in the reduction of mortality due to air-sacculitis (air sac infection) caused by *E. coli* sensitive to oxytetracycline.	Feed for 5 days as the sole ration. Treat at first clinical signs of the disease. Do not feed to laying chickens. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 24 hours before slaughter. Oxytetracycline as provided by No. 066104; salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	066104 016592

(2) *Turkeys*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 100 g/ton	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	066104 069254
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. For No. 066104, withdraw 5 days before slaughter. For No. 069254, zero-day withdrawal period.	066104 069254
(iii) 25 mg/lb of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. For No. 066104, withdraw 5 days before slaughter. For No. 069254, zero-day withdrawal period.	066104 069254

(3) *Swine*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	.....	1. Swine: For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days.	066104 069254

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
		2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for 14 days ...	066104 069254
(ii) 10 mg/lb of body weight daily.	Carbadox, 10 to 25	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not mix in feeds containing bentonite. Do not feed to swine within 42 days of slaughter. Oxytetracycline and carbadox as provided by No. 066104 in § 510.600(c) of this chapter.	066104

(4) *Cattle—*

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	.....	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
		2. Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days in milk replacer or starter feed. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(ii) 75 mg/head/day.	.....	Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	Feed continuously	066104 069254
(iii) 75 mg/head/day.	Lasalocid 25 to 30 ..	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain and improved feed efficiency.	Feed continuously to provide 250 to 360 mg lasalocid and 75 mg of oxytetracycline per head per day. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 75 mg/head/day.	Melengestrol acetate, 0.25 to 2.0.	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously to provide 0.25 to 0.5 mg of melengestrol acetate and 75 mg of oxytetracycline per head per day. Melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 0.5 to 2.0 g/head/day.	.....	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 days before and after arrival in feedlots.	066104 069254

(5) *Minor species—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter.	066104 069254
(ii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	066104 069254
(iii) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day).	Pacific salmon: For marking of skeletal tissue.	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 days following the last administration of medicated feed.	066104
(iv) 2.5 to 3.75 g/100 lb of fish/day.	1. Salmonids: For control of ulcer disease caused by *Haemophilus piscium,* furunculosis caused by *Aeromonas salmonicida,* bacterial hemorrhagic septicemia caused by *A. liquefaciens,* and pseudomonas disease.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F).	066104
(v) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum.*	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Freshwater-reared *Oncorhynchus mykiss:* For control of mortality due to columnaris disease associated with *Flavobacterium columnare.*	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
(vi) 1 g/lb of medicated feed.	Lobsters: For control of gaffkemia caused by *Aerococcus viridans.*	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 days before harvesting lobsters.	066104

[81 FR 95009, Dec. 27, 2016, as amended at 82 FR 11512, Feb. 24, 2017]

§ 558.455 Oxytetracycline and neomycin.

(a) *Specifications.* Type A medicated articles containing oxytetracycline equivalent to 50 grams per pound (g/lb) oxytetracycline hydrochloride and 50 g/lb neomycin sulfate or oxytetracycline equivalent to 100 g/lb oxytetracycline hydrochloride and 100 g/lb neomycin sulfate.

(b) *Sponsors.* See Nos. 066104 and 069254 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.430 and 556.500 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for oxytetracycline and neomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for oxytetracycline and neomycin shall not be refilled.

(3) Cattle feeds shall bear the following warning statement: ''Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Indications for use*—(1) *Chickens.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) [Reserved].			

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter..	066104 069254
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104 069254
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac- infection) caused by *E. coli* susceptible to oxytetracycline..	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter..	066104 069254

(2) *Turkeys*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) [Reserved].			
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	066104 069254
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption..	066104 069254
(iv) To provide 25 milligrams per pound (mg/lb) of body weight daily..	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption..	066104 069254

(3) *Swine*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) [Reserved].			
(ii) To provide 10 mg/lb of body weight daily..	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter..	066104 069254
	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline..	Feed continuously for not more than 14 d; withdraw 5 d before slaughter..	066104 069254

(4) *Cattle and sheep*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i)–(ii) [Reserved].			

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(iii) To provide 10 mg/lb of body weight daily..	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter..	066104 069254
	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter..	066104 069254
	3. Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter..	066104 069254
(iv) [Reserved].			
(v) To provide 75 mg/head/day.	Growing cattle (over 400 lb): For reduction of liver condemnation due to liver abscesses..	Feed continuously.	066104 069254
(vi) To provide 0.5 to 2.0 g/head/ day.	Cattle: For prevention and treatment of the early stages of shipping fever complex..	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older..	066104 069254

[71 FR 16225, Mar. 31, 2006, as amended at 74 FR 40724, Aug. 13, 2009; 80 FR 13232, Mar. 13, 2015; 81 FR 95012, Dec. 27, 2016]

§ 558.464 Poloxalene.

(a) *Approvals.* (1) Dry Type A medicated articles: 53 percent to 054771 in § 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 054771 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A article and liquid Type A article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by adding the Type A article to a small quantity of feed, mixing thoroughly, then adding this mixture to the remaining feed and again mixing thoroughly. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the

last treatment. Do not exceed the higher dosage levels in any 24-hour period.

[40 FR 39857, Aug. 29, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 79 FR 13545, Mar. 11, 2014]

§ 558.465 Poloxalene free-choice liquid Type C feed.

(a) *Approvals.* Type A medicated articles: 99.5 percent to 066104 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid Type C feed (1.65 percent weight/weight). Each animal must consume 0.2 pound of Type C feed per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene per pound of liquid Type C feed (2.2 percent weight/weight). Each animal must consume 0.15 pound of Type C feed per 100 pounds of body weight daily for adequate protection. If consumption exceeds 0.2 pound of Type C feed per 100 pounds of body weight daily, cattle should be changed to a Type C feed containing 7.5 grams of poloxalene per pound.

(3) Poloxalene liquid Type A article must be thoroughly blended and evenly distributed into a liquid Type C feed and offered to cattle in a covered liquid Type C feed feeder with lick wheels. The formula for the liquid Type C feed, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.66 percent, phosphoric acid (75 percent) 3.37 percent, sulfuric acid 1.00 percent, water 10.00 percent, and molasses sufficient to make 100.00 percent, vitamins A and D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C feed must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C feed and to lick wheel feedings. If the medicated liquid wheel Type C feed feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 21281, Apr. 26, 1977; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001]

§ 558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 9.6, 19.2, 48, or 80 grams per pound pyrantel tartrate.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section:

(1) No. 066104: 9.6, 19.2, 48, and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2)–(4) [Reserved]

(5) No. 051311: 19.2 and 48 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) [Reserved]

(7) Nos. 017135 and 054771: 48 grams per pound for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations.* (1) See § 500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

(e) *Conditions of use.* It is used as follows:

(1) *Swine*—(i) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Feed continuously as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(ii) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Feed for 3 days as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(iii) *Amount per ton.* 800 grams (0.0881 percent).

(A) *Indications for use.* For the removal and control of large roundworm

(*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* As sole ration for a single therapeutic treatment in Type C feed; feed at the rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over; withdraw 24 hours prior to slaughter.

(2) *Horses*—(i) *Amount.* Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. Not for use in horses intended for food. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ii) [Reserved]

(3) Pyrantel may also be used in combination with:

(i) Lincomycin as in § 558.325.

(ii) Tylosin as in § 558.325.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.485, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45.4 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See Nos. 054771 and 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.* (1) Labeling of Type B and Type C feeds shall bear the following: ''Not for animals intended for breeding.''

(2) Labeling of Type B and Type C swine feeds shall bear the following:

(i) ''No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton.''

(ii) ''Ractopamine may increase the number of injured and/or fatigued pigs during marketing.''

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: ''No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton.''

(4) Tylosin in combinations as tylosin phosphate.

(5) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5 or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(e) *Conditions of use*—(1) *Swine*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9.0	.....	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as sole ration.	058198, 054771
(ii)–(iv) [Reserved].				

(2) *Cattle*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed..	058198, 054771
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	As in paragraph (e)(2)(i) of this section; see paragraph § 558.355(d) of this chapter. Ractopamine as provided by Nos. 058198 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198, 054771
(iii)–(v) [Reserved].				
(vi) 9.8 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	058198, 054771
(vii) 9.8 to 24.6 ...	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	As in paragraph (e)(2)(vi) of this section; see paragraph § 558.355(d) of this chapter. Ractopamine as provided by Nos. 058198 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198, 054771
(viii) 9.8 to 24.6 ..	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat)..	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by Nos. 058198 and 054771 or 021641 in § 510.600(c) of this chapter..	058198, 054771
(ix)–(x) [Reserved].				
(xi) Not to exceed 800; to provide 70 to 400 mg/head/day..	.....	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section..	Top dress in a minimum of 1.0 lb of medicated feed..	058198, 054771
(xii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d). Ractopamine as provided by Nos. 058198 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198, 054771

(3) *Turkeys*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 11.8 (5 to 13 ppm).	.....	Finishing hen turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 7 to 14 days prior to slaughter..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter..	058198
(ii) 4.6 to 11.8 (5 to 13 ppm).	.....	Finishing tom turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 14 days prior to slaughter..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality..	058198
(iii) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing hen turkeys: As in paragraph (e)(3)(i) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter. See § 558.355(d)..	058198
(iv) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing tom turkeys: As in paragraph (e)(3)(ii) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality. See § 558.355(d)..	058198

(4) Ractopamine may also be used in combination with tylosin in as in § 558.625.

[67 FR 71820, Dec. 3, 2002, as amended at 68 FR 54659, Sept. 18, 2003; 69 FR 12068, Mar. 15, 2004; 69 FR 51174, Aug. 18, 2004; 71 FR 31074, June 1, 2006; 71 FR 67301, Nov. 21, 2006; 72 FR 10358, Mar. 8, 2007; 72 FR 41619, July 31, 2007; 72 FR 56897, Oct. 5, 2007; 72 FR 62571, Nov. 6, 2007; 72 FR 65667, Nov. 23, 2007; 72 FR 70777, Dec. 13, 2007; 73 FR 72715, Dec. 1, 2008; 73 FR 75323, Dec. 11, 2008; 74 FR 66914, Dec. 17, 2009; 75 FR 1276, Jan. 11, 2010; 75 FR 5888, Feb. 5, 2010; 75 FR 20917, Apr. 22, 2010; 75 FR 54018, Sept. 3, 2010; 77 FR 31724, May 30, 2012; 78 FR 63872, Oct. 25, 2013; 79 FR 13546, Mar. 11, 2014; 79 FR 37621, July 2, 2014; 79 FR 44278, July 31, 2014; 79 FR 53136, Sept. 8, 2014; 80 FR 61298, Oct. 13, 2015; 81 FR 48703, July 26, 2016; 81 FR 95013, Dec. 27, 2016]

§ 558.515 Robenidine.

(a) *Approvals.* Type A medicated articles: 30 grams per pound to 054771 in § 510.600(c) of this chapter.

(b) *Special considerations.* Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.580 of this chapter.

(d) *Conditions of use.* It is used in feed for chickens as follows:

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
30 (0.0033 pct) ...	.....	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*..	Feed continuously as sole ration. Do not feed to chickens producing eggs for food. Withdraw 5 days prior to slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 27 to 50.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For improved feed efficiency..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
.....	Bacitracin (as bacitracin methylenedisalicylate) 50.	For broiler and fryer chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter..	054771
.....	Bacitracin (as bacitracin methylenedisalicylate) 100 to 200.	For broiler and fryer chickens: As an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin..	To control a necrotic enteritis outbreak, start medication at first clinical signs of disease; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin methylenedisalicylate to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter..	054771
.....	Bacitracin (as bacitracin zinc) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771 054771
.....	Bacitracin (as bacitracin zinc) 27 to 50.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For improved feed efficiency..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	054771 054771

(e) Robenidine may also be used in combination with:

(1) Chlortetracycline as in § 558.128.

(2) Lincomycin as in § 558.325.

(3) Oxytetracycline as in § 558.450.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.515, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass).

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 016592 for use as in paragraph (d) of this section.

(2) No. 069254 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

(c) [Reserved]

(d) *Conditions of use.* (1) Broilers: It is used as follows:

(i)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*c*) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii) [Reserved]

(iii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylenedisalicylate 4 to 30 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* for incresed rate of weight gain and improved feed efficiency.

(*c*) *Limitation.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentially fed to adult turkeys or horses. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iv)–(v) [Reserved]

(vi)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylenedisalicylate 4 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria*

tenella, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(vii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin zinc 10 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.

(viii)–(xix) [Reserved]

(xx)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylenedisalicylate, 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.

(xxi)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylenedisalicylate, 100 to 200 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 016592; bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) in this chapter.

(xxii) [Reserved]

(xxiii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus bambermycins, 1 to 3 grams.

(*a*) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; and for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses. Salinomycin and bambermycins as provided by No. 016592in § 510.600(c) of this chapter.

(xxiv) [Reserved]

(2) *Quail*—(i)(*a*) *Amount per ton.* Salinomycin 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Do not feed to laying hens producing eggs for human consumption.

(ii) [Reserved]

(3) *Roaster and replacement (breeder and layer) chickens*: It is used as follows:

(i)(A) *Amount per ton.* Salinomycin 40 to 60 grams.

(B) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to horses or adult turkeys.

(ii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylenedisalicylate, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylenedisalicylate, 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iv) [Reserved]

(v) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylenedisalicylate, 100 to 200 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(vi)–(vii) [Reserved]

(4) *Chickens*: It is used in chicken feed as follows:

(i) *Amount per ton.* Salinomycin, 40 to 60 grams; plus oxytetracycline, 500 grams.

(*a*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; and for reduction of mortality due to air sacculitis (air-sac-infection) caused by *Escherichia coli* susceptible to oxytetracycline.

(*b*) *Limitations.* Feed continuously for 5 days; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter. Salinomycin as provided by No. 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.

(ii) [Reserved]

(5) Salinomycin may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

[48 FR 30616, July 5, 1983]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.550, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

2. At 81 FR 95013, Dec. 27, 2016, § 558.550 was amended in part by revising paragraph (d)(4); however, the amendment could not be incorporated because no revised text for (d)(4) was set out.

§ 558.555 Semduramicin.

(a) *Specifications.* Type A medicated article containing:

(1) 22.7 grams (g) per pound (lb) (50 g/kilogram (kg)) semduramicin (as semduramicin sodium).

(2) 22.7 g/lb (50 g/kg) semduramicin (as semduramicin sodium biomass).

(b) *Approvals.* See No. 066104 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d) of this section; for use

of product described in paragraph (a)(2) as in paragraph (e) of this section.

(c) *Related tolerances.* See § 556.597 of this chapter.

(d) *Conditions of use in chickens.* It is used in chicken feed as follows:

Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/E. mitis, E. necatrix*, and *E. tenella.*	Do not feed to laying hens.	066104
(2) 22.7	Bacitracin methylenedisalicylate 10 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	066104

(e) *Conditions of use in chickens.* It is used in chicken feed as follows:

Semduramicin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix, and E. mitis.*	Do not feed to laying hens.	066104
(2) [Reserved]				

(f) Semduramycin may also be used in combination with virginiamycin as in § 558.635.

[59 FR 17477, Apr. 13, 1994, as amended at 60 FR 57928, Nov. 24, 1995; 61 FR 29481, June 11, 1996; 61 FR 43451, Aug. 23, 1996; 61 FR 66584, Dec. 18, 1996; 62 FR 66985, Dec. 23, 1997; 64 FR 48296, Sept. 3, 1999; 66 FR 47964, Sept. 17, 2001; 69 FR 13221, Mar. 22, 2004; 70 FR 41961, July 21, 2005; 73 FR 812, Jan. 4, 2008; 74 FR 41631, Aug. 18, 2009; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95013, Dec. 27, 2016]

§ 558.575 Sulfadimethoxine and ormetoprim.

(a) *Specifications.* Type A medicated articles containing either:

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim; or

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraphs (e)(1), (e)(2), (e)(3), (e)(4), and (e)(7) of this section.

(2) No. 015331 for use of the product described in paragraph (a)(2) as in paragraphs (e)(5) and (e)(6) of this section.

(c) *Related tolerances.* See §§ 556.490 and 556.640 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for sulfadimethoxine and ormetoprim medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfadimethoxine and ormetoprim shall not be refilled.

(e) *Conditions of use.* It is used in feeds for animals as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by

all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(*b*) *Limitations.* Feed as sole ration; withdraw 5 days before slaughter.

(ii) [Reserved]

(2) *Replacement chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.

(3) *Turkeys*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(iii) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

(4) *Ducks*—(i) *Amount per ton.* Sulfadimethoxine, 227 grams (0.025 percent) plus ormetoprim, 136.2 grams (0.015 percent).

(*a*) *Indications for use.* As an aid in the control of bacterial infections due to *P. multocida* (fowl cholera) in ducks, including breeding ducks.

(*b*) *Limitations.* Feed as sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; do not feed to ducks producing eggs for food.

(ii) *Amount per ton.* Sulfadimethoxine, 454 grams (0.05 percent) plus ormetoprim, 272.4 grams (0.03 percent).

(*a*) *Indications for use.* As an aid in the control of bacterial infections due to *E. coli, Riemerella anatipestifer,* and severe challenge of *P. multocida* (fowl cholera) in ducks.

(*b*) *Limitations.* Feed as a sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; not for breeding ducks; do not feed to ducks producing eggs for food.

(5) *Salmonids*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications of use.* For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 42 days before release as stocker fish or slaughter.

(6) *Catfish*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications for use.* For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 3 days before slaughter or release as stocker fish.

(7) *Chukar partridges*—(i) *Amount per ton.* Sulfadimethoxine 113.5 grams (0.0125 percent) plus ormetoprim 68.1 grams (0.0075 percent).

(ii) *Indications for use.* For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis.*

(iii) *Limitations.* Feed continuously to young birds up to 8 weeks of age as sole ration.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 13550, Mar. 11, 1977; 49 FR 33442, Aug. 23, 1984; 49 FR 46371, Nov. 26, 1984; 51 FR 7400, Mar. 3, 1986; 51 FR 18884, May 23, 1986; 52 FR 2686, Jan. 26, 1987; 54 FR 1686, Jan. 17, 1989; 63 FR 27846, May 21, 1998; 64 FR 26672, May 17, 1999; 64 FR 43910, Aug. 12, 1999; 66 FR 46707, Sept. 7, 2001; 70 FR 52292, Sept. 2, 2005; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 95013, Dec. 27, 2016; 83 FR 13637, Mar. 30, 2018]

§ 558.582 Sulfamerazine.

(a) *Specifications.* Type A medicated articles containing 99 percent sulfamerazine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.660 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for sulfamerazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfamerazine shall not be refilled.

(e) *Conditions of use.* It is used in fish feed for as follows:

Sulfamerazine grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) To deliver 10 grams of sulfamerazine per 100 pounds of fish per day.	.....	Rainbow trout, brook trout, and brown trout: For control of furunculosis.	Formulate to deliver 10 grams of sulfamerazine per 100 pounds of fish per day. Treat for not more than 14 days. Do not treat within 3 weeks of marketing or stocking in stream open to fishing.	054771
(2) [Reserved].				

[81 FR 95013, Dec. 27, 2016]

§ 558.586 Sulfaquinoxaline.

(a) *Specifications.* Type A medicated articles containing 40 percent sulfaquinoxaline.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.685 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for sulfaquinoxaline medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfaquinoxaline shall not be refilled.

(e) *Conditions of use*—(1) *Chickens*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.015 percent	.....	As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti* under average conditions of exposure.	Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.	016592

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 0.0175 percent	.....	As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti* where excessive exposure to coccidia is increased due to overcrowding or other management factors.	Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.	016592
(iii) 0.1 to 0.05 percent.	.....	As an aid in controlling outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti*.	Feed at 0.1 percent level for first 48 to 72 hours. Skip 3 days; 0.05 percent for 2 days, skip 3 days; 0.05 percent for 2 days. If bloody droppings recur, give 0.05 percent for another 2 days. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.	016592
(iv) 0.05 or 0.1 percent.	.....	As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.	Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption.	016592

(2) *Turkeys*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.0175 percent	.....	As an aid in preventing outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides*.	Feed continuously during time birds are closely confined. May be continued for a week to 10 days after flock is transferred to range to reduce danger of an outbreak following moving of the flock. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.	016592

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 0.05 percent ...	.....	As an aid in controlling outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides*.	Feed for 2 days. Follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Again follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Continue this schedule if necessary until all signs of the outbreaks have subsided. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.	016592
(iii) 0.05 or 0.1 percent.	.....	As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.	Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption.	016592

(3) *Rabbits*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.025 percent	.....	As an aid in preventing coccidiosis caused by *Eimeria stiedae*.	Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2 days out of every week until marketing. Do not treat within 10 days of slaughter.	016592
(ii) 0.1 percent	.....	As an aid in controlling outbreaks of coccidiosis caused by *Eimeria stiedae*.	Feed for 2 weeks. Do not treat within 10 days of slaughter.	016592

[81 FR 95013, Dec. 27, 2016]

§ 558.600 Thiabendazole.

(a) *Approvals*. Dry Type A medicated articles: 22, 44.1, 66.1, and 88.2 percent to 050604 in § 510.600(c) of this chapter. The 66.1 percent Type A is solely for the manufacture of cane molasses liquid Type B feed which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Special considerations*. Do not use in Type B or Type C medicated feed containing bentonite.

(c) *Related tolerances*. See § 556.730 of this chapter.

(d) *Conditions of use*. It is used in feed for animals as follows:

(1) *Cattle*—(i) *Amount*. 3 grams per 100 lb. body weight.

(*a*) *Indications for use*. Control of infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Nematodirus spp.*, *Oesophagostomum radiatum*).

(*b*) *Limitations*. Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations.* Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

(5) *Pheasants*—(i) *Amount.* 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) *Indications for use.* For the treatment of gapeworms (*Syngamus trachea*) in pheasants.

(iii) *Limitations.* Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.

[40 FR 13959, Mar. 27, 1975, as amended at 47 FR 49641, Nov. 2, 1982; 49 FR 29958, July 25, 1984; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 62 FR 63271, Nov. 28, 1997. Redesignated at 80 FR 13232, Mar. 13, 2015]

§ 558.612 Tiamulin.

(a) *Specifications.* Type A article containing 363.2 grams of tiamulin hydrogen fumarate per pound.

(b) *Approvals.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.732 of this chapter.

(d) *Special considerations*—(1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

(3) Use as sole source of tiamulin.

(e) *Conditions of use*—(1) *Swine.* It is used as follows:

Tiamulin hydrogen fumarate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 35		1. For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter.	058198
		2. For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.	Feed continuously as the sole ration for not less than 10 days. Withdraw 2 days before slaughter.	058198
(ii) 200		For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter.	058198

(2) Tiamulin may also be used in combination with chlortetracycline as in § 558.128.

[67 FR 7268, Feb. 19, 2002, as amended at 69 FR 62407, Oct. 26, 2004; 70 FR 75018, Dec. 19, 2005; 74 FR 6, Jan. 2, 2009; 77 FR 24139, Apr. 23, 2012; 79 FR 13546, Mar. 11, 2014. Redesignated and amended at 80 FR 13232, Mar. 13, 2015; 81 FR 95015, Dec. 27, 2016]

§ 558.618 Tilmicosin.

(a) *Specifications*. Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).

(b) *Approvals*. *See* Nos. 016592 and 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.735 of this chapter.

(d) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) VFDs for tilmicosin phosphate shall not be refilled.

(3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:

(i) Do not allow horses or other equines access to feeds containing tilmicosin.

(ii) [Reserved]

(4) Special considerations for use of tilmicosin medicated swine feeds include the following:

(i) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for swine must bear the following warning: ''Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.''

(iii) Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial.

(5) Special consideration for use of tilmicosin medicated cattle feeds include the following:

(i) The expiration date of VFDs for cattle must not exceed 45 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for cattle must bear the following warning: ''Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.''

(iii) To assure both food safety and responsible use in cattle, administration of feed containing tilmicosin to cattle experiencing an outbreak of BRD must be initiated during the first 45 days of the production period, shall not exceed a single 14-consecutive-day treatment, should not occur concurrent with or following administration of an injectable macrolide, and should not occur within 3 days following administration of a nonmacrolide

injectable BRD therapy. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative nonmacrolide therapy.

(e) *Conditions of use.* It is used in feed as follows:

(1) *Swine—*

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 181 to 363		Swine: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*	Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an anticipated disease outbreak. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.	058198, 016592
(ii) [Reserved]				

(2) *Cattle—*

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 568 to 757		Beef and nonlactating dairy cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.	058198, 016592
(ii) 568 to 757	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency; and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter. Tilmicosin as provided by Nos. 000986 or 016952; monensin as provided by No. 000986 in § 510.600(c) of this chapter..	016952, 058198

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 568 to 757	Monensin, 10 to 40 ...	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter. Tilmicosin as provided by Nos. 000986 or 016952; monensin as provided by No. 000986 in § 510.600(c) of this chapter..	016952, 058198

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000; 67 FR 21997, May 2, 2002; 69 FR 78306, Dec. 30, 2004; 76 FR 76894, Dec. 9, 2011; 77 FR 60623, Oct. 4, 2012; 78 FR 19987, Apr. 3, 2013; 80 FR 61298, Oct. 13, 2015; 80 FR 76387, Dec. 9, 2015; 81 FR 48703, July 26, 2016; 81 FR 59135, Aug. 29, 2016; 81 FR 67153, Sept. 30, 2016]

§ 558.625 Tylosin.

(a) *Specifications.* Type A medicated articles containing tylosin phosphate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 016592: Type medicated article containing 100 grams per pound.

(2) No. 054771: Type medicated article containing 40 grams per pound.

(3) No. 058198: Type medicated article containing 10, 40, or 100 grams per pound.

(4) No. 066104: Type medicated article containing 20 or 40 grams per pound.

(c) *Related tolerances.* See § 556.740 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for tylosin medicated feeds must not exceed 6 months from the date of issuance. VFDs for tylosin shall not be refilled.

(3) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(4) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.

(5) Do not use tylosin liquid Type B medicated feeds in any liquid feed containing sodium metabisulfite or in any finished feed (supplement, concentrate, or complete feed) containing in excess of 2 percent bentonite.

(e) *Conditions of use*—(1) *Swine*—

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 40 or 100	.....	For control of swine dysentery associated with *Brachyspira hyodysenteriae*.	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight.	016592 054771 058198 066104
(ii) 40 or 100	Pyrantel, 96	For control of swine dysentery associated with *Brachyspira hyodysenteriae;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(iii) 40 or 100	.....	For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight.	016592 054771 058198 066104
(iv) 40 or 100	Pyrantel, 96	For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(v) 40 or 100	Ractopamine, 4.5 to 9.0.	Finishing swine: For the control of swine dysentery associated with *Brachyspira hyodysenteriae;* for control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 100 g/ton of tylosin for at least 3 weeks, followed by 40 g/ton until market weight. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	016592 054771 058198
(vi) 40 to 100	.....	For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin in drinking water.	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in § 520.2640(d)(3) of this chapter.	016592 054771 058198 066104
(vii) 40 or 100	Pyrantel, 96	For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin in drinking water; and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in § 520.2640(d)(3) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(viii) 40 to 100	.....	For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with tylosin in drinking water.	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in § 520.2640(d)(3) of this chapter.	016592 054771 058198 066104
(ix) 40 or 100	Pyrantel, 96	For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with tylosin in drinking water; and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in § 520.2640(d)(3) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(x) 40 to 100	Ractopamine, 4.5 to 9.0.	Finishing swine: For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae*, for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 40 to 100 grams of tylosin phosphate per ton of complete feed for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in § 520.2640(d)(3) of this chapter. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	016592 054771 058198
(xi) 100	.....	For reduction in severity of effects of atrophic rhinitis.	Feed continuously as the sole ration.	016592 054771 058198 066104
(xii) 100	Pyrantel, 96	For reduction in severity of effects of atrophic rhinitis; aid as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed continuously as the sole ration. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xiii) 100	Ractopamine, 4.5 to 9.0.	For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 100 g/ton of tylosin for 3 weeks. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	016592 054771 058198

(2) Cattle—

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 8 to 10	.....	Beef cattle: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.	Feed continuously as the sole ration to provide 60 to 90 mg/head/day tylosin.	016592, 054771, 058198, 066104
(ii) 90 to 360	Lasalocid, 100 to 1440 plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Feed to heifers at the rate of 0.5 to 2.0 pound(s) per head per day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate per head per day (specify one level), 100 to 360 mg lasalocid per head per day (specify one level), and 90 mg tylosin per head per day. This Type C product may be top dressed onto or mixed into a complete feed prior to feeding. Tylosin as provided by Nos. 058198 and 016592; lasalocid as provided by No. 054771; melengestrol as provided by Nos. 054771 and 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.342(d) in this chapter.	054771 016592
(iii) 90 to 360	Melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Each pound contains 0.125 to 1.0 mg melengestrol acetate and 45 to 180 mg of tylosin. Feed to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg melengestrol acetate and 60 to 90 mg tylosin per head per day. Prior to feeding, this Type C product must be top-dressed onto a complete feed or mixed into the amount of complete feed consumed by an animal per day. Tylosin provided by No. 058198; melengestrol provided by No. 054771 in § 510.600(c) of this chapter. See § 558.342(d) in this chapter.	054771
(iv) 8 to 10	Monensin, 5 to 40 ..	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for improved feed efficiency.	Feed continuously as sole ration to provide 50 to 480 monensin mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198 in § 510.600(c) of this chapter. See § 558.355(d) in this chapter.	016592 058198

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(v) 8 to 10	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for prevention of coccidiosis caused by *Eimeria bovis* and *E zuernii*.	Feed continuously as sole ration to provide 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for preruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198 in § 510.600(c) of this chapter. See § 558.355(d) in this chapter.	016592 058198
(vi) 8 to 10	Monensin, 5 to 30 plus decoquinate, 13.6 to 22.7.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for improved feed efficiency.	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin/head/day, and 60 to 90 mg of tylosin/head/day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. A withdrawal time has not been established for preruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by Nos. 016592 and 058198; monensin as provided by No. 058198; decoquinate as provided by No. 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.355(d) in this chapter.	016592 054771

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(vii) 8 to 10	Monensin, 10 to 40 plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; melengestrol provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.342(d) and 558.355(d) in this chapter.	016592 054771 058198
(viii) 8 to 10	Monensin, 10 to 40 plus ractopamine, 8.2 to 24.6.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 70 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.355(d) and 558.500(d) in this chapter.	054771 058198

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(ix) 8 to 10	Monensin, 10 to 40 plus ractopamine, not to exceed 800.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed a minimum of 1.0 lb/head/day ractopamine Type C top dress feed continuously to cattle fed in confinement for slaughter, to provide 70 to 400 mg/head/day ractopamine for the last 28 to 42 days on feed. Feed on top of a ration containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin phosphate, to provide 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.355(d) and 558.500(d) in this chapter.	054771 058198
(x) 8 to 10	Monensin 10 to 40 plus ractopamine 9.8 to 24.6.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine as provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.355(d) and 558.500(d) in this chapter.	054771 058198

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(xi) 8 to 10	Monensin, 10 to 40 plus ractopamine, 9.8 to 24.6 plus melengestrol, 0.125 to 1 mg/lb.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and suppression of estrus (heat).	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine as provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.342(d), 558.355(d), and 558.500(d) in this chapter.	054771 058198
(xii) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed.	Feed continuously as the sole ration to cattle during the last 20 to 40 days on feed to provide 60 to 90 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Do not use in veal calves. Withdrawal period 3 days. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061 in § 510.600(c) of this chapter. See §§ 558.355(d) and 558.665(d) in this chapter.	000061 016592
(xiii) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 to 24.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed.	Feed this component feed continuously to cattle during the last 20 to 40 days on feed to provide 60 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Do not use in veal calves. Withdrawal period 3 days. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061 in § 510.600(c) of this chapter. See §§ 558.355(d) and 558.665(d) in this chapter.	000061 016592

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(xiv) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 plus melengestrol, 0.125 to 1 mg/lb.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously as the sole ration to cattle during the last 20 to 40 days on feed to provide 60 to 90 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). Do not use in veal calves. Withdrawal period 3 days. Tylosin as provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061; melengestrol provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.342(d), 558.355(d) and 558.665(d) in this chapter.	000061 016592 058198
(xv) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 to 24 plus melengestrol, 0.125 to 1 mg/lb.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed this component feed continuously to cattle during the last 20 to 40 days on feed to provide 60 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). Do not use in veal calves. Withdrawal period 3 days. Tylosin as provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061; melengestrol provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.342(d), 558.355(d) and 558.665(d) in this chapter.	000061 016592 058198

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing equal amounts of tylosin phosphate and sulfamethazine, available in concentrations of 5, 10, 20, or 40 grams each, per pound.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 058198 for use as in paragraph (e)(1) of this section.

(2) No. 054771: 10 or 40 grams per pound each for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for tylosin and sulfamethazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for tylosin and sulfamethazine shall not be refilled.

(3) Labeling shall bear the statement: ''Do not use in medicated feeds containing in excess of 2% bentonite.''

(e) *Conditions of use.* It is used in feed for swine as follows:

Tylosin phosphate and sulfamethazine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(1) 100 each	.....	For reduction in the severity of effects of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae;* control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*); reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci.* Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.	Withdraw 15 days before swine are slaughtered.	058198
(2) 100 each	.....	For reduction in the severity of effects of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae;* and control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*).	Withdraw 15 days before swine are slaughtered.	054771

[81 FR 95021, Dec. 27, 2016]

§ 558.633 Tylvalosin.

(a) *Specifications.* Type A medicated articles containing 77.12 grams tylvalosin per pound as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) VFDs for tylvalosin shall not be refilled.

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form.

(e) *Conditions of use in swine*—(1) *Amount.* Administer 38.6 grams tylvalosin per ton of Type C medicated feed (42.5 ppm) as the sole ration for 14 consecutive days.

(2) *Indications for use.* For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

[81 FR 36790, June 8, 2016, as amended at 81 FR 67153, Sept. 30, 2016]

§ 558.635 Virginiamycin.

(a) *Specifications.* Type A medicated articles containing 10, 20, 50, or 227 grams virginiamycin per pound.

(b) *Sponsors.* See No. 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.750 of this chapter.

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for virginiamycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for virginiamycin shall not be refilled.

(3) Not for use in breeding swine over 120 pounds.

(4) Dilute Type A article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of Type C feed.

(e) *Conditions of use*—(1) *Chickens*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 20		Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.	Not for use in layers	066104
(ii) 20	Amprolium 72.6 to 113.5.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella.*	For field conditions where only *E. tenella* is the major problem, feed continuously as the sole ration. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in § 510.600(c) of this chapter.	066104
(iii) 20	Amprolium 113.5 to 227.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis where immunity to coccidiosis is not desired.	For most field conditions as they exist under modern management practices, feed 113.5 g/ton amprolium continuously. Where severe coccidiosis conditions exist, feed 227 g/ton. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in § 510.600(c) of this chapter.	066104
(iv) 20	Diclazuril 0.91	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati),* and *E. maxima.* Because diclazuril is effective against *E. maxima* late in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima.*	Feed continuously as the sole ration. Do not use in hens producing eggs for human food. Diclazuril as provided by No. 016592 in § 510.600(c) of this chapter.	016592

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(v) 20	Lasalocid 68 to 113	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Feed continuously as the sole ration. Do not feed to laying chickens. For broiler or fryer chickens only. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	066104
(vi) 20	Monensin 90 to 110	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati.*	Feed continuously as the sole ration. Do not feed to laying chickens. See § 558.355(d) in this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(vii) 20	Salinomycin 40 to 60.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	
(viii) 20	Semduramicin 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella.*	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(ix) 20	Semduramicin (biomass) 22.7.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella.*	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104

(2) *Swine*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 25		Growing-finishing swine: As an aid in control of dysentery in swine up to 120 pounds in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.		066104
(ii) 50 or 100		Growing-finishing swine: For treatment and control of swine dysentery in swine up to 120 pounds.	Feed 100 grams per ton for 2 weeks, 50 grams per ton thereafter.	066104
(iii) 100		Growing-finishing swine: For treatment of swine dysentery in nonbreeding swine over 120 pounds.	Feed for 2 weeks	066104

(3) *Cattle*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.5 to 16.0	.....	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses.	Feed continuously as the sole ration to provide 85 to 240 milligrams per head per day. Not for use in animals intended for breeding.	066104
(ii) [Reserved]				

[81 FR 95022, Dec. 27, 2016, as amended at 82 FR 11512, Feb. 24, 2017; 82 FR 21692, May 10, 2017]

§ 558.665 Zilpaterol.

(a) *Specifications.* Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

(b) *Approvals.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.765 of this chapter.

(d) *Special considerations*—(1) Labeling shall bear the following caution statements: ''Zilpaterol hydrochloride is not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.''

(2) Labeling of Type A medicated articles and Type B medicated feeds used to manufacture complete Type C medicated feeds shall bear the caution statement in paragraph (d)(3) of this section.

(3) Labeling of complete Type C medicated feeds shall bear the following caution statements: ''Not to be fed to cattle in excess of 90 mg zilpaterol/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed.''

(4) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Conditions of use in cattle.* It is administered in feed as follows:

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(2) 6.8	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.355(d) of this chapter Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	000061 058198
(3) 6.8	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. Melengestrol acetate as provided by Nos. 058198 or 054771 in § 510.600(c) of this chapter.	000061 058198
(4) 6.8	Monensin 10 to 40 plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 058198; melengestrol acetate as provided by Nos. 058198 or 054771 in § 510.600(c) of this chapter.	000061 058198
(5)–(6) [Reserved].				
(7) 6.8 to 24	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061
(8) 6.8 to 24	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.355(d) of this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	000061

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(9) 6.8 to 24	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.342(d) of this part. Melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter.	000061
(10) 6.8 to 24	Monensin 10 to 40, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 058198; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter.	000061

(f) Zilpaterol may also be used in combination with tylosin as in § 558.625.

[71 FR 53006, Sept. 8, 2006, as amended at 72 FR 9245, Mar. 1, 2007; 72 FR 6019, Feb. 1, 2008; 73 FR 14385, Mar. 18, 2008; 73 FR 16755, Mar. 31, 2008; 73 FR 18959, Apr. 8, 2008; 73 FR 19432, Apr. 10, 2008; 74 FR 61517, Nov. 25, 2009; 75 FR 11451, Mar. 11, 2010; 77 FR 31724, May 30, 2012; 78 FR 42008, July 15, 2013; 78 FR 52852, Aug. 27, 2013; 80 FR 13232, Mar. 13, 2015; 80 FR 53460, Sept. 4, 2015; 81 FR 48703, July 26, 2016; 81 FR 95025, Dec. 27, 2016]

§ 558.680 Zoalene.

(a) *Specifications.* Type A medicated article containing 25 percent zoalene.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.770 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5		Replacement chickens: For development of active immunity to coccidiosis.	Grower ration not to be fed to birds over 14 weeks of age; as follows:	054771

Growing conditions	Starter ration Grams per ton	Grower ration Grams per ton
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%)

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3–113.5	Bacitracin methylenedisalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 36.3–113.5	Bacitracin methylenedisalicylate 50.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 36.3–113.5	Bacitracin methylenedisalicylate 100 to 200.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 113.5	.....	Broiler chickens: For prevention and control of coccidiosis.	Feed continuously as sole ration	054771
(vi) 113.5	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) 113.5	Bacitracin methylenedisalicylate 50.	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 113.5	Bacitracin methylenedisalicylate 100 to 200.	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 113.5	Bambermycins 1	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592

(2) *Turkeys*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3	.....	Growing turkeys: For prevention and control of coccidiosis.	Feed continuously as sole ration. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771
(ii) 113.5 to 170.3 ...	Bacitracin methylenedisalicylate 4 to 50.	Growing turkeys: For prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 14 to 16 weeks of age. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771

(3) Zoalene may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Lincomycin as in §558.325.

[41 FR 11005, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 20817, Apr. 22, 1977; 42 FR 36995, July 19, 1977; 51 FR 7401, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8461, Mar. 8, 1990; 57 FR 8403, Mar. 10, 1992; 57 FR 8578, Mar. 11, 1992; 61 FR 35957, July 9, 1996; 63 FR 38750, July 20, 1998; 67 FR 6868, Feb. 14, 2002; 71 FR 16223, Mar. 31, 2006; 71 FR 27958, May 15, 2006; 76 FR 17027, Mar. 28, 2011; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 17610, Mar. 30, 2016; 81 FR 95025, Dec. 27, 2016; 82 FR 21693, May 10, 2017]

PART 564 [RESERVED]

PART 570—FOOD ADDITIVES

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301–392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals of the species to which the substance is intended to be fed (and, for food-producing animals fed with such substance, also means a substantial history of consumption by humans consuming human foods derived from those food-producing animals), prior to January 1, 1958.

(g) The word *substance* in the definition of the term *food additive* includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) *Scientific procedures* include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use;

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet;

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

(j) The term *nonperishable processed food* means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Not included are hermetically sealed foods and other processed foods requiring refrigeration.

(k) *General recognition of safety* shall be in accordance with § 570.30.

(l) *Prior sanction* means an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by the Food Drug and Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) *Food* includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

(n) *Food-producing animal* means an animal used to produce human food.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 55206, Oct. 14, 1977; 81 FR 55051, Aug. 17, 2016]

§ 570.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquirers as to the

safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Pub. L. 85–929, Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: ''A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health''.

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or

(2) Is generally recognized as safe (GRAS); or

(3) Has prior sanction or approval under that amendment; or

(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance (HFV–200), 7500 Standish Pl., Rockville, MD 20855, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in regulations in this Subchapter E if the articles are used in accordance with the requirements of such regulations.

[41 FR 38644, Sept. 10, 1976, as amended at 54 FR 18281, Apr. 28, 1989; 57 FR 6476, Feb. 25, 1992]

§ 570.13 Indirect food additives resulting from packaging materials prior sanctioned for animal feed and pet food.

Regulations providing for the use of food packaging materials as prior sanctioned in part 181 of this chapter are incorporated in Subchapter E as applicable to packaging materials used for animal feed and pet food.

[42 FR 14091, Mar. 15, 1977]

§ 570.14 Indirect food additives resulting from packaging materials for animal feed and pet food.

Regulations providing for the use of food packaging materials in parts 174 through 179 of this chapter are incorporated in Subchapter E as applicable to packaging materials used for animal feed and pet food.

[42 FR 14091, Mar. 15, 1977]

§ 570.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall proceed as provided in part 10 of this chapter.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977]

§ 570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with §511.1 of this chapter or by the Department of Agriculture in accordance with 9 CFR 309.17, and it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in part 58 of this chapter.

[41 FR 38644, Sept. 10, 1976, as amended at 43 FR 60023, Dec. 22, 1978]

§ 570.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.

(2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(3) Add the percentages so obtained for all residues present.

(4) The sum of the percentages shall not exceed 100 percent.

§ 570.19 Pesticide chemicals in processed foods.

When pesticide chemical residues occur in processed foods due to the use of raw agricultural commodities that bore or contained a pesticide chemical

in conformity with an exemption granted or a tolerance prescribed under section 408 of the act, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 570.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferable. For the purposes of this section, the principles for evaluating safety of additives set forth in the above-mentioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 570.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful to either the target animal or to humans consuming human food derived from food-producing animals under the conditions of its intended use (see § 570.3(i)).

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall address safety

for both the target animal and for humans consuming human food derived from food-producing animals and shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance in the same animal species prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also § 570.3(i)) for both the target animal and for humans consuming human food derived from food-producing animals. Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

(d) The food ingredients listed as GRAS in part 582 of this chapter or affirmed as GRAS in part 584 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in part 582 or part 584 of this chapter.

(e) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(f) A food ingredient that is listed as GRAS in part 582 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable specifications, or in the absence of such specifications, shall be of a purity suitable for its intended use.

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to

achieve its intended purpose in that article.

(g) New information may at any time require reconsideration of the GRAS status of a food ingredient. Any change in status shall be accomplished pursuant to § 570.38.

(h) If a substance is affirmed as GRAS pursuant to § 570.35 and listed in a regulation with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(i) If an ingredient is affirmed as GRAS pursuant to § 570.35 and listed in a regulation with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(j) Pursuant to § 570.35, a food ingredient may be affirmed as GRAS and listed in a regulation for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

[42 FR 55206, Oct. 14, 1977, as amended at 81 FR 55052, Aug. 17, 2016]

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, on his own initiative, may affirm that a substance that directly or indirectly becomes a component of food is GRAS under the conditions of its intended use.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS under the conditions of its intended use, he will place all of the data and information on which he relies on public file in the office of the Division of Dockets Management and will publish in the FEDERAL REGISTER a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Division of Dockets Management. Copies of all comments received shall be made available for examination in the Division of Dockets Management's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS under the conditions of its intended use as described in § 570.30, he will publish a notice in the FEDERAL REGISTER listing the GRAS conditions of use in this subchapter E.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS under the conditions of its intended use and that it should be considered a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 570.38.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 10, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 54 FR 18281, Apr. 28, 1989; 62 FR 40600, July 29, 1997; 81 FR 55052, Aug. 17, 2016]

§ 570.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 570.35(b)(4), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS under the conditions of its intended use and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 571.130(b) of this chapter. The Commissioner will place all of the data and information on which he relies on public file in the Division of Dockets Management and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Division of Dockets Management. Copies of all comments shall be made available for examination in the Division of Dockets Management.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance in this subchapter E as GRAS.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food-contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under this subchapter E. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this subchapter E., incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[41 FR 38644, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 42 FR 55207, Oct. 14, 1977; 54 FR 18281, Apr. 28, 1989; 81 FR 55052, Aug. 17, 2016]

Subparts C–D [Reserved]

Subpart E—Generally Recognized as Safe (GRAS) Notice

SOURCE: 81 FR 55052, Aug. 17, 2016, unless otherwise noted.

§ 570.203 Definitions.

The definitions and interpretations of terms in § 570.3 apply to such terms when used in this subpart. The following definitions also apply:

Amendment means any data and information that you submit regarding a filed GRAS notice before we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

GRAS means generally recognized as safe.

GRAS notice means a submission that informs us of your view that a substance is not subject to the premarket

approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is GRAS under the conditions of its intended use in accordance with § 570.30.

Notified substance means the substance that is the subject of your GRAS notice.

Notifier means the person (*e.g.,* an individual, partnership, corporation, association, or other legal entity) who is responsible for the GRAS notice, even if another person (such as an attorney, agent, or qualified expert) prepares or submits the notice or provides an opinion about the basis for a conclusion of GRAS status.

Qualified expert means an individual who is qualified by scientific training and experience to evaluate the safety of substances under the conditions of their intended use in animal food.

Supplement means any data and information that you submit regarding a filed GRAS notice after we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

We, our, and *us* refer to the United States Food and Drug Administration (FDA).

You and *your* refer to a notifier.

§ 570.205 Opportunity to submit a GRAS notice.

Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use.

§ 570.210 How to send your GRAS notice to FDA.

(a) Send your GRAS notice to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

(b) When you submit your GRAS notice, you may do so either in an electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.

§ 570.215 Incorporation into a GRAS notice.

You may incorporate into your GRAS notice either specifically identified data and information that you previously submitted to the Center for Veterinary Medicine (CVM), or specifically identified publicly available data and information submitted by another party, when such data and information remain in CVM's records, such as data and information contained in a previous GRAS notice or a food additive petition.

§ 570.220 General requirements applicable to a GRAS notice.

(a) A GRAS notice has seven parts as required by §§ 570.225 through 570.255. You must submit the data and information specified in each of these parts on separate pages or sets of pages.

(b) You must include each of the seven parts in your GRAS notice. If you do not include a part, you must include with your GRAS notice an explanation of why that part does not apply to your GRAS notice.

§ 570.225 Part 1 of a GRAS notice: Signed statements and certification.

(a) Part 1 of your GRAS notice must be dated and signed by a responsible official of your organization, or by your attorney or agent.

(b) Except as required by paragraph (c)(8) of this section, you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice.

(c) In Part 1 of your GRAS notice, you must:

(1) Inform us that you are submitting a GRAS notice in accordance with this subpart;

(2) Provide the name and address of your organization;

(3) Provide the name of the notified substance, using an appropriately descriptive term;

(4) Describe the intended conditions of use of the notified substance, including stating whether the substance will be added to food (including drinking water) for animals in which the substance will be used; identifying the foods to which it will be added, the levels of use in such foods, and the animal

species for which these foods are intended (including, when appropriate, a description of a subpopulation expected to consume the notified substance); and the purposes for which the substance will be used;

(5) Inform us of the statutory basis for your conclusion of GRAS status (*i.e.*, through scientific procedures in accordance with § 570.30(a) and (b) or through experience based on common use in animal food in accordance with § 570.30(a) and (c));

(6) State your view that the notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the notified substance is GRAS under the conditions of its intended use;

(7) State that, if we ask to see the data and information that are the basis for your conclusion of GRAS status, either during or after our evaluation of your notice, you will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon our request, you will allow us to review and copy the data and information during customary business hours at the address you specify for where these data and information will be available to us; and

(B) Upon our request, you will provide us with a complete copy of the data and information either in an electronic format that is accessible for our evaluation or on paper;

(8) State your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (*e.g.*, as trade secret or as commercial or financial information that is privileged or confidential);

(9) Certify that, to the best of your knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance; and

(10) State both the name and the position or title of the person who signs the GRAS notice.

§ 570.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.

In Part 2 of your GRAS notice, you must include:

(a) Scientific data and information that identifies the notified substance.

(1) Examples of appropriate data and information include the chemical name, applicable registry numbers (such as a Chemical Abstracts Service (CAS) registry number or an Enzyme Commission (EC) number), empirical formula, structural formula, quantitative composition, and characteristic properties.

(2) When the source of a notified substance is a biological material, you must include data and information sufficient to identify:

(i) The taxonomic source (*e.g.*, genus, species), including as applicable data and information at the sub-species level (*e.g.*, variety, strain);

(ii) The part of any plant or animal used as the source; and

(iii) Any known toxicants that could be in the source;

(b) A description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured;

(c) Specifications for material that is of appropriate grade for use in animal food; and

(d) When necessary to demonstrate safety, relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.

§ 570.235 Part 3 of a GRAS notice: Target animal and human exposures.

In part 3 of your GRAS notice, you must provide data and information about exposure to the target animal and to humans consuming human food derived from food-producing animals, regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food, as follows:

(a) For exposure to the target animal, you must provide:

(1) The amount of the notified substance that different target animal species are likely to consume in the animal food (including drinking water) as part of the animal's total diet, including the intended use and all other sources in the total diet; and

(2) When applicable, the amount of any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.*, hydrolytic products or reaction products);

(3) When applicable, the amount of any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.*, contaminants or by-products);

(4) The data and information you rely on to establish the amount of the notified substance and the amounts of any other substance in accordance with paragraphs (a)(1) through (a)(3) of this section that different target animal species are likely to consume in the animal food (including drinking water) as part of the animal's total diet; and

(b) When the intended use is in food for food-producing animals, you must provide:

(1) The potential quantities of any residues that humans may be exposed to in edible animal tissues, including:

(i) Residues of the notified substance;

(ii) Residues of any other substance that is expected to be formed in or on the animal food because of the use of the notified substance; and

(iii) Residues from any other substance that is present with the notified substance whether naturally, due to its manufacture (*e.g.*, contaminants or by-products), or produced as a metabolite in edible animal tissues when the notified substance is consumed by a food-producing animal; and

(2) The data and information you rely on to establish, in accordance with paragraph (b)(1) of this section, the potential quantities of any residues that humans may be exposed to in edible animal tissues.

§ 570.240 Part 4 of a GRAS notice: Self-limiting levels of use.

In circumstances where the amount of the notified substance that can be added to animal food is limited because animal food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical, in Part 4 of your GRAS notice you must include data and information on such self-limiting levels of use.

§ 570.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.

If the statutory basis for your conclusion of GRAS status is through experience based on common use in animal food, in Part 5 of your GRAS notice you must include evidence of a substantial history of consumption of the notified substance for food use by a significant number of animals of the species to which the substance is intended to be fed prior to January 1, 1958, and evidence of a substantial history of consumption by humans consuming human foods derived from food-producing animals prior to January 1, 1958.

§ 570.250 Part 6 of a GRAS notice: Narrative.

In Part 6 of your GRAS notice, you must include a narrative that provides the basis for your conclusion of GRAS status, in which:

(a)(1) You must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals. In your explanation, you must address the safety of the notified substance, considering all animal food (including drinking water) as part of the animal's total diet, taking into account any chemically or pharmacologically related substances in such diet. In your explanation, you must also address the safety of the notified substance in regard to human exposure, considering all dietary sources and taking into account any chemically or pharmacologically related substances;

(2) In your explanation, you must identify what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are

generally available, and what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are not generally available, by providing citations to the list of data and information that you include in Part 7 of your GRAS notice in accordance with § 570.255;

(b) You must explain how the generally available data and information that you rely on to establish safety in accordance with paragraph (a) of this section provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals;

(c) You must either:

(1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available; or

(2) State that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status;

(d) If you view any of the data and information in your notice as exempt from disclosure under the Freedom of Information Act, you must identify the specific data and information; and

(e) For non-public, safety-related data and information considered in reaching a conclusion of GRAS status, you must explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to such data and information.

§ 570.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.

(a) In part 7 of your GRAS notice, you must include a list of all of the data and information that you discuss in Part 6 of your GRAS notice to provide a basis for your view that the notified substance is safe under the conditions of its intended use as described in accordance with § 570.250(a)(1).

(b) You must specify which data and information that you list in accordance with paragraph (a) of this section are generally available, and which data and information are not generally available.

§ 570.260 Steps you may take before FDA responds to your GRAS notice.

(a) You may submit a timely amendment to your filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

(b) At any time before we respond to your notice by letter in accordance with § 570.265(b)(1), you may request in writing that we cease to evaluate your GRAS notice. Your request does not preclude you from submitting a future GRAS notice in accordance with this subpart with respect to the notified substance.

§ 570.265 What FDA will do with a GRAS notice.

(a)(1) We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use.

(2) If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing.

(3) If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provide our reasons for not filing the submission as a GRAS notice.

(4) We will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter in accordance with paragraph (b)(1) of this section, if we deem that doing so is feasible within the timeframes established in paragraph (b) of this section. If we deem that considering your amendment is not feasible within the timeframes established in paragraph (b) of this section or if we have granted your request to cease to evaluate your notice, we will inform you that we are not considering your amendment.

(b)(1) Within 180 days of filing, we will respond to you by letter based on

our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis.

(2) If we extend the timeframe, we will inform you in writing of the extension as soon as practicable but no later than within 180 days of filing.

(3) If you ask us to cease to evaluate your GRAS notice in accordance with § 570.260(b), we will send you a letter informing you of our decision regarding your request.

(c) If circumstances warrant, we will send you a subsequent letter about the notice.

§ 570.275 Public disclosure of a GRAS notice.

(a) The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice, or incorporated into your GRAS notice) are:

(1) Considered a mandatory, rather than voluntary, submission for purposes of their status under the Freedom of Information Act and our public information requirements in part 20 of this chapter; and

(2) Available for public disclosure in accordance with part 20 of this chapter as of the date that we receive your GRAS notice.

(b) We will make the following readily accessible to the public:

(1) A list of filed GRAS notices, including the information described in § 570.225(c)(2) through (c)(5);

(2) The text of any letter that we issue under § 570.265(b)(1) or (c); and

(3) The text of any letter that we issue under § 570.265(b)(3) if we grant your request that we cease to evaluate your notice.

(c) We will disclose all remaining data and information that are not exempt from public disclosure in accordance with part 20 of this chapter.

§ 570.280 Submission of a supplement.

If circumstances warrant, you may submit a supplement to a filed GRAS notice after we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

PART 571—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

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571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

SOURCE: 41 FR 38647, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 571.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food-additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner _____
Post office address _____
Date _____
Name of food additive and proposed use ____

Food and Drug Administration
CENTER FOR VETERINARY MEDICINE,
Director, Division of Animal Feeds (HFV–220),
7500 Standish Pl., Rockville, MD 20855.

DEAR SIRS: The undersigned, _____

submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and

Cosmetic Act with respect to _____

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to ensure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.

If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

(A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should

include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.)

F. Proposed tolerances for the food additive, if tolerances are required in order to ensure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed, and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if and to the extent he obtains the manufacturer's written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner. Nothing herein shall prevent reference to published data.

(g) A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the act are lacking or are not set forth so as to be readily understood.

(h)(1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(i) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(v) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(2) The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade

secret or confidential commercial or financial information as defined in §20.61 of this chapter:

(i) Manufacturing methods or processes, including quality control procedures.

(ii) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(iii) Quantitative or semiquantitative formulas.

(3) All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of part 20 of this chapter when the food additive regulation is published in the FEDERAL REGISTER.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all studies and tests on a food additive for identity, stability, purity, potency, performance, and usefulness.

(i)(1) Within 15 days after receipt, the Commissioner will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 409(b)(5) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing.

(2) The Commissioner will publish in the FEDERAL REGISTER within 30 days from the date of filing of such petition, a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. In the case of a food additive which becomes a component of food by migration from packaging material, the notice shall include the name of the migratory substance, and where it is different from that of one of the original components, the name of the parent component, the maximum quantity of the migratory substance that is proposed for use in food, and the physical or other technical effect which the migratory substance or its parent component is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the FEDERAL REGISTER for publication.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for, the production of the food additive, or a sample of the food additive, articles used as components thereof, or of the food in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, or articles used as components thereof, or of the food in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c)(2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each study, either a statement that the study was conducted in compliance with the requirements set forth in part

58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

[41 FR 38647, Sept. 10, 1976, as amended at 42 FR 15675, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8583, Mar. 19, 1987; 57 FR 6476, Feb. 25, 1992; 62 FR 40600, July 29, 1997]

§ 571.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason or the noncompliance.

[41 FR 38647, Sept. 10, 1976, as amended at 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

§ 571.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 571.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

Subpart B—Administrative Actions on Applications

§ 571.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 571.102 Effective date of regulation.

A regulation published in accordance with § 571.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 571.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409(c), (d), or (h) of the act shall be governed by part 12 of this chapter.

[42 FR 4717, Jan. 25, 1977, as amended at 42 FR 15676, Mar. 22, 1977]

§ 571.115 Application of the cancer clause of section 409 of the act.

Food additives intended for use as an ingredient in food for animals that are raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

[52 FR 49588, Dec. 31, 1987]

§ 571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in § 571.1 for submitting petitions.

[42 FR 4717, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977]

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

Subpart A [Reserved]

Subpart B—Food Additive Listing

Sec.

573.120 Acrylamide-acrylic acid resin.
573.130 Aminoglycoside 3′-phospho- transferase II.
573.140 Ammoniated cottonseed meal.
573.160 Ammoniated rice hulls.
573.170 Ammonium formate.
573.180 Anhydrous ammonia.
573.200 Condensed animal protein hydrolysate.
573.210 Benzoic acid.
573.220 Feed-grade biuret.
573.225 1,3-Butylene glycol.
573.240 Calcium periodate.
573.260 Calcium silicate.
573.280 Feed-grade calcium stearate and sodium stearate.
573.300 Choline xanthate.
573.304 Chromium propionate.
573.310 Crambe meal, heat toasted.
573.320 Diammonium phosphate.
573.340 Diatomaceous earth.
573.360 Disodium EDTA.
573.380 Ethoxyquin in animal feeds.
573.400 Ethoxyquin in certain dehydrated forage crops.
573.420 Ethyl cellulose.
573.440 Ethylene dichloride.
573.450 Fermented ammoniated condensed whey.
573.460 Formaldehyde.
573.480 Formic acid.
573.490 Gamma-linolenic acid safflower meal.
573.492 Gamma-linolenic acid safflower oil.
573.496 Guanidinoacetic acid.
573.500 Condensed, extracted glutamic acid fermentation product.
573.520 Hemicellulose extract.
573.530 Hydrogenated corn syrup.
573.540 Hydrolyzed leather meal.
573.560 Iron ammonium citrate.
573.580 Iron-choline citrate complex.
573.600 Lignin sulfonates.
573.620 Menadione dimethylpyrimidinol bisulfite.
573.625 Menadione nicotinamide bisulfite.
573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).
573.640 Methyl esters of higher fatty acids.
573.660 Methyl glucoside-coconut oil ester.
573.680 Mineral oil.
573.685 Natamycin.
573.696 Feed grade sodium formate.
573.700 Sodium nitrite.
573.720 Petrolatum.
573.740 Odorless light petroleum hydrocarbons.
573.750 Pichia pastoris dried yeast.
573.760 Poloxalene.
573.780 Polyethylene.
573.800 Polyethylene glycol (400) mono- and dioleate.
573.820 Polyoxyethylene glycol (400) mono- and dioleates.
573.840 Polysorbate 60.
573.860 Polysorbate 80.
573.870 Poly(2-vinylpyridine-co-styrene).
573.880 Normal propyl alcohol.
573.900 Pyrophyllite.
573.914 Salts of volatile fatty acids.
573.920 Selenium.
573.940 Silicon dioxide.
573.960 Sorbitan monostearate.
573.980 Taurine.
573.1000 Verxite.
573.1010 Xanthan gum.
573.1020 Yellow prussiate of soda.

AUTHORITY: 21 U.S.C. 321, 342, 348.

SOURCE: 41 FR 38652, Sept. 10, 1976, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Food Additive Listing

§ 573.120 Acrylamide-acrylic acid resin.

Acrylamide-acrylic acid resin (hydrolized polyacrylamide), only for the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.

(b) The additive meets the following specifications:

(1) A minimum molecular weight of 3 million.

(2) Viscosity range: 3,000 to 6,000 centipoises at 77 °F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.

(3) Residual acrylamide: Not more than 0.05 percent.

(c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

[41 FR 38652, Sept. 10, 1976, as amended at 45 FR 38058, June 6, 1980]

§ 573.130 Aminoglycoside 3′-phosphotransferase II.

The food additive aminoglycoside 3′-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

(a) The food additive is the enzyme aminoglycoside 3′-phosphotransferase II (CAS Reg. No. 58943–39–8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.

(b) Aminoglycoside 3′-phosphotransferase II is encoded by the *kan*^{r} gene originally isolated from transposon Tn*5* of the bacterium *Escherichia coli*.

(c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the *kan*^{r} gene along with the genetic material of interest.

[59 FR 26711, May 23, 1994]

§ 573.140 Ammoniated cottonseed meal.

The food additive ammoniated cottonseed meal may be safely used in accordance with the following conditions:

(a) The food additive is the product obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached.

(b) It is used or intended for use in the feed of ruminants as a source of protein and/or as a source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use, the label and labeling of the additive and of any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration.

(4) A statement:

(i) That not more than one-third of the total protein in the feed should come from nonprotein nitrogen sources.

(ii) That the additive is not to be given to debilitated or starved animals.

(iii) ''Warning—This feed should be used only in accordance with directions furnished on the label.''

[41 FR 38652, Sept. 10, 1976, as amended at 42 FR 52397, Sept. 30, 1977]

§ 573.160 Ammoniated rice hulls.

The food additive ammoniated rice hulls may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the product obtained by the treatment of ground rice hulls with monocalcium phosphate

and anhydrous ammonia at a temperature of 350 °F and a pressure of 175 pounds per square inch.

(b) It is used or intended for use in the feed of beef cattle as a source of crude fiber and as the sole source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration, and a prominent statement: ''Warning—This feed should be used only in accordance with the directions furnished on the label.''

§ 573.170 Ammonium formate.

The food additive, ammonium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).

(2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[75 FR 41725, July 19, 2010, as amended at 78 FR 42692, July 17, 2013; 82 FR 52209, Nov. 13, 2017]

§ 573.180 Anhydrous ammonia.

(a) The food additive anhydrous ammonia is applied directly to corn plant material and thoroughly blended prior to ensiling. It is used or intended for use as a source of nonprotein nitrogen in cattle feed in accordance with paragraphs (a)(1), (2), or (3) as follows:

(1)(i) The food additive anhydrous ammonia is applied as a component of an aqueous premix containing 16 to 17 percent ammonia, with molasses, minerals, and not less than 83 percent crude protein. The premix is a source of nonprotein nitrogen and minerals.

(ii) In addition to the requirements of paragraph (b) of this section, the labeling shall bear an expiration date of not more than 10 weeks after date of manufacture; a statement that additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day nor beef cattle consuming less than 1 percent of body weight daily in shelled corn; and a warning not to use additional trace mineral supplementation with treated silage.

(2)(i) The food additive anhydrous ammonia is applied directly to corn plant material for use in dairy or beef cattle rations.

(ii) The anhydrous ammonia is applied at a rate not to exceed the equivalent of 0.35 percent of the corn plant material.

(iii) It is applied to corn plant material containing 30 to 35 percent dry matter.

(iv) It is applied so that 75 to 85 percent of the additive is liquid at ambient pressure.

(3)(i) The food additive anhydrous ammonia is applied after being diluted to a 15 to 30 percent aqueous ammonia solution (by weight).

(ii) The anhydrous ammonia solution is applied at a rate not to exceed anhydrous ammonia equivalent to 0.3 percent of the corn plant material.

(iii) It is applied to corn plant material containing 28 to 38 percent dry matter.

(iv) The silage treated with aqueous ammonia is to be fed to dairy cattle only.

(b) Its labeling shall bear, in addition to the other requirements of the act, the name of the additive, the concentration of ammonia, the maximum percentage of equivalent crude protein from nonprotein nitrogen, and directions for use consistent with this section.

[44 FR 40284, July 10, 1979]

§ 573.200 Condensed animal protein hydrolysate.

(a) *Identity.* The condensed animal protein hydrolysate is produced from the meat byproducts scraped from cured (salted) hides taken from cattle slaughtered for food consumption. The meat byproduct is hydrolyzed with heat and phosphoric acid.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 45 percent nor more than 50 percent.
Protein, not less than 24 percent.
Salt (NaCl), not more than 15 percent.
Phosphorus, not less than 2.25 percent.

(c) *Uses.* It is used or intended for use as a source of animal protein, phosphorus, and salt (NaCl) as follows:

(1) In poultry and swine feed in an amount not to exceed 5 percent by weight of the feed.

(2) In feed concentrates for cattle in an amount not to exceed 10 percent by weight of the concentrate.

(d) *Labeling.* The label and labeling shall bear, in addition to the other information required by the act:

(1) The name of the additive, condensed animal protein hydrolysate.

(2) Adequate directions for use including maximum quantities permitted for each species and a guaranteed analysis of the additive.

§ 573.210 Benzoic acid.

The food additive, benzoic acid, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 0.5 percent of the complete feed.

(b) The additive consists of not less than 99.5 percent benzoic acid (CAS 65–85–0) by weight with the sum of 2-methylbiphenyl, 3-methylbiphenyl, 4-methylbiphenyl, benzyl benzoate, and isomers of dimethylbiphenyl not to exceed 0.01 percent by weight.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) of this section, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that benzoic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds

so treated shall be labeled as containing benzoic acid.

(3) Appropriate warnings and safety precautions concerning benzoic acid.

(4) A warning statement identifying benzoic acid as a possible irritant.

(5) Information about emergency aid in case of accidental exposure.

(6) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[79 FR 14176, Mar. 13, 2014]

§ 573.220 Feed-grade biuret.

The food additive feed grade biuret may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the controlled pyrolysis of urea conforming to the following specifications:

	Percent
Biuret	55 minimum.
Urea	15 maximum.
Cyanuric acid and triuret	30 maximum.
Mineral oil	0.5 maximum.
Total nitrogen (equivalent to 218.75 pct crude protein).	35 minimum.

(b) It is used in ruminant feeds as a source of nonprotein nitrogen.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(i) The name of the additive.

(ii) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(2) The label shall recommend that the diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of nonprotein nitrogen exceed one-third of the total crude protein in the total daily ration.

[41 FR 38652, Sept. 10, 1976, as amended at 68 FR 27904, May 22, 2003]

§ 573.225 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (1,3-butanediol) may be safely used in accordance with the following prescribed conditions:

(a) It complies with the specifications in § 173.220(a) of this chapter.

(b) It is intended for use in swine feed as a source of energy.

(c) It is to be thoroughly mixed into feed at levels not to exceed 9 percent of the dry matter of the total ration.

(d) 1,3-Butylene glycol should be mixed in feed with equipment adapted for the addition of liquids, and the feed should be mixed not less than 5 minutes after its addition.

[53 FR 40061, Oct. 13, 1988]

§ 573.240 Calcium periodate.

The food additive calcium periodate may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by reacting calcium iodate with calcium hydroxide or calcium oxide to form a substance consisting of not less than 60 percent by weight of penta calcium orthoperiodate containing 28 to 31 percent by weight of iodine.

(b) It is used or intended for use in salt for livestock as a source of iodine.

§ 573.260 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used as an anticaking agent in animal feed, provided that the amount of calcium silicate does not exceed 2 percent.

§ 573.280 Feed-grade calcium stearate and sodium stearate.

Feed-grade calcium stearate and sodium stearate may be safely used in an animal feed in accordance with the following prescribed conditions:

(a) Feed-grade calcium stearate and sodium stearate are the calcium or sodium salts of a fatty acid mixture that is predominately stearic acid. Associated fatty acids, including palmitic acid and minor amounts of lauric, myristic, pentadecanoic, margaric, arachidic, and other fatty acids may be contained in the mixture, but such associated fatty acids in aggregate do not exceed 35 percent by weight of the mixture. The fatty acids may be derived from feed-grade fats or oils.

(b) The additives meet the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) They are free of chick-edema factor.

(c) The additives are manufactured so that in aqueous solution they are exposed for 1 hour or longer to temperature in excess of 180 °F.

(d) They are used as anticaking agents in animal feeds in accordance with current good manufacturing practices.

[63 FR 8573, Feb. 20, 1998]

§ 573.300 Choline xanthate.

Choline xanthate may be safely used as a component of animal feed as an added source of choline to supplement the diets of poultry, ruminants, and swine in accordance with good feeding practice.

§ 573.304 Chromium Propionate.

The food additive chromium propionate may be safely used in animal feed as a source of supplemental chromium in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(mu_3-oxo) hexakis (mu_2-propionato-*O,O′*) trichromium propionate with the empirical formula, $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]CH_3CH_2CO_2$.

(b) The additive shall be incorporated at a level not to exceed 0.2 milligrams of chromium from chromium propionate per kilogram feed in broiler chicken complete feed.

(c) The additive meets the following specifications:

(1) Total chromium content, 8 to 10 percent.

(2) Hexavalent chromium content, less than 2 parts per million.

(3) Arsenic, less than 1 part per million.

(4) Cadmium, less than 1 part per million.

(5) Lead, less than 0.5 part per million.

(6) Mercury, less than 0.5 part per million.

(7) Viscosity, not more than 2,000 centipoise.

(d) The additive shall be incorporated into feed as follows:

(1) It shall be incorporated into each ton of complete feed by adding no less than one pound of a premix containing no more than 181.4 milligrams of added chromium from chromium propionate per pound.

(2) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.

(3) Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A guarantee for added chromium content.

(ii) Adequate directions for use and cautions for use including this statement: Caution: Follow label directions. Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.

[81 FR 35611, June 3, 2016]

§ 573.310 Crambe meal, heat toasted.

(a) The additive is the seed meal of *Crambe abyssinica* obtained after the removal of oil from the seed and hull. The oil may be removed by pre-press solvent extraction or by solvent extraction alone. The resulting seed meal is heat toasted.

(b) The additive conforms to the following percent-by-weight specifications: moisture, not more than 11 percent; oil, not more than 4 percent; crude protein, not less than 24 percent; crude fiber, not more than 26 percent; glucosinolate calculated as epiprogoitrin, not more than 4 percent; goitrin, not more than 0.1 percent; nitrile calculated as 1-cyano-2-hydroxy-3-butene, not more than 1.4 percent. At least 50 percent of the nitrogen shall be soluble in 0.5 *M* sodium

chloride. Myrosinase enzyme activity shall be absent.

(c) The additive is used or intended for use in the feed of feedlot cattle as a source of protein in an amount not to exceed 4.2 percent of the total ration.

[46 FR 30082, June 5, 1981]

§ 573.320 Diammonium phosphate.

The food additive diammonium phosphate may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the neutralization of feeding-phosphoric-acid or defluorinated wet-process phosphoric acid with anhydrous ammonia. It contains not less than 106.25 percent equivalent crude protein (nitrogen × 6.25) and 20 percent phosphorus. It contains not more than the following:

1 part fluorine to 100 parts phosphorus.
75 parts per million or arsenic (as As).
30 parts per million of heavy metals, as lead (Pb).

(b) It is used in ruminant feeds as a source of phosphorus and nitrogen in an amount that supplies not more than 2 percent of equivalent crude protein in the total daily ration.

(c) To assure safe use of the additive, the label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) If the feed additive premix, feed additive concentrate, or feed additive supplement contains more than 2 percent equivalent crude protein from diammonium phosphate, adequate directions for use and a prominent statement, ''Warning—This feed should be used only in accordance with directions furnished on the label.''

§ 573.340 Diatomaceous earth.

(a) *Identity.* The additive consists of siliceous skeletal material derived from various species of diatoms.

(b) *Specifications.* The additive shall conform to the following specifications:

Lead, not more than 15 parts per million.
Arsenic (as As), not more than 20 parts per million
Fluorine, not more than 600 parts per million.

(c) *Uses.* It is used or intended for use as an inert carrier or anticaking agent in animal feeds in an amount not to exceed 2 percent by weight of the total ration.

§ 573.360 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in animal feeds, in accordance with the following prescribed conditions:

(a) The food additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(b) It is used to solubilize trace minerals in aqueous solutions, which are then added to animal feeds.

(c) It is used or intended for use in an amount not to exceed 240 parts per million of the additive in finished feed.

(d) To assure safe use of the additive the label and labeling shall bear:

(1) The name of the additive; and

(2) Adequate mixing directions to ensure that the chelated trace-mineral mix is uniformly blended throughout the feed.

§ 573.380 Ethoxyquin in animal feeds.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in animal feeds, when incorporated therein in accordance with the following prescribed conditions.

(a) It is intended for use only: (1) As a chemical preservative for retarding oxidation of carotene, xanthophylls, and vitamins A and E in animal feed and fish food and, (2) as an aid in preventing the development of organic peroxides in canned pet food.

(b) The maximum quantity of the additive permitted to be used and to remain in or on the treated article shall not exceed 150 parts per million.

(c) To assure safe use of the additive, the label and labeling of the food additive container and that of any intermediate premixes prepared therefrom

shall contain, in addition to other information required by the act:

(1) The name of the additive, ethoxyquin.

(2) A statement of the concentration or strength contained therein.

(3) Adequate use directions to provide for a finished article with the proper concentration of the additive as provided in paragraph (b) of this section, whether or not intermediate premixes are to be used.

(d) The label of any animal feed containing the additive shall, in addition to the other information required by the act, bear the statement ''Ethoxyquin, a preservative'' or ''Ethoxyquin added to retard the oxidative destruction of carotene, xanthophylls, and vitamins A and E.''

§ 573.400 Ethoxyquin in certain dehydrated forage crops.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in the dehydrated forage crops listed in paragraph (a) of this section when incorporated therein in accordance with the conditions prescribed in this section:

(a) It may be added to dehydrated forage prepared from:

Alfalfa	Medicago sativa.
Barley	Hordeum vulgare.
Clovers:	
Alsike clover	Trifolium hybridum.
Crimson clover	Trifolium incarnatum.
Red clover	Trifolium pratense.
White clover (including Ladino).	Trifolium repens.
White sweetclover	Melilotus alba.
Yellow sweetclover	Melilotus officinalis.
Coastal Bermudagrass	Cynodon dactylon.
Corn	Zea mays.
Fescue	Festuca sp.
Oats	Avena sativa.
Orchardgrass	Dactylis glomerata.
Reed canarygrass	Pharlaris arundinacea.
Ryegrass (annual and perennial).	Elymus sp. and Lolium perenne.
Sorghums	Sorghum vulgare vars, feterita, shallu, kaoliang, broomcorn.
Sudan grass	Sorghum vulgare sudanense.
Wheat	Triticum aestivum.

or any mixture of such forage crops, for use only as an animal feed.

(b) Such additive is used only as a chemical preservative for the purpose of retarding oxidative destruction of naturally occurring carotenes and vitamin E in the forage crops.

(c) It is added to the dehydrated forage crops in an oil mixture containing only suitable animal or suitable vegetable oil, prior to grinding and mixing.

(d) The maximum quantity of the additive permitted to be used and to remain in or on the dehydrated forage crop shall not exceed 150 parts per million.

(e) To assure the safe use of the additive, the label of the market package shall contain, in addition to other information required by the act:

(1) The name of the additive as specified in this section.

(2) Directions for the incorporation of the additive in the forage crops, as specified in paragraph (c) of this section, with the directive that only suitable animal or suitable vegetable oils are to be used in the oil mix.

(f) The label of any dehydrated forage crops treated with the additive or the label of an animal-feed supplement containing such treated forage crops, shall, in addition to other information required by the act, bear the following statements:

(1) ''Ethoxyquin, a preservative,'' or ''Ethoxyquin added to retard the oxidative destruction of carotene and vitamin E.''

(2) The statement ''For use in animal feed only.''

§ 573.420 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as a binder or filler in dry vitamin preparations to be incorporated into animal feed.

§ 573.440 Ethylene dichloride.

The food additive ethylene dichloride may be safely used in the manufacture of animal feeds in accordance with the following prescribed conditions:

(a) It is used as a solvent in the extraction processing of animal byproducts for use in animal feeds.

(b) The maximum quantity of the additive permitted to remain in or on the

extracted byproducts shall not exceed 300 parts per million.

(c) The extracted animal byproduct is added as a source of protein to a total ration at levels consistent with good feeding practices, but in no event at levels exceeding 13 percent of the total ration.

§ 573.450 Fermented ammoniated condensed whey.

(a) *Identity.* The product is produced by the *Lactobacillus bulgaricus* fermentation of whey with the addition of ammonia.

(b) *Specifications.* The product contains 35 to 55 percent crude protein and not more than 42 percent equivalent crude protein from nonprotein nitrogen sources.

(c) *Uses.* The product is used as a source of protein and nonprotein nitrogen for cattle.

(d) *Limitations.* (1) Store in a closed vented tank equipped for agitation. Agitate 5 minutes before using. Do not store at temperature above 110 °F (43 °C).

(2) The maximum level of use of fermented ammoniated condensed whey and equivalent crude protein from all other added forms of nonprotein nitrogen shall not exceed 30 percent of the dietary crude protein.

(3) The additive may be used as follows:

(i) Mixed with grain, roughage, or grain and roughage prior to feeding.

(ii) As a component of free-choice liquid feeds, used to supplement the diets of cattle fed other sources of nutrients, fermented ammoniated condensed whey shall not exceed 80 percent of the free-choice liquid feed.

(e) *Labeling.* The label shall bear, in addition to other information required by the act:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(3) Adequate directions for use in accordance with the provisions in paragraph (d) of this section.

[43 FR 33708, July 1, 1978, as amended at 46 FR 49115, Oct. 6, 1981]

§ 573.460 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a) The additive is used, or intended for use, to improve the handling characteristics of fat by producing a dry, free-flowing product, as follows:

(1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelletted feeds for beef and nonlactating dairy cattle.

(i) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the ''Official Publication'' of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 303, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) Adequate directions for use providing that the feed as consumed does

not contain more than 25 percent of the mixture.

(2) For soybean and canola seeds and/or meals to which there may be added vegetable oil as a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.

(i) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent. The feed ingredients are those defined by the ''Official Publication'' of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) The statement, ''This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat.''

(C) The minimum and maximum levels of crude fat must be guaranteed and must be between −5 percent and +5 percent of the analyzed fat content for each batch.

(b)(1) The food additive is formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.

(iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation.

(iv) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18281, Apr. 28, 1989; 61 FR 15704, Apr. 9, 1996; 63 FR 53580, Oct. 6, 1998; 68 FR 65633, Nov. 21, 2003]

§ 573.480 Formic acid.

The food additive, formic acid, may be safely used in accordance with the following conditions:

(a) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct cut, as follows:

(1) The top foot of silage stored should not contain formic acid and

(2) Silage should not be fed to livestock within 4 weeks of treatment.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(1) The additive consists of not less than 85 percent formic acid (CAS 64–18–6).

(2) The additive meets the following specifications:

(i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);

(ii) Methyl formate not to exceed 1,000 ppm; and

(iii) Moisture not to exceed 15 percent.

(3) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(4) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug and Cosmetic Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) Adequate directions for use including a statement that formic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing formic acid.

(iii) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(5) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b)(4) of this section, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid).

(ii) Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant.

(iii) Information about emergency aid in case of accidental exposure.

(A) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

[76 FR 7106, Feb. 9, 2011, as amended at 82 FR 52209, Nov. 13, 2017; 83 FR 20, Jan. 2, 2018]

§ 573.490 Gamma-linolenic acid safflower meal.

The food additive consists of the meal obtained after the removal of most of the oil from whole seeds or partially dehulled seeds or both obtained from a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid during seed development. The resulting additive may be safely used in cattle and poultry feeds in accordance with the following prescribed conditions:

(a) The additive shall contain not less than 20 percent crude protein, not more than 40 percent crude fiber, not more than 10 percent moisture, and not more than 2 percent crude fat.

(b) The crude fat in the additive meets the following specifications:

(1) Gamma-linolenic acid content not to exceed 55 percent.

(2) Total content of stearidonic acid and cis, cis-6, 9-octadecadienoic acid not to exceed a total of 0.5 percent.

(3) Total content of palmitic, stearic, oleic, linoleic, and other associated fatty acids to exceed a total of 40 percent.

(c) The additive is used or intended for use in cattle and poultry feeds as a source of protein in accordance with good manufacturing and feeding practices.

(d) To assure safe use of the additive, in addition to the other information required by the Food, Drug, and Cosmetic Act, the label and labeling of the additive, any feed premix, or complete feed shall bear the following:

(1) The name of the additive or the common name, safflower meal.

(2) Adequate directions for use in cattle and poultry feeds.

(e) The additive may be identified by the common or usual name, safflower meal.

[80 FR 35569, June 22, 2015]

§ 573.492 Gamma-linolenic acid safflower oil.

The food additive gamma-linolenic acid (all-*cis*-6,9,12-octadecatrienoic acid) (GLA) safflower oil contains an omega-6 fatty acid that may be safely used in animal food in accordance with the following conditions:

(a) The additive GLA safflower oil is produced in the oil obtained from whole seeds or partially dehulled seeds or both obtained from a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to GLA during seed development. This GLA safflower oil may be safely used in complete dry adult maintenance dog food as a source of GLA and other omega-6 fatty acids in accordance with the following prescribed conditions:

(1) The GLA safflower oil obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the GLA safflower oil or its blend is not less than 99.5 percent.

(ii) GLA content is between 400 and 450 milligrams (mg) GLA per gram of the GLA safflower oil or its blend.

(iii) Total content of stearidonic acid and *cis, cis*-6,9-octadecadienoic acid in the GLA safflower oil or its blend must not exceed a total of 0.3 percent.

(3) Addition of GLA safflower oil, or its blend, to complete dry adult maintenance dog food must meet the following:

(i) Addition of the oil or its blend cannot provide more than 36 mg GLA per kilogram body weight of the dog per day in more than 86 mg of the GLA safflower oil or its blend. This maximum addition rate of the GLA safflower oil, or its blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(ii) Adjustments must be made for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

(b) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:

(1) The name, gamma-linolenic acid (GLA) safflower oil.

(2) A guarantee for the minimum content of gamma-linolenic acid.

(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraph (a)(3) of this section.

[82 FR 38596, Aug. 15, 2017]

§ 573.496 Guanidinoacetic acid.

The food additive, guanidinoacetic acid, may be safely used in broiler chicken and turkey feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.

(b) The additive is used or intended for use to spare arginine and as a precursor of creatine in broiler chicken and turkey feeds at levels not to exceed 0.12 percent of the complete feed.

(c) The additive consists of not less than 97 percent guanidinoacetic acid [*N*-(aminoiminomethyl)-glycine] (CAS 352–97–6) by weight.

(d) The additive meets the following specifications:

(1) Dicyandiamide not to exceed 0.5 percent;

(2) Cyanamide not to exceed 0.01 percent;

(3) Melamine not to exceed 15 parts per million (ppm);

(4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and

(5) Water not to exceed 1 percent.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12 percent of the complete feed for broiler chickens and turkeys; and

(ii) Adequate directions for use.

[81 FR 86269, Nov. 30, 2016]

§ 573.500 Condensed, extracted glutamic acid fermentation product.

Condensed, extracted glutamic acid fermentation product may be safely used in animal feed under the following conditions:

(a) The additive is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of *Corynebacterium lilium* used to produce the glutamic acid.

(b) It is used or intended for use as follows:

(1) In poultry feed as a source of protein in an amount not to exceed 5 percent of the total ration.

(2) In cattle feed as a source of protein in an amount not to exceed 10 percent of the feed.

(c) In order to assure safe use, the label and labeling of the additive shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive.

(2) A statement of the concentration of the additive contained in any mixture.

(3) Adequate directions for use.

§ 573.520 Hemicellulose extract.

Hemicellulose extract may be safely used in animal feed when incorporated therein in accordance with the following conditions:

(a) The additive is produced from the aqueous extract obtained by the treatment of wood with water at elevated temperatures (325 degrees–535 degrees F) and pressure (80 to 900 pounds per square inch) and contains primarily pentose and hexose sugars.

(b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

(c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

[41 FR 38652, Sept. 10, 1976, as amended at 43 FR 11181, Mar. 17, 1978]

§ 573.530 Hydrogenated corn syrup.

(a) *Identity.* The product is produced by hydrogenation of corn syrup over a nickel catalyst.

(b) *Specifications.* The product contains 70 percent hydrogenated corn syrup and a maximum of 0.5 percent reducing sugars.

(c) *Uses.* The product is used as a humectant and plasticizer in preparation of soft-moist dog and cat foods.

(d) *Limitations.* The product is preferably stored in a closed, stainless steel or aluminum container. The level of use of the product shall not exceed 15 percent of the total weight of the pet food formulation.

(e) *Labeling.* The labeling shall bear, in addition to other information required by the Act:

(1) The name of the additive.

(2) Adequate directions for use in accordance with the provisions in paragraph (d) of this section.

[45 FR 22920, Apr. 4, 1980]

§ 573.540 Hydrolyzed leather meal.

(a) *Identity.* Hydrolyzed leather meal is produced from leather scraps that are treated with steam for not less than 33 minutes at a pressure of not less than 125 pounds per square inch.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 5 percent nor more than 10 percent.
Crude protein, not less than 60 percent.
Crude fat, not less than 5 percent.
Crude fiber, not more than 6 percent.
Chromium, not more than 2.75 percent.

(c) *Use.* It is used or intended for use as a source of protein in swine feeds in an amount not to exceed 1.0 percent by weight of the finished feed.

(d) *Labeling.* The labels and labeling shall bear, in addition to the other information required by the Act:

(1) The name of the additive, hydrolyzed leather meal.

(2) Adequate directions to provide finished feeds complying with paragraph (c) of this section.

§ 573.560 Iron ammonium citrate.

Iron ammonium citrate may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used or intended for use as an anticaking agent in salt for animal consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 573.580 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in animal feed.

§ 573.600 Lignin sulfonates.

Lignin sulfonates may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) For the purpose of this section, the food additive is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (*Musa textilis*) or of sisal (*Agave sisalana*) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed 6 percent by weight).

(b) It is used or intended for use in an amount calculated on a dry weight basis, as follows:

(1) As a pelleting aid in the liquid or dry form in an amount not to exceed 4 percent of the finished pellets.

(2) As a binding aid in the liquid form in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain.

(3) As a surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.

(4) As a source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4 percent of the finished feed.

§ 573.620 Menadione dimethylpyrimidinol bisulfite.

The food additive, menadione dimethylpyrimidinol bisulfite, may be safely used in accordance with the following conditions:

(a) The additive is the 2-hydroxy-4,6-dimethylpyrimidinol salt of menadione ($C_{17}H_{18}O_6N_2S$).

(b) The additive is used or intended for use as a nutritional supplement for the prevention of vitamin K deficiency as follows:

(1) In chicken and turkey feed at a level not to exceed 2 grams per ton of complete feed.

(2) In the feed of growing and finishing swine at a level not to exceed 10 grams per ton of feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

§ 573.625 Menadione nicotinamide bisulfite.

The food additive may be safely used as follows:

(a) The additive is 1,2,3,4-tetrahydro-2-methyl-1,4-dioxo-2-naphthalene sulfonic acid with 3-pyridine carboxylic acid amine (CAS No. 73581–79–0).

(b) The additive is used or intended for use as a nutritional supplement for both the prevention of vitamin K deficiency and as a source of supplemental niacin as follows:

(1) In chicken and turkey feeds at a level not to exceed 2 grams per ton of complete feed.

(2) In growing and finishing swine feeds at a level not to exceed 10 grams per ton of complete feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

[64 FR 46840, Aug. 27, 1999]

§ 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids), may be safely used in swine feed in accordance with the prescribed conditions:

(a) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4 percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(b) The additive is used or intended for use in the feed of growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(c) The additive meets the following specifications:

(1) Free methyl alcohol not to exceed 0.015%.

(2) Insoluble impurities not to exceed 0.1%.

(3) Moisture not to exceed 0.5%.

(4) Unsaponifiable matter not to exceed 1.0%.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive and any feed premix shall bear the following:

(i) The name of the additive.

(ii) A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) must not be added to vitamin or mineral premixes.

(2) The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

[73 FR 64198, Oct. 29, 2008]

§ 573.640 Methyl esters of higher fatty acids.

The food additive methyl esters of higher fatty acids may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reaction of methyl alcohol with feed-grade fats or oils and consists of not less than 70 percent methyl esters of the following straight-chain monocarboxylic acids: Docosahexanoic acid, eicosapentanoic acid, linoleic acid, myristic acid, oleic acid, palmitic acid, palmitoleic acid, and stearic acid, and lesser amounts of the associated acid esters.

(b) The food additive meets the following specifications:

(1) Free methyl alcohol not to exceed 150 parts per million.

(2) Unsaponifiable matter not to exceed 2 percent.

(3) It is free of chick-edema factor or other factors toxic to chicks, as evidenced during the bioassay method for determining the chick-edema factor as

prescribed in paragraph (b)(4)(ii) of this section.

(4) For the purposes of this section:

(i) Unsaponifiable matter shall be determined by the method described in Section 28.081, ''Unsaponifiable Residue (20)—Official Final Action'' of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed., 1980, p. 451, which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) The chick-edema factor bioassay method described under ''26. Oils, Fats, and Waxes'' in the *Journal of the Association of Official Agricultural Chemists*, Vol. 44, Page 146 (1961), or the method described under ''Chick-Edema Factor—Bioassay Method (34)—Official Final Action'' in §§ 28.113–28.117, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 12th Ed., 1975, pp. 509–511, which is incorporated by reference, shall be employed. (Copies of the methods are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspectionat the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*) The presence of chick-edema factor shall be determined by a comparison between the mean log of the pericardial fluid volumes of a test group and of a concurrent negative control group. The significance of the difference in pericardial fluid volumes between the test group and the negative control group is determined by calculating a ''*t*'' value according to the formula:

$$t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{\left(s_t^2/n_t\right) + \left(s_c^2/n_c\right)}}$$

where:

$\bar{x}_t$ and $\bar{x}_c$ are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;

n_t and n_c are the number of chicks in the respective groups;

s_t^2 and s_c^2 are the variances of the test and control groups, respectively.

The variances are calculated as follows:

$$s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}$$

where:

Σx is the sum of the logs of the pericardial fluid volumes;

Σx^2 is the sum of the squares of the logs of the pericardial fluid volumes for either the test *t* or control *c* group data.

The test sample is judged to contain chick-edema factor if the calculated ''*t*'' exceeds +1.3 and the mean log of the pericardial fluid volume obtained from the negative control group multiplied by 100 is less than 1.1461.

(iii) ''Other factors toxic to chicks'' referred to in paragraph (b)(3) of this section shall be determined during the course of the bioassay test described in paragraph (b)(4)(ii) of this section, on the basis of chick deaths or other abnormalities not attributable to chick-edema factor or to the experimental conditions of the test.

(c) It is used or intended for use as a supplementary source of fat for animal feed.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive, and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear:

(i) The name of the additive.

(ii) The designation ''feed grade'' in juxtaposition with the name and equally as prominent.

(2) The label or labeling of the additive and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared

therefrom shall bear adequate directions for use.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 9397, Mar. 5, 1982; 54 FR 18281, Apr. 28, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

§ 573.660 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in accordance with the following conditions:

(a) The additive meets the specifications prescribed in § 172.816 of this chapter.

(b) It is used as a surfactant in molasses intended for use in animal feed at a level not to exceed 320 parts per million.

§ 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 172.878 (a) and (b) or in § 178.3620(b)(1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feed.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 41106, Sept. 17, 1982]

§ 573.685 Natamycin.

The food additive natamycin (CAS No. 7681–93–8) may be safely used in broiler chicken feeds in accordance with the following specifications:

(a) The additive is a stereoisomer of 22-[(3-amino-3,6,dideoxy-β-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.$0^{5,7}$] octacosa-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula $C_{33}H_{47}NO_{13}$.

(b) The additive shall conform to U.S.P. specifications.

(c) The additive (as part of a premix composed of calcium carbonate, natamycin, and lactose) is used for retarding the growth of *Aspergillus parasiticus* in broiler chicken feeds for up to 14 days after the addition of natamycin.

(d) Each pound (454 grams (g)) of the premix shall contain 434 (g) of calcium carbonate, 10 g of natamycin activity, and 10 g of lactose. The premix shall be mixed into broiler chicken feed at the rate of 1 pound (0.454 kilograms (kg)) per ton (908 kg) of feed to provide natamycin at a level of 11 parts per million (ppm). The premix shall be thoroughly mixed into the dry components of the broiler chicken feed before adding the liquid components. Broiler feeds to which the natamycin premix is added shall be used within 4 weeks of addition of the premix.

(e) To assure the safe use of the additive, the label or labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name and CAS number of the additive, and its purpose.

(2) A listing of ingredients consisting of calcium carbonate, the additive, and lactose and their proportions in the premix as prescribed under paragraph (d) of this section.

(3) Adequate directions for use to ensure a broiler chicken feed that is in compliance with the limitations prescribed in paragraph (d) of this section.

(4) An appropriate cautionary statement: ''Caution: Store in a tightly-closed, light-resistant container in a cool, dry place.''

(5) An expiration date of 1 year from the date of manufacture.

(6) A contact address and telephone number for reporting adverse reactions experienced by users, or to request a

copy of the Material Safety Data Sheet for natamycin.

[69 FR 19321, Apr. 13, 2004]

§ 573.696 Feed grade sodium formate.

The food additive, feed grade sodium formate, may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of 99 percent formic acid and 50 percent sodium hydroxide in water to produce a solution made up of at least 20.5 percent sodium salt of formic acid and not more than 61 percent formic acid.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use, including a statement that feed grade sodium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing feed grade sodium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To assure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning feed grade sodium formate.

(2) Statements identifying feed grade sodium formate as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[81 FR 67154, Sept. 30, 2016, as amended at 81 FR 95027, Dec. 27, 2016]

§ 573.700 Sodium nitrite.

Sodium nitrite may be safely used in canned pet food containing meat and fish in accordance with the following prescribed conditions:

(a) It is used or intended for use alone as a preservative and color fixative in canned pet food containing fish, meat, and fish and meat byproducts so that the level of sodium nitrite does not exceed 20 parts per million.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (a) of this section.

§ 573.720 Petrolatum.

Petrolatum may be safely used in or on animal feed, subject to the following prescribed conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVI for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280 to 289	0.25
290 to 299	.20
300 to 359	.14
360 to 400	.04

(c) It is used in animal feed for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks, and to improve resistance to moisture of such pellets, cubes, or blocks.

(d) The quantity of petrolatum present in animal feeds from the uses specified in paragraph (c) of this section shall not exceed 3 percent in mineral supplements nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

(e) When used in combination with technical white mineral oil for the uses described in paragraph (c) of this section, the total quantity of combined petrolatum and technical white mineral oil shall not exceed the limits prescribed in paragraph (d) of this section.

(f) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

§ 573.740 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons complying with § 172.884(a) and (b) of this chapter may be safely used in an amount not in excess of that required as a component of insecticide formulations used in compliance with regulations issued in this part.

§ 573.750 Pichia pastoris dried yeast.

(a) *Identity.* The food additive *Pichia pastoris* dried yeast may be used in feed formulations of broiler chickens as a source of protein not to exceed 10 percent by weight of the total formulation.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

(1) Crude protein, not less than 60 percent.

(2) Crude fat, not less than 2 percent.

(3) Crude fiber, not more than 2 percent.

(4) Ash, not more than 13 percent.

(5) Moisture, not more than 6 percent.

(c) *Use.* To ensure safe use, the labeling of the additive and any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to other required information, the name of the additive, directions for use to provide not more than 10 percent by weight of the total ration, and the statement ''Caution: Not to be used in layers or other poultry intended for breeding.''

[58 FR 59170, Nov. 8, 1993]

§ 573.760 Poloxalene.

The food additive poloxalene may be safely used in accordance with the following prescribed conditions:

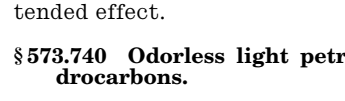
(a) The additive consists of polyoxypropylene-polyoxyethylene glycol nonionic block polymer meeting the following specifications:

(1) Molecular weight range: 2,850–3,150.

(2) Hydroxyl number: 35.7–39.4.

(3) Cloud point (10 percent solution): 42 °C–46 °C.

(4) Structural formula:



(b) In feed as a surfactant for the flaking of feed grains when added to liquid grain conditioner in an amount not to exceed 1.0 percent of the conditioner. The conditioner is added to the feed at a rate of 1 quart per ton of feed.

(c) The label and labeling shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions and warnings for use.

§ 573.780 Polyethylene.

(a) *Identity.* Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(b) *Specifications.* (1) For the purposes of this section, polyethylene shall meet the specifications in item 2.1 of § 177.1520(c) of this chapter.

(2) The polyethylene is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters:

$0.9 \pm 0.1 \times 0.8 \pm 0.1 \times 1.2 \pm 0.1$

(c) *Use.* It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle.

(d) *Labeling.* The labels and labeling shall bear in addition to the other information required by the Act:

(1) The name of the additive ''polyethylene roughage replacement.''

(2) Adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per head per day for 6 successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18282, Apr. 28, 1989]

§ 573.800 Polyethylene glycol (400) mono- and dioleate.

(a) The food additive polyethylene glycol (400) mono- and dioleate meets the following specifications: Saponification number, 80–88; acid number, 5.0 maximum; and average molecular weight range, 640–680.

(b) It is used as a processing aid in the production of animal feeds when present as a result of its addition to molasses in an amount not to exceed 250 parts per million of the molasses.

§ 573.820 Polyoxyethylene glycol (400) mono- and dioleates.

The food additive polyoxyethylene glycol (400) mono- and dioleates may be safely used as an emulsifier in calf-milk replacer formulations.

§ 573.840 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) It is used alone or in combination with sorbitan monostearate as an emulsifier in mineral premixes and dietary supplements for animal feeds.

(b) It is used as an emulsifier in milk-replacer formulations for calves.

§ 573.860 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate) may be safely used as an emulsifier in milk-replacer formulations for calves.

§ 573.870 Poly(2-vinylpyridine-co-styrene).

The food additive poly(2-vinylpyridine-co-styrene) may be safely used as nutrient protectant in feed for beef cattle and dairy cattle and replacement dairy heifers when used in accordance with the following conditions:

(a) The additive meets the following specifications:

Component/property	Limitation
Inherent viscosity	1.0-1.6 deciliter per gram.[1]
Styrene moiety	40 percent maximum.
2-Vinylpyridine moiety.	90 percent maximum.
Residual styrene	200 parts per billion maximum.
Residual 2-vinylstyrene	200 parts per billion maximum.
Heavy metals such as lead	10 parts per million maximum.
Arsenic	3 parts per million maximum.

[1] Inherent viscosity of a 0.25 percent (weight/volume) solution in dimethylformamide.

(b) The additive is used in the manufacture of rumen-stable, abomasum-dispersible nutrient(s) for beef cattle and dairy cattle and replacement dairy heifers such that the maximum use of the additive from all sources does not exceed 5.1 grams per head per day. The additive may be used to protect the following nutrients:

(1) *Methionine.* The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of 55 percent methionine by weight. The coated methionine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(2) *Methionine and lysine.* The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of a combined total of 55 percent methionine and lysine by weight. The coated

methionine and lysine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(c) *Label and labeling.* To ensure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, feed additive premix, or liquid feed supplement prepared therefrom, shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name of the additive.

(2) A statement of the concentration of poly(2-vinylpyridine-co-styrene) in any product or mixture.

(3) Adequate directions for the use of the rumen-stable, abomasum-dispersible nutrient(s) products.

(4) The following statement: ''Warning: Maximum use of poly(2-vinylpyridine-co-styrene) from all sources is not to exceed 5.1 grams per head per day.''

[57 FR 7875, Mar. 5, 1992, as amended at 57 FR 24187, June 8, 1992; 61 FR 11547, Mar. 21, 1996; 70 FR 13100, Mar. 18, 2005]

§ 573.880 Normal propyl alcohol.

Normal propyl alcohol may be safely used in feeds and feed supplements for cattle as a source of metabolizable energy. It is incorporated in the feed or feed supplement in an amount which provides not more than 54.5 grams of the additive per head per day.

§ 573.900 Pyrophyllite.

Pyrophyllite (aluminum silicate monohydrate) may be safely used as the sole anticaking aid, blending agent, pelleting aid, or carrier in animal feed when incorporated therein in an amount not to exceed 2 percent in complete animal feed.

§ 573.914 Salts of volatile fatty acids.

(a) *Identity.* The food additive is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids—isovaleric, 2-methylbutyric, and *n*-valeric.

(b) *Specifications.* The additive contains ammonium or calcium salts of volatile fatty acids and shall conform to the following specifications:

(1) Ammonium salts:

Components	Amount
Ammonium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	48 to 54 percent.
Ammonium salt of isobutyric acid	22 to 26 percent.
Water	28 percent maximum.
Ammonia	0.3 percent maximum.
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

(2) Calcium salts:

Components	Amount
Calcium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	58 to 72 percent.
Calcium salt of isobutyric acid	26 to 34 percent.
Calcium hydroxide	3 percent maximum.
Water	14 percent maximum.
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

(c) *Use.* The additive is used or intended for use as a source of energy in dairy cattle feed.

(d) *Labeling.* The label and labeling of the additive in any feed, feed supplement, feed concentrate, feed premix, or liquid feed supplement prepared therefrom shall bear, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) Adequate directions for use, including statements expressing maximum use levels. For ammonium salts of volatile fatty acids, the statements: ''Not to exceed 160 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.'' For calcium salts of volatile fatty acids, the statement: ''Not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.''

[49 FR 45125, Nov. 15, 1984; 50 FR 8606, Mar. 4, 1985, as amended at 70 FR 13100, Mar. 18, 2005]

§ 573.920 Selenium.

(a) Public Law 103–354 enacted October 13, 1994 (the 1994 Act), states that FDA shall not implement or enforce the final rule issued on September 13, 1993 (58 FR 47962), in which FDA stayed

the 1987 amendments and any modification of such rule issued after enactment of the 1994 Act; unless the Commissioner of Food and Drugs makes a determination that:

(1) Selenium additives are not essential at levels authorized in the absence of such final rule, to maintain animal nutrition and protect animal health;

(2) selenium at such levels is not safe to the animals consuming the additive;

(3) selenium at such levels is not safe to individuals consuming edible portions of animals that receive the additive;

(4) selenium at such levels does not achieve its intended effect of promoting normal growth and reproduction of livestock and poultry; and

(5) the manufacture and use of selenium at such levels cannot reasonably be controlled by adherence to current good manufacturing practice requirements.

(6) Paragraphs (b) through (g) of this section provide the currently acceptable levels of selenium supplementation.

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate or in a controlled-release sodium selenite bolus, as provided in paragraphs (f) and (g) of this section, or as selenium yeast, as provided in paragraph (h) of this section.

(c) It is added to feed as follows:

(1) In complete feed for chickens, swine, turkeys, sheep, cattle, and ducks at a level not to exceed 0.3 part per million.

(2) In feed supplements for limit feeding as follows:

(i) *Sheep:* At a level not to exceed an intake of 0.7 milligram per head per day.

(ii) *Beef cattle:* At a level not to exceed an intake of 3 milligrams per head per day.

(3) In salt-mineral mixtures for free-choice feeding as follows:

(i) *Sheep:* Up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligram per head per day.

(ii) *Beef cattle:* Up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(d) The additive shall be incorporated into feed as follows:

(1) It shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(2) It shall be incorporated into each ton of salt-mineral mixture for sheep or beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

(e) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(f) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: ''Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.''

(g) The additive is orally administered to beef and dairy cattle as an osmotically controlled, constant release bolus containing sodium selenite. Each bolus contains 360 milligrams of selenium as sodium selenite, and delivers 3 milligrams of selenium per day for 120 days. To ensure safe use of the additive:

(1) The osmotically controlled, constant release bolus is for use only in beef and dairy cattle more than 3 months of age or over 200 pounds body weight.

(2) Only one bolus containing 360 milligrams of selenium as sodium selenite is administered orally to each animal in 120 days.

(3) The labeling shall bear the following: ''This bolus delivers the maximum daily allowable amount of selenium and shall be the sole source of supplementation. Do not use in areas containing excess selenium. Do not rebolus within 4 months.''

(h) Selenium yeast is a dried, nonviable yeast (*Saccharomyces cerevisiae*) cultivated in a fed-batch fermentation which provides incremental amounts of

cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2 percent of the total selenium content in the final selenium yeast product.

(1) Selenium, as selenium yeast, is added to feed as follows:

(i) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cattle at a level not to exceed 0.3 part per million.

(ii) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.

(iii) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(2) Guaranteed organic selenium content from selenium yeast must be declared on the selenium yeast product label.

(3) The additive, as selenium yeast, shall be incorporated into feed as follows:

(i) It shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(ii) It shall be incorporated into each ton of salt-mineral mixture for beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

(4) Usage of this additive must conform to the requirements of paragraphs (e) and (f) of this section.

[52 FR 10888, Apr. 6, 1987; 52 FR 21001, June 4, 1987, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989; 60 FR 53703, Oct. 17, 1995; 65 FR 35824, June 6, 2000; 65 FR 53167, Sept. 1, 2000; 67 FR 46851, July 17, 2002; 68 FR 52340, Sept. 3, 2003; 72 FR 39561, July 19, 2007]

EFFECTIVE DATE NOTE: At 58 FR 47973, Sept. 13, 1993, the amendments to § 573.920 that were published at 52 FR 10887, Apr. 6, 1987; 52 FR 21001, June 4, 1987; and 54 FR 14214, Apr. 10, 1989 were stayed until further notice. At 59 FR 45973, Sept. 6, 1994, the stay was confirmed.

§ 573.940 Silicon dioxide.

The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

Feed component	Limitations (percent)
BHT (butylated hydroxytoluene)	2
Methionine hydroxy analog and its calcium salts	1
Piperazine, piperazine salts	0.8
Sodium propionate	1
Urea	1
Vitamins	3

(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

(d) It is used or intended for use in feed components, as a carrier as follows:

Feed component	Limitations (percent)
Flavors	50

(e) To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

[41 FR 38652, Sept. 10, 1976, as amended at 83 FR 8930, Mar. 2, 2018]

§ 573.960 Sorbitan monostearate.

The food additive sorbitan monostearate may be safely used alone or in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal feeds.

§ 573.980 Taurine.

The food additive taurine (2-aminoethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:

(a) It is used as a nutritional supplement in the feed of growing chickens.

(b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.

(c) To assure safe use of the additive, the label and labeling shall bear in addition to the other information required by the Act:

(1) The name of the additive.

(2) The quantity of the additive contained therein.

(3) Adequate directions for use.

§ 573.1000 Verxite.

The food additive verxite may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is a magnesium-aluminum-iron silicate conforming to one of the following:

(1)(i) Verxite granules: The additive contains a minimum of 98 percent of hydrobiotite; it is thermally expanded and has a bulk density of from 5 to 9 pounds per cubic foot.

(ii) It is used or intended for use:

(*a*) In poultry feed at a level not to exceed 5 percent of the weight of the finished feed as a nonnutritive bulking agent for restricting calorie intake in pullet replacement feeds.

(*b*) As an anticaking or blending agent, pelleting aid, or nonnutritive carrier for the incorporation of nutrients in poultry, swine, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5 percent of the dog feed or 5 percent of the final feed for other animals.

(2)(i) Verxite flakes: The additive contains a minimum of 98 percent of hydrobiotite; it has a bulk density of from 20 to 30 pounds per cubic foot.

(ii) It is used or intended for use as an anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed for ruminants.

(3)(i) Verxite grits: The additive contains a minimum of 80 percent of hydrobiotite; it has a bulk density of from 40 to 50 pounds per cubic foot.

(ii) It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed.

(b) To assure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the Act, the name of the additive (verxite granules, verxite flakes, or verxite grits), adequate directions for use, and, when the additive is present in excess of 1 percent, a statement of the quantity of the additive contained therein and the term ''nonnutritive'' in juxtaposition therewith.

§ 573.1010 Xanthan gum.

The food additive xanthan gum may be safely used in animal feed as follows:

(a) The food additive is xanthan gum as defined in § 172.695 of this chapter and meets all of the specifications thereof.

(b) It is used or intended for use as a stabilizer, emulsifier, thickener, suspending agent, or bodying agent in animal feed as follows:

(1) In calf milk replacers at a maximum use level of 0.1 percent, as fed.

(2) In liquid feed supplements for ruminant animals at a maximum use level of 0.25 percent (5 pounds per ton).

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions for use.

[49 FR 44630, Nov. 8, 1984]

§ 573.1020 Yellow prussiate of soda.

Yellow prussiate of soda (sodium ferrocyanide decahydrate: $Na_4Fe(Cn)_6°\text{-}10H_2O$) may be safely used as an anticaking agent in salt for animal consumption at a level not to exceed 13 parts per million. The additive contains a minimum of 99.0 percent by weight of sodium ferrocyanide decahydrate.

[41 FR 38657, Sept. 10, 1976; 41 FR 48100, Nov. 2, 1976]

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

Subpart A—General Provisions

Sec.
579.12 Incorporation of regulations in part 179.

Subpart B—Radiation and Radiation Sources

579.22 Ionizing radiation for treatment of animal diets.
579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371.

Subpart A—General Provisions

§ 579.12 Incorporation of regulations in part 179.

Regulations providing for irradiation in the production, processing, and handling of food in part 179 of this chapter are incorporated in subchapter E as applicable to use in the production, processing, handling, and labeling of animal feed and pet food, except where specifically provided for in this part. Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

[51 FR 5993, Feb. 19, 1986, as amended at 80 FR 56356, Sept. 17, 2015]

Subpart B—Radiation and Radiation Sources

§ 579.22 Ionizing radiation for treatment of animal diets.

Ionizing radiation for treatment of complete diets for animals may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays for sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts.

(b) *Uses.* (1) The ionizing radiation is used or intended for use in single treatment as follows:

Food for irradiation	Limitations	Use
Bagged complete diets, packaged feeds, feed ingredients, bulk feeds, animal treats and chews.	Absorbed dose: Not to exceed 50 kiloGrays. Feeds and feed ingredients treated by irradiation should be formulated to account for nutritional loss.	Microbial disinfection, control or elimination

(2) If an irradiated feed ingredient is less than 5 percent of the final product, the final product can be irradiated without being considered to be re-irradiated.

[51 FR 5993, Feb. 19, 1986; 51 FR 8315, Mar. 11, 1986, as amended at 58 FR 18148, Apr. 8, 1993; 66 FR 18540, Apr. 10, 2001]

§ 579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.

Ionizing radiation for the treatment of complete poultry diets and poultry feed ingredients may be safely used as follows:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of cobalt-60 or cesium-137;

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts (MeV);

(3) X-rays generated from machine sources at energies not to exceed 5 MeV, except as permitted by §179.26(a)(4) of this chapter; or

(4) X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 MeV.

(b) *Limitation.* The ionizing radiation is used for feed or feed ingredients that do not contain drugs.

(c) *Use.* Ionizing radiation is used as a single treatment for rendering complete poultry diets or poultry feed ingredients salmonella negative as follows:

(1) Minimum dose 2.0 kiloGrays (kGy) (0.2 megarad (Mrad)); maximum dose 25 kGy (2.5 megarads Mrad). The absorbed dose of irradiation is to be based on initial concentration of salmonella using

the relationship that 1.0 kGy (0.1 Mrad) reduces salmonella concentration by one log cycle (one decimal reduction).

(2) Feeds treated by irradiation should be formulated to account for nutritional loss.

(3) If an irradiated feed ingredient is less than 5 percent of the final product, the final product can be irradiated without being considered to be re-irradiated.

[60 FR 50099, Sept. 28, 1995, as amended at 78 FR 27304, May 10, 2013; 78 FR 34565, June 10, 2013]

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

582.1 Substances that are generally recognized as safe.
582.10 Spices and other natural seasonings and flavorings.
582.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).
582.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.
582.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
582.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
582.60 Synthetic flavoring substances and adjuvants.
582.80 Trace minerals added to animal feeds.
582.99 Adjuvants for pesticide chemicals.

Subpart B—General Purpose Food Additives

582.1005 Acetic acid.
582.1009 Adipic acid.
582.1033 Citric acid.
582.1057 Hydrochloric acid.
582.1061 Lactic acid.
582.1069 Malic acid.
582.1073 Phosphoric acid.
582.1077 Potassium acid tartrate.
582.1087 Sodium acid pyrophosphate.
582.1091 Succinic acid.
582.1095 Sulfuric acid.
582.1099 Tartaric acid.
582.1125 Aluminum sulfate.
582.1127 Aluminum ammonium sulfate.
582.1129 Aluminum potassium sulfate.
582.1131 Aluminum sodium sulfate.
582.1135 Ammonium bicarbonate.
582.1137 Ammonium carbonate.
582.1139 Ammonium hydroxide.
582.1141 Ammonium phosphate.
582.1143 Ammonium sulfate.
582.1155 Bentonite.
582.1165 Butane.
582.1191 Calcium carbonate.
582.1193 Calcium chloride.
582.1195 Calcium citrate.
582.1199 Calcium gluconate.
582.1205 Calcium hydroxide.
582.1207 Calcium lactate.
582.1210 Calcium oxide.
582.1217 Calcium phosphate.
582.1235 Caramel.
582.1240 Carbon dioxide.
582.1275 Dextrans.
582.1320 Glycerin.
582.1324 Glyceryl monostearate.
582.1355 Helium.
582.1366 Hydrogen peroxide.
582.1400 Lecithin.
582.1425 Magnesium carbonate.
582.1428 Magnesium hydroxide.
582.1431 Magnesium oxide.
582.1480 Methylcellulose.
582.1500 Monoammonium glutamate.
582.1516 Monopotassium glutamate.
582.1540 Nitrogen.
582.1585 Papain.
582.1613 Potassium bicarbonate.
582.1619 Potassium carbonate.
582.1625 Potassium citrate.
582.1631 Potassium hydroxide.
582.1643 Potassium sulfate.
582.1655 Propane.
582.1666 Propylene glycol.
582.1685 Rennet.
582.1711 Silica aerogel.
582.1721 Sodium acetate.
582.1736 Sodium bicarbonate.
582.1742 Sodium carbonate.
582.1745 Sodium carboxymethylcellulose.
582.1748 Sodium caseinate.
582.1751 Sodium citrate.
582.1763 Sodium hydroxide.
582.1775 Sodium pectinate.
582.1778 Sodium phosphate.
582.1781 Sodium aluminum phosphate.
582.1792 Sodium sesquicarbonate.
582.1804 Sodium potassium tartrate.
582.1810 Sodium tripolyphosphate.
582.1901 Triacetin.
582.1973 Beeswax.
582.1975 Bleached beeswax.
582.1978 Carnauba wax.

Subpart C—Anticaking Agents

582.2122 Aluminum calcium silicate.
582.2227 Calcium silicate.
582.2437 Magnesium silicate.
582.2727 Sodium aluminosilicate.
582.2729 Hydrated sodium calcium aluminosilicate.
582.2906 Tricalcium silicate.

Subpart D—Chemical Preservatives

582.3013 Ascorbic acid.

582.3021 Benzoic acid.
582.3041 Erythorbic acid.
582.3081 Propionic acid.
582.3089 Sorbic acid.
582.3109 Thiodipropionic acid.
582.3149 Ascorbyl palmitate.
582.3169 Butylated hydroxyanisole.
582.3173 Butylated hydroxytoluene.
582.3189 Calcium ascorbate.
582.3221 Calcium propionate.
582.3225 Calcium sorbate.
582.3280 Dilauryl thiodipropionate.
582.3336 Gum guaiac.
582.3490 Methylparaben.
582.3616 Potassium bisulfite.
582.3637 Potassium metabisulfite.
582.3640 Potassium sorbate.
582.3660 Propyl gallate.
582.3670 Propylparaben.
582.3731 Sodium ascorbate.
582.3733 Sodium benzoate.
582.3739 Sodium bisulfite.
582.3766 Sodium metabisulfite.
582.3784 Sodium propionate.
582.3795 Sodium sorbate.
582.3798 Sodium sulfite.
582.3845 Stannous chloride.
582.3862 Sulfur dioxide.
582.3890 Tocopherols.

Subpart E—Emulsifying Agents

582.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
582.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
582.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
582.4666 Propylene glycol.

Subpart F—Nutrients and/or Dietary Supplements

582.5013 Ascorbic acid.
582.5017 Aspartic acid.
582.5049 Aminoacetic acid.
582.5065 Linoleic acid.
582.5118 Alanine.
582.5145 Arginine.
582.5159 Biotin.
582.5191 Calcium carbonate.
582.5195 Calcium citrate.
582.5201 Calcium glycerophosphate.
582.5210 Calcium oxide.
582.5212 Calcium pantothenate.
582.5217 Calcium phosphate.
582.5223 Calcium pyrophosphate.
582.5230 Calcium sulfate.
582.5245 Carotene.
582.5250 Choline bitartrate.
582.5252 Choline chloride.
582.5260 Copper gluconate.
582.5271 Cysteine.
582.5273 Cystine.
582.5301 Ferric phosphate.
582.5304 Ferric pyrophosphate.
582.5306 Ferric sodium pyrophosphate.
582.5308 Ferrous gluconate.
582.5311 Ferrous lactate.
582.5315 Ferrous sulfate.
582.5361 Histidine.
582.5370 Inositol.
582.5375 Iron reduced.
582.5381 Isoleucine.
582.5406 Leucine.
582.5411 Lysine.
582.5431 Magnesium oxide.
582.5434 Magnesium phosphate.
582.5443 Magnesium sulfate.
582.5446 Manganese chloride.
582.5449 Manganese citrate.
582.5452 Manganese gluconate.
582.5455 Manganese glycerophosphate.
582.5458 Manganese hypophosphite.
582.5461 Manganese sulfate.
582.5464 Manganous oxide.
582.5470 Mannitol.
582.5475 Methionine.
582.5477 Methionine hydroxy analog and its calcium salts.
582.5530 Niacin.
582.5535 Niacinamide.
582.5580 D-Pantothenyl alcohol.
582.5590 Phenylalanine.
582.5622 Potassium chloride.
582.5628 Potassium glycerophosphate.
582.5634 Potassium iodide.
582.5650 Proline.
582.5676 Pyridoxine hydrochloride.
582.5695 Riboflavin.
582.5697 Riboflavin-5-phosphate.
582.5701 Serine.
582.5772 Sodium pantothenate.
582.5778 Sodium phosphate.
582.5835 Sorbitol.
582.5875 Thiamine hydrochloride.
582.5878 Thiamine mononitrate.
582.5881 Threonine.
582.5890 Tocopherols.
582.5892 α-Tocopherol acetate.
582.5915 Tryptophane.
582.5920 Tyrosine.
582.5925 Valine.
582.5930 Vitamin A.
582.5933 Vitamin A acetate.
582.5936 Vitamin A palmitate.
582.5945 Vitamin B_{12}.
582.5950 Vitamin D_2.
582.5953 Vitamin D_3.
582.5985 Zinc chloride.
582.5988 Zinc gluconate.
582.5991 Zinc oxide.
582.5994 Zinc stearate.
582.5997 Zinc sulfate.

Subpart G—Sequestrants

582.6033 Citric acid.
582.6085 Sodium acid phosphate.
582.6099 Tartaric acid.
582.6185 Calcium acetate.
582.6193 Calcium chloride.

582.6195 Calcium citrate.
582.6197 Calcium diacetate.
582.6199 Calcium gluconate.
582.6203 Calcium hexametaphosphate.
582.6215 Monobasic calcium phosphate.
582.6219 Calcium phytate.
582.6285 Dipotassium phosphate.
582.6290 Disodium phosphate.
582.6386 Isopropyl citrate.
582.6511 Monoisopropyl citrate.
582.6625 Potassium citrate.
582.6751 Sodium citrate.
582.6754 Sodium diacetate.
582.6757 Sodium gluconate.
582.6760 Sodium hexametaphosphate.
582.6769 Sodium metaphosphate.
582.6778 Sodium phosphate.
582.6787 Sodium pyrophosphate.
582.6789 Tetra sodium pyrophosphate.
582.6801 Sodium tartrate.
582.6804 Sodium potassium tartrate.
582.6807 Sodium thiosulfate.
582.6810 Sodium tripolyphosphate.
582.6851 Stearyl citrate.

Subpart H—Stabilizers

582.7115 Agar-agar.
582.7133 Ammonium alginate.
582.7187 Calcium alginate.
582.7255 Chondrus extract.
582.7330 Gum arabic.
582.7333 Gum ghatti.
582.7339 Guar gum.
582.7343 Locust bean gum.
582.7349 Sterculia gum.
582.7351 Gum tragacanth.
582.7610 Potassium alginate.
582.7724 Sodium alginate.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 41 FR 38657, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 582.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. The lists in subparts B through H of this part include additional substances that, when used for the purposes indicated, in accordance with good manufacturing or feeding practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing or feeding practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to animal food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of animal food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for animals.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the Act are listed in subparts B through H of this part. When the status of a substance has been reevaluated and affirmed as GRAS or deleted from subparts B through H of this part, an appropriate explanation will be noted, e.g., ''affirmed as GRAS,'' ''food additive regulation,'' ''interim food additive regulation,'' or ''prohibited from use in food,'' with a reference to the appropriate new regulation. Such notation will apply only to the specific use covered by the review, e.g., direct animal food use and/or indirect animal food use and/or animal feed use and will not affect its status for other uses not specified in the referenced regulation, pending a specific review of such other uses.

§ 582.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Alfalfa herb and seed	*Medicago sativa* L.
Allspice	*Pimenta officinalis* Lindl.
Ambrette seed	*Hibiscus abelmoschus L.*
Angelica	*Angelica archangelica* L. or other spp. of Angelica.
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	*Galipea officinalis* Hancock.
Anise	*Pimpinella anisum* L.
Anise, star	*Illicium verum Hook.* f.
Balm (lemon balm)	*Melissa officinalis* L.
Basil, bush	*Ocimum minimum* L.
Basil, sweet	*Ocimum basilicum L.*
Bay	*Laurus nobilis* L.
Calendula	*Calendula officinalis* L.
Camomile (chamomile), English or Roman	*Anthemis nobilis* L.
Camomile (chamomile), German or Hungarian	*Matricaria chamomilla* L.
Capers	*Capparis spinosa* L.
Capsicum	*Capsicum frutescens* L. or *Capsicum annuum* L.
Caraway	*Carum carvi* L.
Caraway, black (black cumin)	*Nigella sativa* L.
Cardamom (cardamon)	*Elettaria cardamomum* Maton.
Cassia, Chinese	*Cinnamomum cassia* Blume.
Cassia, Padang or Batavia	*Cinnamomum burmanni* Blume.
Cassia, Saigon	*Cinnamomum loureirii* Nees.
Cayenne pepper	*Capsicum frutescens* L. or *Capsicum annuum* L.
Celery seed	*Apium graveolens* L.
Chervil	*Anthriscus cerefolium* (L.) Hoffm.
Chives	*Allium schoenoprasum* L.
Cinnamon, Ceylon	*Cinnamomum zeylanicum* Nees.
Cinnamon, Chinese	*Cinnamomum cassia* Blume.
Cinnamon, Saigon	*Cinnamomum loureirii* Nees.
Clary (clary sage)	*Salvia sclarea L.*
Clover	*Trifolium* spp.
Cloves	*Eugenia caryophyllata* Thunb.
Coriander	*Coriandrum sativum* L.
Cumin (cummin)	*Cuminum cyminum* L.
Cumin, black (black caraway)	*Nigella sativa* L.
Dill	*Anethum graveolens* L.
Elder flowers	*Sambucus canadensis* L.
Fennel, common	*Foeniculum vulgare* Mill.
Fennel, sweet (finocchio, Florence fennel)	*Foeniculum vulgare* Mill. var. duice (DC.) Alex.
Fenugreek	*Trigonella foenum-graecum* L.
Galanga (galangal)	*Alpina officinarum* Hance.
Garlic	*Allium sativum* L.
Geranium	*Pelargonium* spp.
Ginger	*Zingiber officinale* Rosc.
Glycyrrhiza	*Glycyrrhiza glabra* L. and other spp. of *Glycyrrhiza.*
Grains of paradise	*Amomum melegueta* Rosc.
Horehound (hoarhound)	*Marrubium vulgare* L.
Horseradish	*Armoracia lapathifolia* Gilib.
Hyssop	*Hyssopus officinalis* L.
Lavender	*Lavandula officinalis* Chaix.
Licorice	*Glycyrrhiza glabra* L. and other spp. of *Glycyrrhiza.*
Linden flowers	*Tilia* spp.
Mace	*Myristica fragrans* Houtt.
Marigold, pot	*Calendula officinalis* L.
Marjoram, pot	*Majorana onites* (L.) Benth.
Marjoram, sweet	*Majorana hortensis* Moench.
Mustard, black or brown	*Brassica nigra* (L.) Koch.
Mustard, brown	*Brassica juncea* (L.) Coss.
Mustard, white or yellow	*Brassica hirta* Moench.
Nutmeg	*Myristica fragrans* Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan)	*Lippia* spp.
Paprika	*Capsicum annuum* L.
Parsley	*Petroselinum crispum* (Mill.) Mansf.
Pepper, black	*Piper nigrum* L.
Pepper, cayenne	*Capsicum frutescens* L. or *Capsicum annuum* L.
Pepper, red	Do.

Common name	Botanical name of plant source
Pepper, white	*Piper nigrum* L.
Peppermint	*Mentha piperita* L.
Poppy seed	*Papaver somniferum* L.
Pot marigold	*Calendula officinalis* L.
Pot marjoram	*Majorana onites* (L.) Benth.
Rosemary	*Rosmarinus officinalis* L.
Rue	*Ruta graveolens* L.
Saffron	*Crocus sativus* L.
Sage	*Salvia officinalis* L.
Sage, Greek	*Salvia triloba* L.
Savory, summer	*Satureia hortensis* L. (Satureja).
Savory, winter	*Satureia montana* L. (Satureja).
Sesame	*Sesamum indicum* L.
Spearmint	*Mentha spicata* L.
Star anise	*Illicium verum* Hook. f.
Tarragon	*Artemisia dracunculus* L.
Thyme	*Thymus vulgaris* L.
Thyme, wild or creeping	*Thymus serpyllum* L.
Turmeric	*Curcuma longa* L.
Vanilla	*Vanilla planifolia* Andr. or *Vanilla tahitensis* J. W. Moore.
Zedoary	*Curcuma zedoaria* Rosc.

§ 582.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Alfalfa	*Medicago sativa* L.
Allspice	*Pimenta officinalis* Lindl.
Almond, bitter (free from prussic acid)	*Prunus amygdalus* Batsch, *Prunus armeniaca* L. or *Prunus persica* (L.) Batsch.
Ambrette (seed)	*Hibiscus moschatus* Moench.
Angelica root	*Angelica archangelica* L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	*Galipea officinalis* Hancock.
Anise	*Pimpinella anisum* L.
Asafetida	*Ferula assa-foetida* L. and related spp. of Ferula.
Balm (lemon balm)	*Melissa officinalis* L.
Balsam of Peru	*Myroxylon pereirae* Klotzsch.
Basil	*Ocimum basilicum* L.
Bay leaves	*Laurus nobilis* L.
Bay (myrcia oil)	*Pimenta racemosa* (Mill.) J. W. Moore.
Bergamot (bergamot orange)	*Citrus aurantium* L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	*Prunus amygdalus* Batsch, *Prunus armeniaca* L., or *Prunus persica* (L.) Batsch.
Bois de rose	*Aniba rosaeodora* Ducke.
Cacao	*Theobroma cacao* L.
Camomile (chamomile) flowers, Hungarian	*Matricaria chamomilla* L.
Camomile (chamomile) flowers, Roman or English	*Anthemis nobilis* L.
Cananga	*Cananga odorata* Hook. f. and Thoms.
Capsicum	*Capsicum frutescens* L. and *Capsicum annuum* L.
Caraway	*Carum carvi* L.
Cardamom seed (cardamon)	*Elettaria cardamomum* Maton.
Carob bean	*Ceratonia siliqua* L.
Carrot	*Daucus carota* L.
Cascarilla bark	*Croton eluteria* Benn.
Cassia bark, Chinese	*Cinnamomum cassia* Blume.
Cassia bark, Padang or Batavia	*Cinnamomum burmanni* Blume.
Cassia bark, Saigon	*Cinnamomum loureirii* Nees.
Celery seed	*Apium graveolens* L.
Cherry, wild, bark	*Prunus serotina* Ehrh.
Chervil	*Anthriscus cerefolium* (L.) Hoffm.
Chicory	*Cichorium intybus* L.
Cinnamon bark, Ceylon	*Cinnamomum zeylanicum* Nees.
Cinnamon bark, Chinese	*Cinnamomum cassia* Blume.
Cinnamon bark, Saigon	*Cinnamomum loureirii* Nees.

Common name	Botanical name of plant source
Cinnamon leaf, Ceylon	*Cinnamomum zeylanicum* Nees.
Cinnamon leaf, Chinese	*Cinnamomum cassia* Blume.
Cinnamon leaf, Saigon	*Cinnamomum loureirii* Nees.
Citronella	*Cymbopogon nardus* Rendle.
Citrus peels	*Citrus* spp.
Clary (clary sage)	*Salvia sclarea* L.
Clove bud	*Eugenia caryophyllata* Thunb.
Clove leaf	Do.
Clove stem	Do.
Clover	*Trifolium* spp.
Coca (decocainized)	*Erythroxylum coca* Lam. and other spp. of Erythroxylum.
Coffee	*Coffea* spp.
Cola nut	*Cola acuminata* Schott and Endl., and other spp. of Cola.
Coriander	*Coriandrum sativum* L.
Corn silk	*Zea mays* L.
Cumin (cummin)	*Cuminum cyminum* L.
Curacao orange peel (orange, bitter peel)	*Citrus aurantium* L.
Cusparia bark	*Galipea officinalis* Hancock.
Dandelion	*Taraxacum officinale* Weber and *T. laevigatum* DC.
Dandelion root	Do.
Dill	*Anethum graveolens* L.
Dog grass (quackgrass, triticum)	*Agropyron repens* (L.) Beauv.
Elder flowers	*Sambucus canadensis* L. and S. nigra L.
Estragole (esdragol, esdragon, tarragon)	*Artemisia dracunculus* L.
Estragon (tarragon)	Do.
Fennel, sweet	*Foeniculum vulgare* Mill.
Fenugreek	*Trigonella foenum-graecum* L.
Galanga (galangal)	*Alpinia officinarum* Hance.
Garlic	*Allium sativum* L.
Geranium	*Pelargonium* spp.
Geranium, East Indian	*Cymbopogon martini* Stapf.
Geranium, rose	*Pelargonium graveolens* L'Her.
Ginger	*Zingiber officinale* Rosc.
Glycyrrhiza	*Glycyrrhiza glabra* L. and other spp. of Glycyrrhiza.
Glycyrrhizin, ammoniated	Do.
Grapefruit	*Citrus paradisi* Macf.
Guava	*Psidium* spp.
Hickory bark	*Carya* spp.
Horehound (hoarhound)	*Marrubium vulgare* L.
Hops	*Humulus lupulus* L.
Horsemint	*Monarda punctata* L.
Hyssop	*Hyssopus officinalis* L.
Immortelle	*Helichrysum augustifolium* DC.
Jasmine	*Jaminum officinale* L. and other spp. of Jasminum.
Juniper (berries)	*Juniperus communis* L.
Kola nut	*Cola acuminata* Schott and Endl., and other spp. of Cola.
Laurel berries	*Laurus nobilis* L.
Laurel leaves	*Laurus* spp.
Lavender	*Lavandula officinalis* Chaix.
Lavender, spike	*Lavandula latifolia* Vill.
Lavandin	Hybrids between *Lavandula officinalis* Chaix and *Lavandula latifolin* Vill.
Lemon	*Citrus limon* (L.) Burm. f.
Lemon balm (see balm).	
Lemon grass	*Cymbopogon citratus* DC. and *Cymbopogon flexuosus* Stapf.
Lemon peel	*Citrus limon* (L.) Burm. f.
Licorice	*Glycyrrhiza glabra* L. and other spp. of Glycyrrhiza.
Lime	*Citrus aurantifolia* Swingle.
Linden flowers	*Tilia* spp.
Locust bean	*Ceratonia siliqua* L.
Lupulin	*Humulus lupulus* L.
Mace	*Myristica fragrans* Houtt.
Malt (extract)	*Hordeum vulgare* L., or other grains.
Mandarin	*Citrus reticulata* Blanco.
Marjoram, sweet	*Majorana hortensis* Moench.
Mate 1	*Ilex paraguariensis* St. Hil.
Melissa (see balm).	
Menthol	*Mentha* spp.
Menthyl acetate	Do.
Molasses (extract)	*Saccharum officinarum* L.
Mustard	*Brassica* spp.
Naringin	*Citrus paradisi* Macf.
Neroli, bigarade	*Citrus aurantium* L.
Nutmeg	*Myristica fragrans* Houtt.

Common name	Botanical name of plant source
Onion	*Allium cepa* L.
Orange, bitter, flowers	*Citrus aurantium* L.
Orange, bitter, peel	Do.
Orange leaf	*Citrus sinensis* (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	*Origanum* spp.
Palmarosa	*Cymbopogon martini* Stapf.
Paprika	*Capsicum annuum* L.
Parsley	*Petroselinum crispum* (Mill.) Mansf.
Pepper, black	*Piper nigrum* L.
Pepper, white	*Piper nigrum* L.
Peppermint	*Mentha piperita* L.
Peruvian balsam	*Myroxylon pereirae* Klotzsch.
Petitgrain	*Citrus aurantium* L.
Petitgrain lemon	*Citrus limon* (L.) Burm. f.
Petitgrain mandarin or tangerine	*Citrus reticulata* Blanco.
Pimenta	*Pimenta officinalis* Lindl.
Pimenta leaf	*Primenta officinalis* Lindl.
Pipsissewa leaves	*Chimaphila umbellata* Nutt.
Pomegranate	*Punica granatum* L.
Prickly ash bark	*Xanthoxylum* (*or Zanthoxylum*) *Americanum* Mill. or *Xanthoxylum clava-herculis* L.
Rose absolute	*Rosa alba* L., *Rosa centifolia* L., *Rosa damascena* Mill., *Rosa gallica* L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	*Pelargonium graveolens* L'Her.
Rose leaves	*Rosa* spp.
Rosemary	*Rosmarinus officinalis* L.
Rue	*Ruta graveolens* L.
Saffron	*Crocus sativus* L.
Sage	*Salvia officinalis* L.
Sage, Greek	*Salvia triloba* L.
Sage, Spanish	*Salvia lavandulaefolia* Vahl.
St. John's bread	*Ceratonia siliqua* L.
Savory, summer	*Satureia hortensis* L.
Savory, winter	*Satureia montana* L.
Schinus molle	*Schinus molle* L.
Sloe berries (blackthorn berries)	*Prunus spinosa* L.
Spearmint	*Mentha spicata* L.
Spike lavender	*Lavandula latifolia* Vill.
Tamarind	*Tamarindus indica* L.
Tangerine	*Citrus reticulata* Blanco.
Tannic acid	Nutgalls of *Quercus infectoria* Oliver and related spp. of Quercus. Also in many other plants.
Tarragon	*Artemisia dracunculus* L.
Tea	*Thea sinensis* L.
Thyme	*Thymus vulgaris* L. and *Thymus zygis* var. gracilis Boiss.
Thyme, white	Do.
Thyme, wild or creeping	*Thymus serpyllum* L.
Triticum (see dog grass).	
Tuberose	*Polianthes tuberosa* L.
Turmeric	*Curcuma longa* L.
Vanilla	*Vanilla planifolia* Andr. or *Vanilla tahitensis* J. W. Moore.
Violet flowers	*Viola odorata* L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	*Prunus serotina* Ehrh.
Ylang-ylang	*Cananga odorata* Hook. f. and Thoms.
Zedoary bark	*Curcuma zedoaria* Rosc.

§ 582.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.

Natural substances used in conjunction with spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Algae, brown (kelp)	*Laminaria* spp. and *Nereocystis* spp.
Algae, red	*Porphyra* spp. and *Rhodymenia palmata* (L.) Grev.
Dulse	*Rhodymenia palmata* (L.)

§ 582.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Botanical name of plant source
Algae, brown	*Laminaria* spp. and *Nereocystis* spp.
Algae, red	*Porphyra* spp. and *Rhodymenia palmata* (L.) Grev.
Apricot kernel (persic oil)	*Prunus armeniaca* L.
Dulse	*Rhodymenia palmata* (L.) Grev.
Kelp (see algae, brown).	
Peach kernel (persic oil)	*Prunus persica* Sieb. et Zucc.
Peanut stearine	*Arachis hypogaea* L.
Persic oil (see apricot kernel and peach kernel).	
Quince seed	*Cydonia oblonga* Miller.

§ 582.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	Derivation
Ambergris	*Physeter macrocephalus* L.
Castoreum	Castor fiber L. and C. *canadensis* Kuhl.
Civet (zibeth, zibet, zibetum)	Civet cats, *Viverra civetta* Schreber and *Viverra zibetha* Schreber.
Cognac oil, white and green	*Ethyl oenanthate,* so-called.
Musk (Tonquin musk)	Musk deer, *Moschus moschiferus* L.

§ 582.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetaldehyde (ethanal).
Acetoin (acetyl methylcarbinol).
Aconitic acid (equisetic acid, citridic acid, achilleic acid).
Anethole (parapropenyl anisole).
Benzaldehyde (benzoic aldehyde).
N-Butyric acid (butanoic acid).
d- or *l*-Carvone (carvol).
Cinnamaldehyde (cinnamic aldehyde).
Citral (2,6-dimethyloctadien-2,6-*al*-8, geranial, neral).
Decanal (*N*-decylaldhehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde *C*-10).
Diacetyl (2,3-butandeione). Ethyl acetate. Ethyl butyrate.
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).
Ethyl vanillin.
Eugenol.
Geranoil (3,7-dimethyl-2,6 and 3,6-octadien-1-*ol*).
Geranyl acetate (geraniol acetate).

Glycerol (glyceryl) tributyrate (tributyrin, butyrin).
Limonene (*d-*, *l-*, *and dl-*).
Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-*ol*).
Linalyl acetate (bergamol).
l-Malic acid.
Methyl anthranilate (methyl-2-aminobenzoate).
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).
Vanillin.

§ 582.80 Trace minerals added to animal feeds.

These substances added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practice.[1]

Element	Source compounds
Cobalt	Cobalt acetate.
	Cobalt carbonate.
	Cobalt chloride.
	Cobalt oxide.
	Cobalt sulfate.
Copper	Copper carbonate.
	Copper chloride.
	Copper gluconate.
	Copper hydroxide.
	Copper orthophosphate.
	Copper oxide.
	Copper pyrophosphate.
	Copper sulfate.
Iodine	Calcium iodate.
	Calcium iodobehenate.
	Cuprous iodide.
	3,5-Diiodosalicylic acid.
	Ethylenediamine dihydroiodide.
	Potassium iodate.
	Potassium iodide.
	Sodium iodate.
	Sodium iodide.
	Thymol iodide.
Iron	Iron ammonium citrate.
	Iron carbonate.
	Iron chloride.
	Iron gluconate.
	Iron oxide.
	Iron phosphate.
	Iron pyrophosphate.
	Iron sulfate.
	Reduced iron.
Manganese	Manganese acetate.
	Manganese carbonate.
	Manganese citrate (soluble).
	Manganese chloride.
	Manganese gluconate.
	Manganese orthophosphate.
	Manganese phosphate (dibasic).
	Manganese sulfate.
	Manganous oxide.
Zinc	Zinc acetate.
	Zinc carbonate.
	Zinc chloride.
	Zinc oxide.
	Zinc sulfate.

[1] All substances listed may be in anhydrous or hydrated form.

§ 582.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.1001(c) and (d), which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the act.

Subpart B—General Purpose Food Additives

§ 582.1005 Acetic acid.

(a) *Product.* Acetic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1009 Adipic acid.

(a) *Product.* Adipic acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing or feeding practice.

§ 582.1033 Citric acid.

(a) *Product.* Citric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1057 Hydrochloric acid.

(a) *Product.* Hydrochloric acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing or feeding practice.

§ 582.1061 Lactic acid.

(a) *Product.* Lactic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1069 Malic acid.

(a) *Product.* Malic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1073 Phosphoric acid.

(a) *Product.* Phosphoric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1077 Potassium acid tartrate.

(a) *Product.* Potassium acid tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1087 Sodium acid pyrophosphate.

(a) *Product.* Sodium acid pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1091 Succinic acid.

(a) *Product.* Succinic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1095 Sulfuric acid.

(a) *Product.* Sulfuric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1099 Tartaric acid.

(a) *Product.* Tartaric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1125 Aluminum sulfate.

(a) *Product.* Aluminum sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1127 Aluminum ammonium sulfate.

(a) *Product.* Aluminum ammonium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1129 Aluminum potassium sulfate.

(a) *Product.* Aluminum potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1131 Aluminum sodium sulfate.

(a) *Product.* Aluminum sodium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1135 Ammonium bicarbonate.

(a) *Product.* Ammonium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1137 Ammonium carbonate.

(a) *Product.* Ammonium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1139 Ammonium hydroxide.

(a) *Product.* Ammonium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1141 Ammonium phosphate.

(a) *Product.* Ammonium phosphate (mono- and dibasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1143 Ammonium sulfate.

(a) *Product.* Ammonium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1155 Bentonite.

(a) *Product.* Bentonite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1165 Butane.

(a) *Product.* Butane.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1193 Calcium chloride.

(a) *Product.* Calcium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1199 Calcium gluconate.

(a) *Product.* Calcium gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1205 Calcium hydroxide.

(a) *Product.* Calcium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1207 Calcium lactate.

(a) *Product.* Calcium lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1235 Caramel.

(a) *Product.* Caramel.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1240 Carbon dioxide.

(a) *Product.* Carbon dioxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1275 Dextrans.

(a) *Product.* Dextrans of average molecular weight below 100,000.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1320 Glycerin.

(a) *Product.* Glycerin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1324 Glyceryl monostearate.

(a) *Product.* Glyceryl monostearate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1355 Helium.

(a) *Product.* Helium.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1366 Hydrogen peroxide.

(a) *Product.* Hydrogen peroxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a bleaching agent in accordance with good manufacturing or feeding practice.

§ 582.1400 Lecithin.

(a) *Product.* Lecithin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1425 Magnesium carbonate.

(a) *Product.* Magnesium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1428 Magnesium hydroxide.

(a) *Product.* Magnesium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1480 Methylcellulose.

(a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1500 Monoammonium glutamate.

(a) *Product.* Monoammonium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1516 Monopotassium glutamate.

(a) *Product.* Monopotassium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1540 Nitrogen.

(a) *Product.* Nitrogen.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1585 Papain.

(a) *Product.* Papain.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1613 Potassium bicarbonate.

(a) *Product.* Potassium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1619 Potassium carbonate.

(a) *Product.* Potassium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1631 Potassium hydroxide.

(a) *Product.* Potassium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1643 Potassium sulfate.

(a) *Product.* Potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1655 Propane.

(a) *Product.* Propane.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe (except in cat food) when used in accordance with good manufacturing or feeding practice.

[41 FR 38657, Sept. 10, 1976, as amended at 61 FR 19544, May 2, 1996]

§ 582.1685 Rennet.

(a) *Product.* Rennet (rennin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of antifoaming agents in accordance with good manufacturing or feeding practice.

§ 582.1721 Sodium acetate.

(a) *Product.* Sodium acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1736 Sodium bicarbonate.

(a) *Product.* Sodium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1742 Sodium carbonate.

(a) *Product.* Sodium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25 °C.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1763 Sodium hydroxide.

(a) *Product.* Sodium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1775 Sodium pectinate.

(a) *Product.* Sodium pectinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1792 Sodium sesquicarbonate.

(a) *Product.* Sodium sesquicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when

used in accordance with good manufacturing or feeding practice.

§ 582.1804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1901 Triacetin.

(a) *Product.* Triacetin (glyceryl triacetate).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1973 Beeswax.

(a) *Product.* Beeswax (yellow wax).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1975 Bleached beeswax.

(a) *Product.* Bleached beeswax (white wax).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1978 Carnauba wax.

(a) *Product.* Carnauba wax.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart C—Anticaking Agents

§ 582.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

§ 582.2227 Calcium silicate.

(a) *Product.* Calcium silicate.

(b) *Tolerance.* 2 percent and 5 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing or feeding practice.

§ 582.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

§ 582.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing or feeding practice.

§ 582.2729 Hydrated sodium calcium aluminosilicate.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing or feeding practice.

§ 582.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

Subpart D—Chemical Preservatives

§ 582.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3021 Benzoic acid.

(a) *Product.* Benzoic acid.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3041 Erythorbic acid.

(a) *Product.* Erythorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3081 Propionic acid.

(a) *Product.* Propionic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3089 Sorbic acid.

(a) *Product.* Sorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3109 Thiodipropionic acid.

(a) *Product.* Thiodipropionic acid.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3149 Ascorbyl palmitate.

(a) *Product.* Ascorbyl palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3169 Butylated hydroxyanisole.

(a) *Product.* Butylated hydroxyanisole.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3173 Butylated hydroxytoluene.

(a) *Product.* Butylated hydroxytoluene.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3189 Calcium ascorbate.

(a) *Product.* Calcium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3221 Calcium propionate.

(a) *Product.* Calcium propionate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3225 Calcium sorbate.

(a) *Product.* Calcium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3280 Dilauryl thiodipropionate.

(a) *Product.* Dilauryl thiodipropionate.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3336 Gum guaiac.

(a) *Product.* Gum guaiac.

(b) *Tolerance.* 0.1 percent (equivalent antioxidant activity 0.01 percent).

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in edible fats

or oils in accordance with good manufacturing or feeding practice.

§ 582.3490 Methylparaben.

(a) *Product.* Methylparaben (methyl *p*-hydroxybenzoate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3616 Potassium bisulfite.

(a) *Product.* Potassium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3637 Potassium metabisulfite.

(a) *Product.* Potassium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3640 Potassium sorbate.

(a) *Product.* Potassium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3660 Propyl gallate.

(a) *Product.* Propyl gallate.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing or feeding practice.

§ 582.3670 Propylparaben.

(a) *Product.* Propylparaben (propyl *p*-hydroxybenzoate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3731 Sodium ascorbate.

(a) *Product.* Sodium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3733 Sodium benzoate.

(a) *Product.* Sodium benzoate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.1 percent in accordance with good manufacturing or feeding practice.

§ 582.3739 Sodium bisulfite.

(a) *Product.* Sodium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3766 Sodium metabisulfite.

(a) *Product.* Sodium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3784 Sodium propionate.

(a) *Product.* Sodium propionate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3795 Sodium sorbate.

(a) *Product.* Sodium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.3798 Sodium sulfite.

(a) *Product.* Sodium sulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3845 Stannous chloride.

(a) *Product.* Stannous chloride.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.0015 percent calculated as tin in accordance with good manufacturing or feeding practice.

§ 582.3862 Sulfur dioxide.

(a) *Product.* Sulfur dioxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 582.3890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart E—Emulsifying Agents

§ 582.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(a) *Product.* Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.4666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart F—Nutrients and/or Dietary Supplements [1]

§ 582.5013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5017 Aspartic acid.

(a) *Product.* Aspartic acid (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5049 Aminoacetic acid.

(a) *Product.* Glycine (aminoacetic acid).

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5065 Linoleic acid.

(a) *Product.* Linoleic acid prepared from edible fats and oils and free from chick-edema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when

[1] Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

used in accordance with good manufacturing or feeding practice.

§ 582.5118 Alanine.

(a) *Product.* Alanine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5145 Arginine.

(a) *Product.* Arginine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5159 Biotin.

(a) *Product.* Biotin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5212 Calcium pantothenate.

(a) *Product.* Calcium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5230 Calcium sulfate.

(a) *Product.* Calcium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5260 Copper gluconate.

(a) *Product.* Copper gluconate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.005 percent in accordance with good manufacturing or feeding practice.

§ 582.5271 Cysteine.

(a) *Product.* Cysteine (L-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5273 Cystine.

(a) *Product.* Cystine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5361 Histidine.

(a) *Product.* Histidine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5370 Inositol.

(a) *Product.* Inositol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5381 Isoleucine.

(a) *Product.* Isoleucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5406 Leucine.

(a) *Product.* Leucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5411 Lysine.

(a) *Product.* Lysine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5434 Magnesium phosphate.

(a) *Product.* Magnesium phosphate (di- and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when

used in accordance with good manufacturing or feeding practice.

§ 582.5443 Magnesium sulfate.

(a) *Product.* Magnesium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5446 Manganese chloride.

(a) *Product.* Manganese chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5449 Manganese citrate.

(a) *Product.* Manganese citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5452 Manganese gluconate.

(a) *Product.* Manganese gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5458 Manganese hypophosphite.

(a) *Product.* Manganese hypophosphite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5461 Manganese sulfate.

(a) *Product.* Manganese sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5464 Manganous oxide.

(a) *Product.* Manganous oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5470 Mannitol.

(a) *Product.* Mannitol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5475 Methionine.

(a) *Product.* Methionine.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5477 Methionine hydroxy analog and its calcium salts.

(a) *Product.* Methionine hydroxy analog and its calcium salts.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

§ 582.5530 Niacin.

(a) *Product.* Niacin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5535 Niacinamide.

(a) *Product.* Niacinamide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5580 D-Pantothenyl alcohol.

(a) *Product.* D-Pantothenyl alcohol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5590 Phenylalanine.

(a) *Product.* Phenylalanine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5622 Potassium chloride.

(a) *Product.* Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5634 Potassium iodide.

(a) *Product.* Potassium iodide.

(b) *Tolerance.* 0.01 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing or feeding practice.

§ 582.5650 Proline.

(a) *Product.* Proline (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5676 Pyridoxine hydrochloride.

(a) *Product.* Pyridoxine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5695 Riboflavin.

(a) *Product.* Riboflavin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5697 Riboflavin-5-phosphate.

(a) *Product.* Riboflavin-5-phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5701 Serine.

(a) *Product.* Serine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5772 Sodium pantothenate.

(a) *Product.* Sodium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5835 Sorbitol.

(a) *Product.* Sorbitol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5875 Thiamine hydrochloride.

(a) *Product.* Thiamine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5878 Thiamine mononitrate.

(a) *Product.* Thiamine mononitrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5881 Threonine.

(a) *Product.* Threonine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5892 *α*-Tocopherol acetate.

(a) *Product.* *α*-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5915 Tryptophane.

(a) *Product.* Tryptophane (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5920 Tyrosine.

(a) *Product.* Tyrosine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5925 Valine.

(a) *Product.* Valine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5930 Vitamin A.

(a) *Product.* Vitamin A.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5933 Vitamin A acetate.

(a) *Product.* Vitamin A acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5936 Vitamin A palmitate.

(a) *Product.* Vitamin A palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5945 Vitamin B_{12}.

(a) *Product.* Vitamin B_{12}.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5950 Vitamin D_2.

(a) *Product.* Vitamin D_2.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5953 Vitamin D_3.

(a) *Product.* Vitamin D_3.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chick-edema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart G—Sequestrants[2]

§ 582.6033 Citric acid.

(a) *Product.* Citric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6085 Sodium acid phosphate.

(a) *Product.* Sodium acid phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6099 Tartaric acid.

(a) *Product.* Tartaric acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6185 Calcium acetate.

(a) *Product.* Calcium acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6193 Calcium chloride.

(a) *Product.* Calcium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6197 Calcium diacetate.

(a) *Product.* Calcium diacetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6199 Calcium gluconate.

(a) *Product.* Calcium gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6203 Calcium hexametaphosphate.

(a) *Product.* Calcium hexametaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6215 Monobasic calcium phosphate.

(a) *Product.* Monobasic calcium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6219 Calcium phytate.

(a) *Product.* Calcium phytate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6285 Dipotassium phosphate.

(a) *Product.* Dipotassium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6290 Disodium phosphate.

(a) *Product.* Disodium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6386 Isopropyl citrate.

(a) *Product.* Isopropyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.02 percent in accordance with good manufacturing or feeding practice.

§ 582.6511 Monoisopropyl citrate.

(a) *Product.* Monoisopropyl citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

[2] For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 582.6625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

[41 FR 38657, Sept. 10, 1976. Redesignated at 42 FR 14091, Mar. 15, 1977]

§ 582.6751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

[41 FR 38657, Sept. 10, 1976. Redesignated at 42 FR 14091, Mar. 15, 1977]

§ 582.6754 Sodium diacetate.

(a) *Product.* Sodium diacetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6757 Sodium gluconate.

(a) *Product.* Sodium gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6760 Sodium hexametaphosphate.

(a) *Product.* Sodium hexametaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6769 Sodium metaphosphate.

(a) *Product.* Sodium metaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6787 Sodium pyrophosphate.

(a) *Product.* Sodium pyrophosphate.

(b) *Condition of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6789 Tetra sodium pyrophosphate.

(a) *Product.* Tetra sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6801 Sodium tartrate.

(a) *Product.* Sodium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6807 Sodium thiosulfate.

(a) *Product.* Sodium thiosulfate.

(b) *Tolerance.* 0.1 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in salt in accordance with good manufacturing or feeding practice.

§ 582.6810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.6851 Stearyl citrate.

(a) *Product.* Stearyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.15 percent in accordance with good manufacturing or feeding practice.

Subpart H—Stabilizers

§ 582.7115 Agar-agar.

(a) *Product.* Agar-agar.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7133 Ammonium alginate.

(a) *Product.* Ammonium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7187 Calcium alginate.

(a) *Product.* Calcium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7255 Chondrus extract.

(a) *Product.* Chondrus extract (carrageenin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7330 Gum arabic.

(a) *Product.* Acacia (gum arabic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7333 Gum ghatti.

(a) *Product.* Gum ghatti.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7339 Guar gum.

(a) *Product.* Guar gum.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7343 Locust bean gum.

(a) *Product.* Locust (carob) bean gum.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7349 Sterculia gum.

(a) *Product.* Sterculia gum (karaya gum).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7351 Gum tragacanth.

(a) *Product.* Tragacanth (gum tragacanth).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7610 Potassium alginate.

(a) *Product.* Potassium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7724 Sodium alginate.

(a) *Product.* Sodium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

PART 584—FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE IN FEED AND DRINKING WATER OF ANIMALS

Subpart A [Reserved]

Subpart B—Listing of Specific Substances Affirmed as GRAS

Sec.
584.200 Ethyl alcohol containing ethyl acetate.
584.700 Hydrophobic silicas.
584.725 25–Hydroxyvitamin D_3.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

Subpart A [Reserved]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 584.200 Ethyl alcohol containing ethyl acetate.

The feed additive ethyl alcohol containing ethyl acetate meets the requirement of 27 CFR 21.62, being not less than 92.5 percent ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100 percent ethyl acetate. It is used in accordance

with good feeding practices in ruminant feed supplements as a source of added energy.

[46 FR 52333, Oct. 27, 1981, as amended at 72 FR 41620, July 31, 2007]

§ 584.700 Hydrophobic silicas.

(a) *Product.* Amorphous fumed hydrophobic silica or precipitated hydrophobic silica (CAS Reg. No. 68611–0944–099, silane, dichlorodimethyl-, reaction products with silica).

(b) *Conditions of use.* An anticaking/free-flow agent in vitamin preparations for animal feed.

(c) *Limitations.* Not to exceed 5 percent in the vitamin preparation. It shall be used in accordance with good manufacturing or feeding practices. It must be of purity suitable for intended use, and it must comply with the following specifications:

(i) Amorphous fumed hydrophobic silica: Not less than 99.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 2.5 percent loss on drying. Not more than 2 percent loss on ignition after drying. Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

(ii) Precipated hydrophobic silica: Not less than 94.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 7 percent loss on drying. Not more than 8.5 percent loss on ignition after drying. Not more than 5 percent soluble ionizable salts (as sodium sulfate). Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

[61 FR 43453, Aug. 23, 1996]

§ 584.725 25–Hydroxyvitamin D_3.

(a) *Product.* 25–Hydroxyvitamin D_3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(b) *Conditions of use.* This substance is generally recognized as safe as a source of vitamin D_3 activity in feed or drinking water of broiler chickens when used in accordance with the limitations in paragraph (c) of this section.

(c) *Limitations.* (1) Not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water. It shall be used in accordance with good manufacturing and feeding practices.

(2) The product must comply with the following specifications:

(i) Not less than 94.0 percent 25-hydroxyvitamin D_3.

(ii) Not more than 1 percent of any individual sterol.

(iii) Not more than 5 percent water.

(iv) Not more than 20 parts per million (ppm) lead.

(v) Not more than 20 ppm aluminum.

(vi) Not more than 1.0 percent solvents and non-detectable levels of 2′. 4′. 5′. 7′-tetraiodofluorescin.

(3) Product labeling shall bear the following:

(i) A statement to indicate that the maximum use level of 25-hydroxyvitamin D_3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water.

(ii) Adequate use directions to ensure that 25-hydroxyvitamin D_3 (and all premixes) is uniformly blended throughout the feed or drinking water.

(iii) An expiration date on all premix labeling.

(iv) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D_3 should not be used simultaneously in both feed and water.

[72 FR 12564, Mar. 16, 2007]

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Subpart A—General Provisions

Sec.

589.1 Substances prohibited from use in animal food or feed.

Subpart B—Listing of Specific Substances Prohibited From Use in Animal Food or Feed

589.1000 Gentian violet.
589.1001 Propylene glycol in or on cat food.
589.2000 Animal proteins prohibited in ruminant feed.
589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371.

Subpart A—General Provisions

§ 589.1 Substances prohibited from use in animal food or feed.

(a) The substances listed in this part have been prohibited from use in animal food or feed by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in such food or feed. Use of any of these substances in violation of this part causes the animal food or feed involved to be adulterated and in violation of the Act.

(b) This part includes only a partial list of substances prohibited from use in animal food or feed; it is for easy reference purposes and is not a complete list of substances that may not lawfully be used in such animal food or feed. No substance may be used in animal food or feed unless it meets all applicable requirements of the Act.

(c) The Food and Drug Administration either on its own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this part on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, shall be the form set forth in §571.1 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable ground.

[45 FR 28319, Apr. 29, 1980]

Subpart B—Listing of Specific Substances Prohibited From Use in Animal Food or Feed

§ 589.1000 Gentian violet.

The Food and Drug Administration has determined that gentian violet has not been shown by adequate scientific data to be safe for use in animal feed. Use of gentian violet in animal feed causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under §570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act, or an index listing under section 572 of the act, or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter or §516.125 of this chapter.

[72 FR 69131, Dec. 6, 2007]

§ 589.1001 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under §570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

[61 FR 19544, May 2, 1996]

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) *Definitions*—(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in §589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

(2) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) *Blender* means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) *Feed manufacturer* includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) *Nonmammalian protein* includes proteins from nonmammalian animals.

(6) *Distributor* includes persons who distribute or transport feeds or feed ingredients intended for animals.

(7) *Ruminant* includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) *Food additive status.* The Food and Drug Administration has determined that protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter.

(c) *Requirements for renderers that are not included in paragraph (e) of this section.* (1) Renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following measures to ensure that materials identified in paragraph (b) of this section are not used in the feed of ruminants:

(i) Label the materials as follows: ''Do not feed to cattle or other ruminants''; and

(ii) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by the Food and Drug Administration.

(2) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section if they:

(i) Use exclusively a manufacturing method that has been validated by the Food and Drug Administration to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) and whose design has been made available to the public;

(ii) Use routinely a test method that has been validated by the Food and Drug Administration to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Renderers whose products test positive for agents that cause TSE's must comply with paragraphs (c)(1)(i) and (c)(1)(ii) of this section. Records of the test results shall be made available for inspection by the Food and Drug Administration; or

(iii) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by the Food and Drug Administration.

(3) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraph (c)(1)(ii) of this section if they use a permanent method, approved by FDA, to make a mark indicating that the product contains or may contain protein derived from mammalian tissue. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the Food and Drug Administration and

whose design has been made available to the public.

(4) Renderers shall comply with all applicable requirements under § 589.2001.

(d) *Requirements for protein blenders, feed manufacturers, and distributors that are not included in paragraph (e) of this section.* (1) Protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with paragraph (c)(1) of this section.

(2) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraphs (d)(1) of this section if they:

(i) Purchase animal products from renderers that certified compliance with paragraph (c)(2) of this section or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(2) of this section; or

(ii) Comply with the requirements of paragraph (c)(2) of this section where appropriate.

(3) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraph (c)(1)(ii) of this section if they:

(i) Purchase animal protein products that are marked in accordance with paragraph (c)(3) of this section or purchase such materials from renderers that certified compliance with paragraph (c)(3) of this section, or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(3) of this section; or

(ii) Comply with the requirements of paragraph (c)(3) of this section where appropriate.

(4) Pet food products that are sold or are intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feeds for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.

(5) Copies of certifications as described in paragraphs (d)(2) and (d)(3) of this section, shall be made available for inspection and copying by the Food and Drug Administration.

(e) *Requirements for persons that intend to separate mammalian and nonmammalian materials.* (1) Renderers, protein blenders, feed manufacturers, distributors, and others that manufacture, process, blend and distribute both products that contain or may contain protein derived from mammalian tissues or feeds containing such products, and protein products from other animal tissues or feeds containing such products, and that intend to keep those products separate shall:

(i) Comply with paragraphs (c)(1) or (d)(1) of this section as appropriate except that the labeling requirement shall apply only to products that contain or may contain protein derived from mammalian tissues or feeds containing such products;

(ii) In the case of a renderer, obtain nonmammalian or pure porcine or pure equine materials only from single-species slaughter facilities;

(iii) Provide for measures to avoid commingling or cross-contamination;

(A) Maintain separate equipment or facilities for the manufacture, processing, or blending of such materials; or

(B) Use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants; and

(iv) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment.

(2) Renderers, blenders, feed manufacturers, and distributors will be exempted from applicable requirements of paragraph (e)(1) of this section, if they meet the criteria for exemption under paragraphs (c)(2) or (c)(3) of this section, and (d)(2) or (d)(3) of this section.

(3) Renderers shall comply with all applicable requirements under § 589.2001.

(f) *Requirements for establishments and individuals that are responsible for feeding ruminant animals.* Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration.

(g) *Adulteration and misbranding.* (1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs (c) through (f) of this section, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the act.

(2) Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of this section will be deemed misbranded under section 403(a)(1) or 403(f) of the act.

(h) *Inspection; records retention.* (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of 1 year.

(2) Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

[62 FR 30976, June 5, 1997, as amended at 73 FR 22756, Apr. 25, 2008]

EFFECTIVE DATE NOTE: At 62 FR 30976, June 5, 1997, § 589.2000 was added. Paragraph (e)(1)(iv) of this section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.

(a) *Purpose*—The purpose of this section is to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of bovine spongiform encephalopathy (BSE) within the United States.

(b) *Definitions*—(1) *Cattle materials prohibited in animal feed* include:

(i) The entire carcass of BSE-positive cattle;

(ii) The brains and spinal cords of cattle 30 months of age and older;

(iii) The entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed;

(iv) Mechanically separated beef as defined in paragraph (b)(3) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section; and

(v) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section.

(vi) Cattle materials prohibited in animal feed do not include:

(A) Tallow derivatives as defined in paragraph (b)(6) of this section;

(B) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section and that contains no more than 0.15 percent insoluble impurities. Insoluble impurities must be measured by the method entitled ''Insoluble Impurities'' (AOCS Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from the AOCS (*http://www.aocs.org*), 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(C) Materials as defined in paragraphs (b)(1)(ii), (b)(1)(iii), (b)(1)(iv) (other than mechanically separated beef from the carcass of a BSE-positive cattle), and (b)(1)(v) of this section from cattle from a country that has been designated under paragraph (f) of this section.

(2) *Cattle not inspected and passed for human consumption* means cattle that did not pass antemortem inspection by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Nonambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(3) *Mechanically separated beef* means a finely comminuted meat food product, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined in this paragraph) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues.

(6) *Tallow derivative* means any product obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

(c) *Requirements.* (1) No animal feed or feed ingredient shall be manufactured from, processed with, or otherwise contain, cattle materials prohibited in animal feed as defined in paragraph (b)(1) of this section.

(2) Renderers that receive, manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (b)(1) of this section, or products that contain or may contain cattle materials prohibited in animal feed, shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Exclude from use in animal feed the entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section if:

(A) The brain and spinal cord are not effectively removed from such cattle or the brain and spinal cord from such cattle are not otherwise effectively excluded from animal feed; and

(B) Such cattle are 30 months of age or older.

(ii) If renderers remove brain and spinal cord from cattle not inspected and passed for human consumption, or separate such animals based on whether or not they are 30 months of age or older, renderers must maintain adequate written procedures specifying how these processes are carried out.

(iii) Once cattle materials prohibited in animal feed have been separated from other cattle materials, provide for measures to avoid cross-contamination;

(A) Use separate equipment while handling cattle materials prohibited in animal feed; or

(B) Use separate containers that adequately prevent contact with animal feed, animal feed ingredients, or equipment surfaces;

(iv) Label the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed in a conspicuous manner as follows: ''Do not feed to animals'';

(v) Mark the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed with an agent that can be readily detected on visual inspection; and

(vi) Establish and maintain records sufficient to track cattle materials

prohibited in animal feed to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by the Food and Drug Administration.

(3) Renderers that receive, manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not used in animal feed:

(i) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed and make copies of all records available for inspection and copying by the Food and Drug Administration. With respect to cattle materials obtained from establishments which have segregated cattle materials prohibited in animal feed, such records must demonstrate that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude cattle materials prohibited in animal feed; and these records shall be considered sufficient to meet this requirement if they include either:

(A) Certification or other documentation from the supplier that material supplied to the renderer does not include cattle materials prohibited in animal feed; such certification or documentation is acceptable, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation; or

(B) Documentation of another method acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded cattle materials prohibited in animal feed.

(ii) Comply with all applicable requirements under §589.2000 regarding animal proteins prohibited in ruminant feed.

(d) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (c)(2)(i) through (c)(2)(iii), (c)(2)(v) and (c)(2)(vi), or (c)(3)(i) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) Animal feed or feed ingredients that are not in compliance with paragraph (c)(1) of this section are adulterated under section 402(a)(2), 402(a)(3), or 402(a)(5) of the act.

(3) Animal feed or feed ingredients that are not in compliance with the labeling requirements of paragraph (c)(2)(iv) of this section are misbranded under section 403(a)(1) or 403(f) of the act.

(4) Failure of a renderer to comply with the requirements in paragraph (e) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(e) *Inspection; records retention.* Records required to be made available for inspection and copying by the Food and Drug Administration, as required by this section, shall be kept for a minimum of 1 year.

(f) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Veterinary Medicine, at the address designated in §5.1100 of this chapter. The request shall include information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in paragraph (b)(1) of this section. FDA shall respond in writing to any such request and may impose conditions in granting any such request. Any grant by FDA of such a request under this paragraph will be subject to future review by FDA and may be revoked if FDA determines that the granted request is no longer appropriate.

[73 FR 22756, Apr. 25, 2008, as amended at 81 FR 5596, Feb. 3, 2016]

PARTS 590–599 [RESERVED]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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List of CFR Sections Affected

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For changes to this volume of the CFR prior to this listing, consult the annual edition of the monthly List of CFR Sections Affected (LSA). The LSA is available at *www.fdsys.gov*. For changes to this volume of the CFR prior to 2001, see the ''List of CFR Sections Affected, 1949–1963, 1964–1972, 1973–1985, and 1986–2000'' published in 11 separate volumes. The ''List of CFR Sections Affected 1986–2000'' is available at *www.fdsys.gov*.

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558.95 (d)(5)(iii) through (x) redesignated as (d)(5)(iv) through (xi); new (d)(5)(iii) added 10965
(d)(5) revised 10982
(a)(2), (d)(2)(i), (ii), (3)(i) and (ii) amended 19815
558.105 Removed 74021
558.120 Removed 10982
558.128 (e)(7) revised 10982
(b)(1), (e)(1) through (5) tables, (6)(iv) and (5) amended 13544
558.140 (a) amended; (c)(3) revised 13544
Revised 37622
558.145 (a)(1) and (2) amended 13544
(a)(2) amended 37623
558.155 (a)(1) and (2) amended 13545
Removed 15541
558.175 (d)(9) redesignated as (d)(11); (d)(5) through (8) redesignated as (d)(6) through (9); new (d)(5) and (10) added 10965
(d)(3) and (8) removed; (d)(4) through (7) redesignated as (d)(3) through (6); (d)(9), (10) and (11) redesignated as (d)(7), (8) and (9) 10982
(d) table and (6) amended 13545
558.195 (e)(1)(iv) and (v) removed; (e)(1)(vi) through (ix) redesignated as (e)(1)(iv) through (vii) 10982
(b), (e)(1) table, (2) table and (3) table amended 13545
(e)(1)(vii) correctly removed 17860
558.198 (d)(1)(iii), (iv) and (vi) removed; (d)(1)(v), (vii) and (viii) redesignated as (d)(1)(iii), (iv) and (v) 10982
(d)(1) table and (2) table amended 13545
558.248 (d)(3) removed; heading revised 10982
558.258 (e)(2)(ii) through (vii) tables amended 13545
558.261 (e)(2)(ii) and (iii) amended 18159

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558.265 (d)(1)(v), (viii) and (3)(ii) removed 10982
558.274 Revised 10982
(a) introductory text, (c)(1)(i) and (2)(i) amended; (a)(2) and (3) removed; (a)(4) redesignated as new (a)(2) 19815
558.305 (b) and (e) table amended 13545
558.311 (e)(1)(ii) and (xv) amended; (e)(5) revised 10983
(b)(1) through (4), (6), (7), (e)(1) table, (2)(v), (3)(v) and (4)(v) amended 13545
558.325 (d)(3) revised 10983
(a)(1), (c)(3)(i), (d)(1) table and (2) table amended 13545
(a) through (d) redesignated as (b) through (e); new (a) added; new (b) revised; new (e)(2) amended 19815
558.340 Heading revised 10983
(a) amended 13545
558.342 (b)(1) and (e)(1) table amended 13545
558.348 (a) amended 13545
558.355 (f)(1)(ii), (vii), (x), (xi), (xii), (xv), (xvi), (xvii), (xviii), (xix), (xx), (xxiii), (xxvi), (xxvii), second (4)(iv), (vi) and (vii) removed 10983
(b)(8), (9), (11), (f)(1)(iii)(*b*), (iv)(*b*), (v)(*b*), (vii)(*b*), (xiv)(*b*), (xxv)(*b*), (xxix)(*b*), (xxx)(*b*), (2)(ii)(*b*), (iii)(*b*), (4)(ii)(*b*), (iii)(*b*), (iv)(*b*) and (v)(*b*) amended; (f)(1)(i)(*b*) revised 13545
(b)(3) correctly removed 17860
(f)(1)(xxxi) added 74021
558.363 (a)(2), (5), (6), (d)(1)(ii), (v), (vii), (viii), (ix), (3)(iii) and (iv) removed; (d)(1)(iii) and (iv) redesignated as (d)(1)(ii) and (iii); (d)(1)(vi) redesignated as (d)(1)(iv); (d)(1)(x) and (xi) redesignated as (d)(1)(v) and (vi) 10983
(a)(6), (7), (d)(1)(vi)(B) and (x)(B) amended 13545
558.364 (a) and (d) table amended 13545
558.366 (d) table amended 10983, 13545
558.369 (a) amended 13545
558.415 (a) revised; (b) and (c) redesignated as (c) and (d); new (b) added 13545

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558.430 (a) revised; (b) and (c) redesignated as (c) and (d); new (b) added 13545
558.460 (d)(2) removed 10983
(b), (d)(1)(i) table, (ii) and (iii) amended 13545
558.464 (a)(1) and (2) amended 13545
558.485 (b)(7) and (e)(1)(xii)(C) amended 13546
(b)(3) and (6) removed 19815
558.500 (e)(2)(viii) and (x) amended 13546
(e)(1)(ii), (iii), (iv), (2)(viii), (ix), (x) and (xiii) amended 37621
(e)(2)(viii) table and (x) table amended 44278
(e)(2)(ii), (iv), (vii), (ix), (x), (xii) and (xiii) revised 53136
558.515 (d) amended 10983
(a) and (d) table amended 13546
558.530 Removed 10983
558.550 (d)(1)(ii), (iv), (v), (viii), (ix), (xii), (xiv), (xv), (xvii), (xviii), (xix), (xxiv), (3)(iv), (vi) and (vii) removed 10983
(b)(1), (d)(1)(iii)(*c*), (vi)(*c*), (vii)(*c*), (xiii)(*c*), (xvi)(*c*), (xx)(c), (xxi)(C), (xxii)(B), (xxiii)(*b*), (3)(ii)(B), (iii)(B), (v)(B) and (4)(i)(*b*) amended 13546
(d)(1)(i)(*c*) and (2)(i)(*c*) amended 18159
(d)(1)(xxii)(B) amended 53138
558.555 (d)(3), (4) and (8) removed; (d)(5), (6) and (7) redesignated as (d)(3), (4) and (5) 10983
(d)(2), (3), (4) and (8) amended 13546
558.575 (d)(1)(ii) removed 10983
(a)(1) amended 13546
558.582 (a) amended 13546
558.600 (e)(1)(iii) amended 13546
558.625 (b)(10) added; (b)(54) amended; (b)(57) and (83) removed 13546
(b)(2) through (24), (26) through (38), (40) through (53) and (55) through (88) removed; (b)(25), (39), (54), (89) and (90) redesignated as new (b)(2) through (6) 19815
558.630 (b)(5) amended 13546
(b) revised 19815
558.635 (a)(2) amended 13546
(d)(4)(v), (vi) and (vii) correctly revised 17860
(a) revised 19815

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558.680 (d) revised 10983
(b) amended 13546
573.210 Added 14176

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500.23 Revised 56337
507 Added 56337
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507.3 Eff. date pending in part 56337
507.12 Eff. date pending in part 56337
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507.105 Eff. date pending in part 56337
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507.110 Eff. date pending in part 56337
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507.130 Eff. date pending in part 56337
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507.135 Eff. date pending in part 56337
507.175 Eff. date pending in part 56337
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510.600 (c)(1) table and (2) table amended 13228, 18775, 34278, 61295, 73104, 76386
514 Authority citation revised 31733
514.1 (b)(9) revised 31733
520 Drug application approvals withdrawn 76387
520.43 (c)(2) revised 18775
520.48 (b) revised 34278
520.88g (c)(2)(i) amended 34278
520.154a Heading revised; (d)(1)(ii), (2)(i)(A), (ii)(A), (3)(ii) and (4)(ii) amended 34278
520.301 Redesignated from 520.310 13229
520.302 Redesignated from 520.312 13229
520.304 Redesignated from 520.309; (b)(3) added 13229
(b)(3) amended 34278
(b)(2) amended 61296
520.309 Redesignated as 520.304 13229
520.310 Redesignated as 520.301 13229

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520.312 Redesignated as 520.302 13229
520.370 (a) and (b) revised; (c)(2) amended 13229
520.441 (b)(1) amended 13229
(b)(4) amended 18775
520.446 (b)(1) amended 76386
520.580 (d) heading restored; CFR correction 12081
520.804 (c)(i), (ii) and (iii) redesignated as (c)(1), (2) and (3) 34278
520.905a (a) and (e)(4)(i) revised; (e)(4)(iii) amended; (e)(5) added 76386
520.1156 Added 18775
520.1193 (b)(2) corrected; CFR correction 12081
520.1315 (c)(1) revised 53459
520.1367 (b)(2) amended 53459
520.1443 (b) amended 18776
520.1447 (b) amended 18776
520.1510 Heading and (b) revised; (d)(1)(ii)(B) amended 18776
520.1660d (b)(6), (d)(1)(ii)(A)(*3*), (B)(*3*) and (C)(*3*) amended 13229
(a)(4) revised 34278
520.1855 (b) amended 34278
(c)(1) revised 53459
520.2043 (b)(2) amended 76386
520.2158 (b) amended 18776
(d)(1) and (2) revised; (d)(3) added 61296
520.2218 (d)(1)(i)(A), (B), (2)(i)(A) and (B) revised 34278
520.2261b (d)(4)(iii) amended 61296
520.2455 (b)(3) and (c) revised 13229
520.2598 (a) amended 53460
520.2640 (e)(2)(iii) and (3)(iii) amended 34278
522 Drug application approval withdrawn 18777
522.167 Added 18776
522.230 (b) amended 18776
522.246 (b)(3) amended 13229
522.558 (a) and (b) revised 13229
522.690 (d)(1) and (2) redesignated as (d)(2) and (4); new (d)(1) added; new (d)(2)(ii) and (3)(ii) amended; (a), (b), (c) and new (d)(4) introductory text revised 61296
(b)(2) and (d)(1)(i) revised; (b)(3) added 76386
522.812 (e)(3)(i) removed; (e)(3)(ii) and (iii) redesignated as new (e)(3)(i) and (ii); (b)(2) and new (e)(3)(i) revised 13229

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(b)(3) added 18776
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522.955 (a), (b), (d)(1) heading, (i) introductory text, (C), (ii) introductory text and (C) revised 61296
(b)(2) amended 76386
522.1004 Removed 18776
522.1073 Removed 34278
522.1075 Removed 34278
522.1077 Revised 34279
522.1145 (e)(2)(i) amended 34279
522.1222 (b) revised 13229
522.1289 (a) amended 61297
522.2005 (b)(2) revised; (b)(3) removed 18776
522.2075 Added 61297
522.2470 (b) revised 34279
522.2474 (b) amended 13230
522.2483 (b) revised 34279
522.2630 (b)(1), (2), (d)(1)(ii)(A), (B) and (iii) revised 13230
522.2662 (b)(4) amended 13230
522.2670 (b)(1) amended 13230
524.154 (a)(1), (2) and (b)(2) revised 61297
524.955 Added 13230
524.957 Added 76387
524.1044a Revised 18776
524.1044i (c)(2) revised 13230
524.1450 (a), (b) and (d) revised; (e) removed 53460
524.1484g (a) and (b) revised 61297
526.313 (d)(1)(ii) revised 34279
528.1070 (b) amended 34279
528.1092 Added 73104
529.1186 (b) amended 18776
529.1350 (b) amended 18776
529.2150 (b) amended 18776
556.60 Removed 78970
556.68 Added 61297
556.732 Redesignated from 556.738 13230
556.738 Redesignated as 556.732 13230
558 Authority citation revised 31733
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558.3 (b)(1)(ii), (6), (7), (9) and (11) revised; (b)(12) added 31733
558.4 (d) table amended 61297, 78970
558.6 Revised 31733
(b)(5) and (c) introductory text corrected 35841
558.68 Added 61297
(c)(1) revised 76387

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558.76 (d)(1)(iv) amended 13230
(d)(3)(xiii) removed 78970
(b), (c) and (d) redesignated as (c), (d) and (e); new (b) added; heading, (a) and new (e)(1) revised 79474
558.95 (d)(4)(v) added 13230
(d)(4)(ii) table amended 53460
558.128 (b)(1), (e)(1)(i), (ii), (iii), (2)(i) through (iv), (3)(i) through (iv), (4)(i), (ii), (iv), (vii), (viii) and (5)(i) amended; (e)(1)(iv), (4)(v) and (ix) revised 13231
(b)(2), (e)(1) table, (2) table, (3) table, (iv) and (4) table amended 18776
558.140 (b)(1) amended 13231
558.145 (a)(2) amended 13231
558.195 (e)(2)(iv) amended 13231
558.261 (c)(1) and (2) revised 76387
558.355 (f)(1)(xiv)(*b*) amended 13231
558.369 Removed 78970
558.450 (a)(2), (d)(1)(i) through (iv), (2)(i) through (iv), (3)(i), (ii), (4)(i) through (v), (5)(i), (ii) and (iii) amended 13232
558.455 (b), (e)(1)(i) through (iv), (2)(i) through (iv), (3)(i), (ii) and (4)(i) through (vi) amended 13232
558.460 (a) and (b) revised 61298
558.500 (e)(1)(ii), (iii), (iv), (2)(iv), (ix), (x) and (xiii) amended 61298
558.550 (b)(3) and (d)(1)(xvi)(*c*) amended 13232
558.600 Redesignated as 558.612; redesignated from 558.615 13232
558.612 Redesignated from 558.600; (c) and (e)(1)(iii) amended 13232
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558.618 (e)(2)(i) amended 61298
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558.625 (b)(5) amended 13232
(b)(5) removed; (b)(6) redesignated as new (b)(5) 76387
558.630 (b)(2) amended 13232, 76387
558.665 (d)(1) and (e)(1) revised; (d)(2) redesignated as (d)(4); new (d)(2), (3), (e)(7) and (8) added 13232
(e)(9) added 18776
(d)(2) and (e) revised 53460
573.490 Added 35569
578.3 Amended 75804
578.87 (b)(4) amended 75804

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578.103 (a)(4) through (17) redesignated as (a)(5) through (18); new (a)(4) added 75804
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510.600 (c)(1) table and (2) table amended 3324, 17606, 36788, 48702, 59133, 67151
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520.441 (b)(2), (d)(1)(i)(A)(*1*), (2)(i)(A)(*1*), (4)(iii)(B), (C) and (iv)(B) amended 17607
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520.905a (a) amended 22523
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520.1084 Added 36789
520.1193 (b)(2) amended..... 17607
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520.1263c (b) revised..... 22523
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(c) redesignated as (d); new (c) added; new (d)(3) revised 94990
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520.2041 (b) amended 22523
520.2043 (b)(1) amended 17607
520.2044 (b)(2) amended 17607
520.2075 (a) and (c) revised 59133
520.2086 Added 22523
520.2123b (d)(1)(i) removed; (d)(1)(ii) and (iii) redesignated as new (d)(1)(i) and (ii); (d)(2) amended 94990
520.2123c (b) amended 22523
520.2130 (b) amended 48702
520.2134 (b) amended 48702
520.2184 (d)(3) amended 94990
520.2200 (b) amended 17607
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520.2218 (b) amended 22523
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520.2220a (b)(1) amended 22523
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520.2260a (a)(1) amended 17607
520.2260b (f)(1) amended 22523
520.2261a (b) amended 17607, 36789
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520.2261b (b) amended 17607
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520.2345c (d)(1)(iii) removed 67151
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520.2471 (d)(2) revised 17608
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522.224 Added 67151
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522.690 (b)(3) amended 36789
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522.840 (b) amended 48702
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522.1044 (b)(4) amended 22524
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522.1066 (b) amended 17608
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522.1182 (b)(6) amended; (b)(8) removed 22524
(b) introductory text, (7) introductory text, (i) and (ii) amended 59134
522.1192 (b)(2) amended 59134
522.1260 (b)(2) amended 59134
522.1315 (c)(1)(i) and (2)(i) amended 22524
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Revised 94995
558.140 (b)(2) amended 63054
(d) redesignated as (e); new (d) added 95004
558.145 (a)(2) removed 63054
Removed 95004

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558.175 (d)(2) amended 17609
(b) amended; (c) and (e) added; (d)(5) and (6) removed 95004
558.195 (e)(1)(ii) amended 17609
(e)(1)(i) table, (2)(i) table, (3)(i)1 table, (ii)1 table, (i)2 table and (ii)2 table amended 22525
(e)(1)(vi), (2)(iii) and (v) amended 67152
(e)(1)(iv), (v), (vi), (2)(ii), (iv) and (vii) removed; (e)(4) added 95004
558.198 (d)(1)(ii) and (2)(ii) amended 17609
(d)(1)(iv) and (v) removed; (d)(3) added 95004
558.248 (a) and (b) revised; (d)(1)(iii) removed 36790
(d) redesignated as (e); new (d) added; (a) and new (e) revised 95004
558.258 (e)(2)(vi) and (vii) amended 17609
(e)(2)(ii) through (v) removed; (e)(6) added 95005
558.261 (c)(2)(i) and (ii) redesignated as (c)(2)(ii) and (i); new (c)(2)(ii) revised; (c)(4) added 17609
(c) and (d) redesignated as (d) and (c) 67152
558.265 (d)(1)(vi) and (2)(ii) amended 17609
(d)(1)(iii), (iv) and (vii) removed; (d)(4) added 95005
558.274 (a)(1), (c)(1)(i), (ii), (2)(i) and (ii) amended 48703
(c)(1)(ii) and (2)(ii) removed 59135
Revised 95005
558.295 (b) removed 67152
558.300 (e)(2), (3) and (9) amended 17609
(e)(4) through (7) removed; (f) added 95005
558.305 (e)(2), (3), (5) and (6) removed; (e)(4) redesignated as new (e)(2); (f) added 95005
558.311 (e)(1)(iv), (x) and (xv) amended 17609
(e)(1)(i), (vi), (vii) and (xv) amended; (e)(1)(iii), (v) and (xx) through (xxviii) removed; (e)(5)(i) redesignated as (e)(5)(ii); new (e)(5)(i) and (iii) added 95005
558.325 (d)(3) revised 67152
Revised 95005

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558.340 (c)(1)(i) and (ii) redesignated as (c)(2) and (3); new (c)(2) revised 22525
558.342 (b)(2), (e)(1)(i) through (iv), (ix) and (x) amended 48703
(e)(1)(iv), (ix), (x) and (xi) amended 67152
(e)(1)(iii), (iv), (viii), (ix) and (xi) removed; (e)(2) revised 95009
558.355 (f)(1)(iii)(*b*), (xxiv), (xxix) introductory text, (*b*), (xxx) introductory text, (*b*), (2)(ii) introductory text, (*b*), (iii) introductory text, (*a*), (*b*), (4)(ii) introductory text, (*b*), (iii) introductory text, (*b*), (v) introductory text and (*b*) amended 17609
(f)(1)(xxiv) and (xxv) introductory text revised; (f)(1)(xxx), (4)(iv) and (v) removed 22525
(b)(1), (2), (4) through (9), (11), (12), (14), (f)(1)(xiii)(*b*), (xxi)(*b*), (xxii)(*b*), (xxviii)(*b*), (xxix)(*b*), (xxxi)(*b*), (3)(i)(*b*)(*2*)(*iii*), (ii)(*b*), (xii)(*b*), (4)(ii)(*b*), (iii)(*b*) and (6)(i)(*b*)(*2*)(*iii*) amended 48703
(f)(1)(xxviii) removed; (f)(8)(i) and (ii) revised 59135
(a) and (b) and (f)(8) revised; (f)(1)(viii), (ix), (xiii), (xiv), (xxi), (xxii), (xxxi), (2)(iv), (3)(ii) and (xii) removed 95009
558.363 (d)(1)(iv) introductory text, (B) and (3)(ii) amended 17609
(a)(1), (3), (8), (d)(1)(ii)(B), (iii)(B), (iv)(B), (v)(B) and (vi)(B) amended 48703
(d)(1)(vi) removed 59135
558.364 (d) redesignated as (e); (a) through (d) revised 95009
558.366 (d) amended 17609
(b) and (d) amended 48703
(d) amended 67153
(d) table amended; (e) added 95009
558.435 Removed 95009
558.450 (d)(5)(v) amended 17609
Revised 95009
558.455 (d) revised; (e)(1)(i), (2)(i), (3)(i), (4)(i), (ii) and (iv) removed; (e)(4)(v) amended 95012
558.460 Removed 95013
558.485 (e)(1)(v) through (xii) removed; (e)(3) added 95013
558.500 (b), (e)(1)(i) through (iv), (2)(i) through (xiii) and (3)(i) through (iv) amended 48703

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(e)(1)(ii), (iii), (iv), (2)(iv), (ix), (x) and (xiii) removed; (e)(4) added 95013
558.515 (d) amended 17609
(d) table amended 22525
(d) table amended; (e) added 95013
558.550 (d)(1)(iii)(*a*), (*c*), (vi)(*a*), (*c*), (xx)(A), (C), (xxi)(A), (C), (3)(ii) introductory text, (B), (iii) introductory text, (B), (v) introductory text and (B) amended 17609
(b)(1), (d)(1)(xvi)(c), (xx)(C), (xxii)(B), (xxiii)(b), (3)(ii)(B), (iii)(B), (v)(B) and (4)(i)(b) amended; (b)(2) removed; (b)(3) redesignated as new (2) 22525
(d)(1)(xxii)(B) amended 48703
(d)(1)(xxii) removed 59135
(d)(1)(x), (xi), (xiii) and (xvi) removed; (d)(4) revised 95013
558.555 (d)(2) amended 17609
(d)(3), (4), (5), (e)(2), (3) and (4) removed; (f) added 95013
558.575 Heading and (a) revised; (b), (c) and (d) redesignated as (c), (d) and (e); new (b) and (d) added 95013
558.582 Revised 95013
558.586 (b) amended 22525
Revised 95013
558.612 (e)(1)(i) and (iii) removed; (e)(1)(ii) and (iv) redesignated as new (e)(1)(i) and (ii); (e)(2) added 95015
558.618 (b), (e)(1)(i) and (2)(i) through (iii) amended 48703
(e)(2)(ii) and (iii) amended 59135
(c) and (d) redesignated as (d) and (c) 67153
558.625 (b)(3) removed; (b)(4) and (5) redesignated as new (b)(3) and (4) 36790
(b)(1), (f)(2)(i), (iii) and (vii) revised; (f)(2)(viii) and (ix) removed 59135
(b)(1) amended 48703
(d) removed; (c), (e) and (f) redesignated as (d), (c) and (e); (b), new (d) and new (e) revised 95015
558.630 (b)(1) amended 48703
(b)(1) revised 59135
Revised 95021
558.633 Added 36790
(d)(1) revised 67153
558.635 Revised 95022

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558.665 (e)(2) through (6), (8), (10), (11) and (12) amended 48703
(e)(5), (6), (11) and (12) removed; (f) added 95025
558.680 (d)(1)(ii), (iii), (iv), (vi), (vii), (viii) and (2)(ii) amended 17609
(d)(1)(x) removed; (e)(3) added 95025
570.3 (f), (h) and (k) revised; (i) amended; (n) added 55051
Regulation at 81 FR 55051 eff. date corrected 62004
570.30 (a) and (i) amended; (b), (c) and (d) revised 55052
Regulation at 81 FR 55052 eff. date corrected 62004
570.35 (a), (b)(1), (3) and (4) revised; (c) removed 55052
Regulation at 81 FR 55052 eff. date corrected 62004
570.38 (a) revised 55052
Regulation at 81 FR 55052 eff. date corrected 62004
570.203—570.280 (Subpart E) Added 55052
Regulation at 81 FR 55052 eff. date corrected 62004
573.304 Added 35611
Regulation at 81 FR 35611 eff. date confirmed; comment period extended 41441
573.496 Added 86269
573.696 Added 67154
Introductory text and (b) revised 95027
589.2001 (b)(1)(vi)(B) amended 5596

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507 Policy statement 51345
507.75 Revised 14147
510 Drug application approvals withdrawn 12170
510.600 (c)(1) table and (2) table amended 11508, 12168, 21690, 43484, 58555
511.1 Heading and (c)(6) revised; (c)(1) and (2) amended; (c)(1)(i), (ii), (2)(i) and (ii) added 61446
516.2065 Added 12169
520.48 (b) amended 21690
520.88g (b) amended 11508
(c)(1)(ii) and (2)(ii) amended 43484
Heading, (a), and (b) revised 58556

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520.304 (b)(1) and (2) revised; (b)(3) removed 43484
520.370 (c)(2) amended 12169
520.540c (b) amended 11508
520.955 (b) revised 12169
520.980 (b) amended 21690
520.1189 Added 12169
520.1445 (c)(1)(ii) revised 58556
520.1454 (b) amended 21690
520.2041 (b) amended 12169
520.2086 (c)(2) revised 12169
520.2325b (b) amended 12169
522 Drug application approvals withdrawn 12170, 21694
522.90b (a) amended 21690
522.304 (b) revised 43484
522.313c (b) amended 12169
522.540 (d)(2)(i) amended 11508
522.970 (b)(1) revised; (b)(3), (e)(2)(ii)(B) and (iii) removed; (e)(2)(ii) amended 43484
522.1002 (b) removed; (c) redesignated as new (b) 21690
(b)(1) revised 43484
522.1055 (b) amended 11508, 21690
522.1182 (b)(3) amended 11508
522.1335 (b) amended 58556
522.1362 (b) amended 21690
522.1380 (b) amended 11508
522.1450 (b) amended 21690
522.1660a (e)(1)(ii) amended 43484
522.1662a (e)(1) revised; (e)(3)(i)(*c*) amended 21690
522.2075 (c) revised 12170
522.2470 (b), (c)(1)(i), (ii), and (2) revised 58556
522.2473 (b) amended 21691
522.2477 (b)(2) revised; (d)(4) added 21691
(b)(2) revised; (d)(1)(iii) through (4)(iii) amended; (d)(5) added 43484
522.2615 (b) amended 11508
524 Drug application approvals withdrawn 11509
524.998 (c)(2) added 43485
524.1005 (b)(1) amended 11508
524.1450 (b)(1) amended 21691
524.1465 (b) amended 11508
524.1580a (d)(3) amended 58556
529 Drug application approvals withdrawn 12170
529.1030 (d)(1)(ii), (2)(iii), and (3) revised; (d)(2)(i) table and (ii) table amended 58556
529.1186 (b) amended 12170
558 Drug application approvals withdrawn 11509

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558.4 (d) table amended 21691, 43485
558.58 (f)(4) and (5) removed 58557
558.68 (e)(1)(ii) revised 11509
558.76 (e)(1)(vii) removed 21691
558.115 (d)(4) revised 21691
558.128 (b)(1), (e)(1)(i), (v), (3)(v), (4)(iii) amended; (e)(4)(xxiv) and (xxv) redesignated as (e)(4)(xxv) and (xxvi); new (e)(4)(xxiv) added 21691
(e)(4)(iii), (xi), (xii), (xiii), (5)(ii), (iii) and (6)(v) amended 43485
558.140 (b)(1) amended 21691
558.325 (e)(1)(ii) revised 12170
(e)(2)(vii) and (viii) redesignated as (xvi) and (xvii); new (e)(2)(vii) added 21691
558.366 (e) revised 21692
(e) removed 58557
558.450 (e)(4)(iii) redesignated as (e)(4)(v); new (e)(4)(iii) and (iv) added 11512
558.485 (e)(1)(iv) removed 21692
558.550 (d)(5) added 21692
558.625 (d)(2) revised; (d)(4) and (5) added; (e)(2)(iv), (v), (vi), (vii), (viii), (ix), (x), (xi), (xii), (xiii), (xiv) and (xv) amended 21692
(e)(1)(vii), (ix), (2)(ii), (iii), (vi) through (xv) amended 43485
558.635 (a) and (e) revised; (d)(1) and (2) added 11512
(e)(1) revised 21692
558.680 (e) removed; (d)(3) added 21693
573.170 (c) and (d) redesignated as (d) and (e); new (c) and new (d)(3) added; new (e) introductory text revised 52209
573.480 (b)(3) and (4) redesignated as (b)(4) and (5); new (b)(3) and (b)(4)(iii) added; new (b)(5) introductory text revised 52209

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573.492 Added 38596

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507 Policy statement 598
510.600 (c)(1) table and (2) table amended 13634
(c)(1) table and (2) table amended; eff. 4-9-18 13635
520.48 (b) amended 13635
520.1447 (d)(1)(ii) amended 13635
520.2645 (d)(1) and (2) revised 13635
522 Drug application approval withdrawn 13637
522.300 Removed; eff. 4-9-18 13635
522.540 (b)(2) and (c)(2) revised; eff. 4-9-18 13635
522.1081 (b)(1) amended; eff. 4-9-18 13635
522.1662a (h)(3)(ii) amended 13635
522.1680 (b) amended 13635
524.970 Added 13635
524.1132 (a) revised 13635
524.1193 (b)(2) amended 13635
556.286 (c) amended 13635
558.4 (d) table amended 13635
558.128 (e)(3) table and (4) table amended 13636
558.325 (d)(2) revised 13637
558.575 (e)(2)(ii) amended 13637
573.480 (b) introductory text and (5)(iii)(B) revised 20
573.940 (d) and (e) added 8930