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

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

(a) New information requires a re-evaluation 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 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 502(a) (5) and/or 502(a) 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.

§ 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]

§ 500.35 Animal feeds contaminated with Salmonella microorganisms.

(a) Investigations by the Food and Drug Administration, the Centers for Disease Control of the U.S. Public Health Service, the Animal Health Division of the Agricultural Research Service, U.S. Department of Agriculture, and by various State public health agencies have revealed that processed fish meal, poultry meal, meat meal, tankage, and other animal byproducts intended for use in animal feed may be contaminated with Salmonella bacteria, an organism pathogenic to man and animals. Contamination of these products may occur through inadequate heat treatment of the product during its processing or through recontamination of the heat-treated product during a time of improper storage or handling subsequent to processing.

(b) Articles used in food for animals are included within the definition of
§ 500.45 21 CFR Ch. I (4-1-98 Edition)

food in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Further, Salmonella contamination of such animal feeds having the potentiality for producing infection and disease in animals must be regarded as an adulterant within the meaning of section 402(a) of the act. Therefore, the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of the following when intended for animal feed and encountered in interstate commerce and found upon examination to be contaminated with Salmonella microorganisms: Bone meal, blood meal, crab meal, feather meal, fish meal, fish solubles, meat scraps, poultry meat meal, tankage, or other similar animal byproducts, or blended mixtures of these.

[40 FR 13802, Mar. 27, 1975, as amended at 54 FR 18279, Apr. 28, 1989]

§ 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 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 at levels not exceeding 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 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 or supplemental 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-
§ 500.50
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 in accordance with directions for use contained on the label or labeling.
(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.

§ 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 it to be misbranded 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 therefor 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
§ 500.80  

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 under §5.10 of this chapter) 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 provides an operational definition of no residue and identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidelines contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidelines are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests for these guidelines should be identified with Docket No. 83D-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.

§ 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:


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.

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 permitted concentration.

Preslaughter withdrawal period or milk discard time means the time after cessation of administration of the sponsored compound for the residue of carcinogenic concern in the edible product.
to deplete to the concentration that will satisfy the operational definition of no residue.

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 \( S_m \) in the last tissue to deplete to its permitted concentration.

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 permitted concentration of residue of carcinogenic concern for a specific edible tissue.

\( S_o \) means the concentration of the 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. For the purpose of this subpart, FDA will also assume that this \( S_o \) will correspond to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people.

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.

§ 500.84 Operational definition of "no residue".

(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 analyze the data from the bioassays using a statistical extrapolation procedure.

(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 \( S_m \).

(2) FDA will consider that "no residue" of the compound remains in the edible tissue when conditions of use of the sponsored compound, including any required preslaughter withdrawal period or milk discard time, ensure that the concentration of the residue of carcinogenic concern in the total diet of people will not exceed \( S_o \). Because the total diet is not derived from food-producing animals, FDA will designate as \( S_o \) the concentration of residue of carcinogenic concern that is permitted in a specific edible product.

§ 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
§ 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 reliably measure and confirm the identity of the marker residue in the target tissue at concentrations equal to and above \( R_m \).

(c) FDA will publish in the \textit{Federal Register} the complete regulatory method for measuring the marker residue in the target tissue in accordance with the provisions of sections 408(c)(3)(A), 512(d)(1)(H) and (i), and 721(b)(5)(B) of the act.

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

§ 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)
Subpart B—Specific Animal Food Labeling Requirements

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

Subparts C–E [Reserved]

Subpart F—Exemptions From Animal Food Labeling Requirements

501.100 Animal food; exemptions from labeling.
501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
501.105 Declaration of net quantity of contents when exempt.
501.110 Animal feed labeling; collective names for feed ingredients.


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

Subpart A—General Provisions

§ 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

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§ 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 \( \frac{3}{16} \) 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 \( \frac{3}{16} \) 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 \( \frac{3}{16} \) 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 \( \frac{3}{16} \) 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
§ 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 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.

§ 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 recon-
stitute the ingredient to single
strength. Any water added in excess of
the amount of water needed to recon-
stitute the ingredient to single
strength shall be declared as
water
in
the ingredient statement.

§ 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 man-
ufacturer, packer, or distributor.

(b) The requirement for declaration
of the name of the manufacturer, pack-
er, 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 indi-
vidual, partnership, or association, the
name under which the business is con-
ducted shall be used.

(c) Where the food is not manufac-
tured by the person whose name ap-
ppears 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 ad-
dress, city, state, and ZIP Code; how-
ever, the street address may be omitted
if it is shown in a current city direc-
tory or telephone directory. The re-
quirement 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 in-
voice).

(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 con-
junction 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 serv-
ing; however, such statement may be
expressed in terms that differ from the
terms used in the required statement
of net quantity of contents (for exam-
ple, cupfuls, tablespoonfuls, etc.) when
such differing term is common to cook-
ery 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 prod-
uct standard promulgated pursuant to
the procedures found in 15 CFR part 10
by the Department of Commerce, quan-
titatively defining the meaning of the
term serving with respect to a particu-
lar 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 in-
formation required by or under authority
of the act to appear on the label may
lack that prominence and conspicuous-
ness required by section 403(f) of the
act by reason (among other reasons) of:

(1) The failure of such word, state-
ment, or information to appear on the
§ 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.

§ 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, Cardamom, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard
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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.

(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 non-flavor 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

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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 through-out 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 transmission 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.


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
(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.

§ 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
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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 ½ 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 \(\frac{1}{16}\) 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 paragraph (m)(6) 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 ounces 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.

4. 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).

5. On a random package, declaration of \(\frac{3}{4}\) pound avoirdupois may be expressed as Net Wt. .75 lb.

6. A declaration of 2½ gallons liquid measure shall be declared 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.
- ounce oz.
- pound lb.
- fluid fl.

(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

\[\text{Food and Drug Administration, HHS} \]
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.


§ 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
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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 “containing (or contains)” 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 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) 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.

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.
(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
§ 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.


§ 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 the 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.

(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
§ 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 Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12240 Parklawn Dr., Rockville, MD 20857.

§ 510.3


(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) The term sponsor means the person responsible for an investigation of a new animal drug, including responsibility for compliance with applicable provisions of the act and regulations. 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.
§ 510.95 Designated journals.

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

- All Pet’s Magazine (Jersey City).
- American Journal of Veterinary Research (Chicago).
- Animal Nutrition & Health (Sausalito, CA).
- Animal Production (Edinburgh).
- Avian Diseases (Amherst).
- British Poultry Science (Edinburgh).
- Canadian Journal of Comparative Medicine and Veterinary Science (Gardenvale, Quebec).
- Canadian Veterinary Journal (Guelph, Ontario).
- Cornell Veterinarian (Ithaca).
- Experimental Parasitology (New York).
- The Feed Bag (Milwaukee).
- Feedstuffs (Minneapolis).
- Hoard’s Dairyman (Fort Atkinson).
- Journal of the American Veterinary Medical Association (Chicago).
- Journal of Dairy Science (Champaign).
- Journal of Economic Entomology (Baltimore).
- Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, IL).
- National Hog Farmer (Grundy Center, IA).
- New Zealand Veterinary Journal (Wellington).
- Poultry Science (Guelph, Ontario).
- Praktische Tierarzt (Postfach, Germany).
- Research in Veterinary Science (Chicago).
- Small Animal Clinician (Kansas City, MO).
- Veterinaermedizin (Konstanz, Germany).
- Veterinarian (London).
- Veterinarian (International) (New York).
- The Veterinary Bulletin (Farnham Royal, England).
- Veterinary Medicine (Kansas City, MO).
- Veterinary Record (Croydon, England).
- Zentralblatt Fuer Veterinaermedizin Zentr.
- Veterinaermed (Berlin).

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985]
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)(D) 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 warning, "Milk that has been taken from animals during treatment and within ______ hours (______ milkings) after the latest treatment must not be used for food," the blanks to be filled in with the number of hours (not to exceed 96) and milkings that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry 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.

§ 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 (— milkings) after the latest treatment must not be used for food", the first blank being filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use, and the second figure shall be the first number divided by 12. 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 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, he may exempt the drug from bearing either of the above warning statements.

§ 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
Food and Drug Administration, HHS

§ 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

intramammary infusion, intrauterine, and oral preparations (except certifiable antibiotics), including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives. An antibiotic application (see §431.50 of this chapter) will be required for all medicated premixes containing certifiable antibiotics.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]
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.


Subpart C [Reserved]

Subpart D—Records and Reports

§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) On receiving notification that an application submitted pursuant to §514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug, all advertising other than that contained in the application used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of §514.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports
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covering information of the following kinds:

(i) Information concerning a mixup in the new animal drug or its labeling with another article.

(ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal 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.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records of reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, 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.

(ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraphs (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:

(i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.

(ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) of this section with respect to more than one approved application for preparations containing the same new animal drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.

(iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section shall be submitted.

(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(d) If the Food and Drug Administration finds 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 the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the applicant notice and opportunity for a hearing on the question of whether to
§ 510.301  Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved 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) 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.

(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 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 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.

§ 510.302  Reporting forms.

(a) The information described in §510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD-2301 “Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.”

(b) All adverse experiences with new animal drugs as described in §510.300(b)(2) or §510.301(b) whether or not related to a required periodic report submitted on a Form FD-2301, shall be reported on Form FD-1932 “Adverse Drug Reaction” (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but
any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD-1932. A separate “Adverse Drug Reaction” form should be submitted for each patient where feasible.

(c) In lieu of Form FD-1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD-1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD-1932 and FD-2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health and Human Services, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.


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 New animal drug requirements regarding free-choice administration in feeds.

(a) For the purpose of this section, free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Such methods of administering drugs 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 animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations for medicated feeds.

(b) The Food and Drug Administration has concluded that there are questions about the safety and effectiveness of drugs when administered in free-choice feeds. Therefore, such methods of administration cause the drugs so administered to be new animal drugs, for which approved new animal drug applications (NADA’s) are required. (See §510.3(i)). In addition, the exemption from the requirement of an approved medicated feed application provided in §558.4 of this chapter does not apply to any free-choice medicated feed.

(c) An NADA or supplemental NADA for products for free-choice feeding submitted for approval under section 512(b) of the act shall provide for:

(1) The manufacture of a finished product for the free-choice administration of a new animal drug. Such an approval will not provide a basis upon which an application can be approved under section 512(m) of the act; or

(2) The manufacture of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. The approved NADA will provide a basis upon which an application can be approved under section 512(m) of the act. Data for a specific free-choice product may, if desired, be generated and submitted to the Food and Drug Administration by the manufacturer of the free-choice feed in the form of a master file which can be referenced in the NADA or supplemental NADA submitted by the new animal drug sponsor.

(d) Approval of the NADA or supplemental NADA submitted under paragraph (c) of this section will be reflected in a regulation in part 558 of this chapter published under section 512(i) of the act. The regulation will either state the formulation of the approved free-choice product or specify the specific free-choice administration products in which the drug is approved for use. If the approval is for a Type A medicated article, the regulation in part 558 of this chapter will indicate that each use of the Type A medicated article in a free-choice product must be the subject of an approved supplemental NADA.

(e) An application submitted under section 512(m) of the act to provide for manufacture of a specific free-choice feed from an approved Type A medicated article will be approved if, in addition to the information required by the medicated feed application, it includes a reference to the exact formula of the product to be manufactured as follows:

(1) The formula is the same as the one published in the new animal drug regulations; or

(2) The data in a master file have been referenced in an NADA or supplemental NADA; and
(3) Use of the Type A medicated article in the specific formulation has been approved on the basis that:

(i) The formula is the same as the one for which acceptable data have been submitted in a master file by the medicated feed applicant; or

(ii) The medicated feed applicant has written authority to reference a master file that has acceptable data for the formula in question.

(Approved by the Office of Management and Budget under control number 0910-0205)

[51 FR 19827, June 3, 1986]

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(3) (29) [Reserved]

(c) It is intended for use as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Use levels</th>
<th>Indications for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nicarbazin</td>
<td>Chickens</td>
<td>0.01 to 0.02 percent</td>
<td>For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency.</td>
</tr>
<tr>
<td></td>
<td>do</td>
<td>2.4 to 50 g/ton</td>
<td>Do.</td>
</tr>
<tr>
<td>2. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.</td>
</tr>
<tr>
<td>Bacitracin methylene disalicylate</td>
<td>do</td>
<td>4 to 50 g/ton</td>
<td>Do.</td>
</tr>
<tr>
<td>3. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.</td>
</tr>
<tr>
<td>Bacitracin methylene disalicylate</td>
<td>do</td>
<td>4 to 50 g/ton</td>
<td>Do.</td>
</tr>
<tr>
<td>3-Nitro-4-hydroxyphenylarsonic acid</td>
<td>do</td>
<td>0.0025 to 0.005 percent</td>
<td>For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.</td>
</tr>
<tr>
<td>4. Nicarbazin</td>
<td>do</td>
<td>0.01 to 0.02 percent</td>
<td>Do.</td>
</tr>
<tr>
<td>Procaine penicillin</td>
<td>do</td>
<td>2.4 to 50 g/ton</td>
<td>Do.</td>
</tr>
<tr>
<td>3-Nitro-4-hydroxyphenylarsonic acid</td>
<td>do</td>
<td>0.0025 to 0.005 percent</td>
<td>Do.</td>
</tr>
</tbody>
</table>
§ 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 510 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—Continued

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<td>American Veterinary Products, Inc., 749 South Lenexa, Suite A-231, Fort Collins, CO 80525</td>
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<td>Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333-2435</td>
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<td>Biopure Corp., 11 Hurley St., Cambridge, MA 02141</td>
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(1) A LPHABETICAL LISTING OF S PONSORS— Continued

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Food and Drug Administration, HHS

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<td>Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewlsburg, OH 43338.</td>
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<td>Orion Corp. ORION-FARMOS, P.O. Box 425, SF-20101 Turku, Finland.</td>
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<td>Planolquima Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 12052-120, Campinas, Sao Alto, Brazil.</td>
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<th>Drug labeler code</th>
<th>Firm name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>061651</td>
<td>Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.</td>
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<tr>
<td>062161</td>
<td>Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305.</td>
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<tr>
<td>062925</td>
<td>Veterinary Specialties Inc., 387 North Valley Ct., Banting, IL 60016.</td>
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<tr>
<td>063075</td>
<td>Biopure Corp., 11 Hurley St., Cambridge, MA 02141.</td>
</tr>
<tr>
<td>063112</td>
<td>Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.</td>
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<tr>
<td>063271</td>
<td>Kolfuk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92037.</td>
</tr>
<tr>
<td>063604</td>
<td>Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.</td>
</tr>
<tr>
<td>063765</td>
<td>Akzo Nobel Surface Chemistry AB, Box 851, S-44485 Stenungsund, Sweden.</td>
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[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For Federal Register citations affecting § 510.600, see the List of CFR Sections Affected in the Finding Aids section of this volume.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE


§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the 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 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 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.

(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 the Food and Drug Administration 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, whether 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:
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(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) 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) 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 the Food and Drug Administration pursuant to part 16 of this chapter.

(6) On written request of the Food and Drug Administration, 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 the Food and Drug Administration 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 the Food and Drug Administration 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
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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) Withdrawal of eligibility to receive investigational-use new animal drugs.

(1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has submitted false information either to the sponsor of the investigation or in any required report, the Center for Veterinary Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on whether the exemption should be terminated. If a danger to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 (see 42 FR 15675, March 22, 1977) of this chapter on the question of whether the exemption should be reinstated.

(2) If, after evaluating all available information, including any explanation presented by the investigator, the Commissioner determines that the investigator has repeatedly or deliberately submitted false information to the sponsor of an investigation, the investigator shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on whether the investigator is entitled to receive investigational new animal drugs.

(3) Each “Notice of Claimed Investigational Exemption for a New Animal Drug” and each approved new animal drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use new animal drugs will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new animal drug application.

(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, he shall first notify the sponsor, who shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter on whether the exemption should be terminated. If a danger to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 (see 42 FR 15675, March 22, 1977) of this chapter on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are such that a new animal drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 512(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use new animal drugs when the Commissioner determines that he has presented adequate assurance that he will employ such new animal drugs solely in compliance with the exempting regulations in this section for investigational-use new animal drugs.

(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 the Food and Drug Administration 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 the Food and Drug Administration.

(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.

Subpart C—Hearing Procedures

§ 514.200 Contents of notice of opportunity for a hearing.

§ 514.201 Procedure for hearings.

Subparts D–E [Reserved]

Subpart F—Judicial Review

§ 514.235 Judicial review.


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 described in paragraph (b) of this section. 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:

(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.

(xii) 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.

(iii) 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...
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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.

(b) 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, consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the new animal drug involved, on the basis of which it could fairly and reasonably be concluded by such experts 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 proposed labeling.

(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 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 previously investigated or marketed new animal drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components, shall be submitted. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted to the Food and Drug Administration by the applicant; with written authorization, information may also be incorporated from the material that another applicant has on file with the Food and Drug Administration. Each ingredient designated as active in any new animal drug combination must make a contribution to the effect in the manner claimed or suggested in the labeling, and, if in the absence of express labeling claims of advantages for the combination such a product purports to be better than either component alone, it must be established that the new animal drug has that purported effectiveness.

(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
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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) [Reserved]

(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 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.
§ 514.2 Applications for animal feeds bearing or containing new animal drugs.

(a) Applications (Form FDA 1900) to be filed under section 512(m) of the act shall be completed, signed, and submitted in triplicate in the form described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B or Type C medicated feed, as defined in §558.3 of this chapter, shall include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill.
§ 514.8 Supplemental new animal drug applications.

(a)(1) After a new animal drug application is approved, a supplemental new animal drug application may propose changes. A supplemental application may omit statements made in the approved application concerning which
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no change is proposed. Each supplemental application shall include up-to-date reports of any of the kinds of information required by §510.300(a) of this chapter that has not previously been submitted. A supplemental application shall be accompanied by 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.

(2) A supplemental new animal drug application shall be submitted for any change beyond the variations provided for in the application, including changes in the scale of production such as from pilot-plant to production batch, that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the new animal drug, or the adequacy of the manufacturing methods, facilities, or controls to preserve them.

(3) 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:

(i) 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

(ii) Any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(4) The supplemental application shall be submitted as follows. A communication proposing a change in a new animal drug application should provide for any one of the following kinds of changes:

(i) Revision in labeling, such as updating information pertaining to effects, dosages, and side effects and contraindications, which includes information headed “side effects,” “warnings,” “precautions,” and “contraindications.”

(ii) Addition of claim.

(iii) Revision in manufacturing or control procedures; for example, changes in components, composition, method of manufacture, analytical control procedures, package or tablet size, etc.

(iv) Change in manufacturing facilities.

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new animal drug (new distributor, packer, supplier, manufacturer, etc.); one firm per submission.

Any number of changes may be submitted at any one time; but if they fall into different categories as listed in paragraphs (a)(4) (i) through (v) of this section, the proposed changes should be covered by separate communications. Where, however, a change necessitates an overlap in categories, it should be submitted in a single communication. For example, a change in tablet potency would require other changes such as in components, composition, and labeling and should be submitted in a single communication.

(5) The following kinds of changes may be placed into effect without the approval of a supplemental application, if such change is fully described in the next periodic report required under §510.300(b)(4) of this chapter or, when such a report is not required, in a written communication to the Food and Drug Administration within 60 days of the effective date of the change (this does not apply to a change proposed because of any mixup or any bacteriological or 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 its specifications):

(i) A different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application.

(ii) Change in personnel not involving new facilities.

(iii) Change in equipment that does not alter the method of manufacture of a new animal drug.

(iv) Change from one commercial batch size to another without any change in manufacturing procedure.

(v) Change to more stringent specification without altering the method described in the approved application.

(vi) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(vii) Alteration of specifications or methods for inactive ingredients to
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bring them into compliance with new or revised specifications or methods in an official compendium.

(viii) Initiation of a product identification coding system.

(ix) Addition to labeling of a reasonable expiration date where none was previously used, with related conditions of drug storage when appropriate, except when evidence shows that a significant deterioration of the drug under marketing conditions has occurred which necessitates the immediate submission of a report under §510.300(b)(1) of this chapter. The report or written communication describing such change in labeling should include stability data justifying the expiration date and recommended conditions of storage.

(x) Change from paper labels to direct printing on glass or other kinds of immediate containers without a change in text.

(6) Approval of a supplemental new animal drug application will not be required to provide for an additional distributor to distribute a drug which is the subject of an approved new animal drug application if the conditions described below are met prior to putting such a change into effect. An order may issue refusing approval if any condition is not met or if any of the reasons for refusing or withdrawing approval, as stated in section 512(d) and (e) of the act or §514.110 applies. For the purposes of maintaining records and making reports under the requirements of §510.300 of this chapter, a distributor provided for under this section shall be considered an applicant within the meaning of §510.300(b) of this chapter. Said conditions are:

(i) A supplemental application is furnished to the Food and Drug Administration to provide for a designated distributor.

(ii) There are no changes from the conditions of the approved application except for a different and suitable proprietary name of the new animal drug (if one is used) and the name and address of the distributor as used on the label and labeling. The name of the distributor shall be accompanied by an appropriate qualifying phrase such as "manufactured for" or "distributed by."

(iii) A distributor’s statement is furnished to the Food and Drug Administration identifying the category of his operations (for example, wholesaler, retailer) and stating: That he will distribute the new animal drug only under the labeling provided for in the new animal drug application; that any other labeling or advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling provided for in the application; and, if the drug is a prescription article, that he is regularly and lawfully engaged in the distribution or dispensing of prescription drugs.

(iv) Nine copies of the printed labels and other labeling to be used by the distributor are submitted, identified with the new animal drug application number.

(b) When necessary for the safety or effectiveness of the drug, a supplemental new animal drug application shall specify a period of time within which the proposed change will be made.

(c) If a material change is made in the components’ composition, manufacturing methods, facilities, or controls, or in the labeling or advertising, from the representations in an approved application for a new animal drug (except changes conforming to the conditions set forth in paragraph (a)(5) and (6) and/or paragraphs (d), (e), (f), and (g) of this section), and the drug is marketed before a supplement is approved for such change, approval of the application may be suspended or withdrawn as provided in section 512(e) of the act.

(d) Changes of the following kinds proposed in supplemental new animal drug applications should be placed into effect at the earliest possible time:

(1) The addition to package labeling, promotional labeling, and prescription drug advertising of additional warning, contraindication, side effect, and precaution information.

(2) The deletion from package labeling, promotional labeling, and drug advertising of false, misleading, or unsupported indications for use or claims for effectiveness.

(3) Changes in the methods, facilities, or controls used for the manufacture,
processing, packing, or holding of the new animal drug (other than utilization of establishments 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.

(e) The Food and Drug Administration will take no action against a new animal drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new animal drug application if all the following conditions are met:

(1) The supplemental new animal drug application providing a full explanation of the basis for the changes has been submitted, plainly marked on the mailing cover and on the supplement, “Special new animal drug application Supplement—changes being effected.”

(2) The applicant specifically informs the Food and Drug Administration of the date on which such changes are being effected and submits to the Administration nine printed copies of any revised labeling to be placed in use, identified with the new animal drug application number.

(3) All promotional labeling and all drug advertising are promptly revised consistent with the changes made in the labeling on or within the new animal drug package.

(f) When a supplemental new animal drug application proposes changes only of the kinds described in paragraph (d) of this section, and the applicant informs the Food and Drug Administration that the changes are being put into effect, such notification will be regarded as an agreement by the applicant to an extension of the time for formal action on the application.

(g) In addition to changes as permitted by paragraphs (d) and (e) of this section, an applicant may place into effect changes proposed in a supplement to a new animal drug application that became effective prior to October 10, 1962, upon written notification from the Food and Drug Administration that such action is permitted, without approval of the supplemental application, pending the completion of the review of the effectiveness of such drug by the National Academy of Sciences-National Research Council and a determination as to whether there are grounds for refusing approval under section 512(d) of the act or for invoking section 512(e) of the act. The Food and Drug Administration will take no action against a new animal drug or an applicant solely because changes that have been permitted in a written communication are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new animal drug application.

(h) Except as provided in paragraphs (e) and (g) of this section, no provision of this section shall limit the authority of the Secretary or of the Commissioner to suspend or withdraw approval of a new animal drug application in accord with the provisions of section 512(e) of the act or to initiate any other regulatory proceedings with respect to a drug or applicant under provisions of the act.

(i) Changes from the conditions of an approved new animal drug application in accord with the provisions of paragraphs (d), (e), and (g) of this section are permitted on the basis of a temporary deferral of final action on the supplemental application under the provisions of section 512(c), (d), or (e) of the act.

(j) When an applicant receives written notification from the Food and Drug Administration, under the provisions of paragraph (g) of this section, that he may place into effect changes proposed in a supplemental application without approval of the supplemental application, he may within 30 days submit a written request that the Food and Drug Administration process the supplemental application. In such case, the change shall not be put into effect until approved. Within 180 days of the receipt of such written request, the Food and Drug Administration will approve the supplemental application or furnish notice of an opportunity for a hearing under the provisions of section 512(d) or (e), or both, of the act on a proposal to refuse approval of the supplemental application or to withdraw approval of the application and supplements thereto.
(k) A supplement to an application that became effective prior to October 10, 1962, may include a written statement to the effect that a temporary deferral of final action under the provisions of paragraph (d), (e), or (g) of this section is unacceptable to the applicant and that the applicant requests action as provided in section 512(c) of the act. Final action on such supplemental applications will be expedited in accord with applicable provisions of section 512 of the act and regulations in this subchapter E. In such cases, if the applicant places into effect any of the proposed changes prior to his receipt of a written notice of approval of the supplemental new animal drug application, such action may be regarded by the Food and Drug Administration as a basis for invoking the provisions of section 512(e)(1)(D) of the act; that is, the applicant may be furnished notice of an opportunity for a hearing on a proposal to withdraw approval of the application on the ground that the application contains an untrue statement of a material fact related to the changes from the conditions approved in the application.

(l) A supplemental application that contains nonclinical laboratory studies 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.

§ 514.10 Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug.

(a) The rules established in §§ 514.11 and 514.12 of this chapter with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.

(b) All records showing the Food and Drug Administration’s testing of and action on a particular lot of a certifiable antibiotic drug for veterinary use are immediately available for public disclosure.

§ 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 §§ 510.300 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 an approval has been published in the Federal Register, unless it has previously been publicly 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 an approval has been published in the Federal Register, no data or information contained in the file is available for public disclosure.
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Before such approval is published, 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, 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 an approval has been published in the Federal Register, 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 on or 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 approval is published in the Federal Register.

(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.


§ 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;

(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 §510.300 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.

§ 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

Subpart B—Administrative Actions on Applications

§ 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
§ 514.105 Approval of applications.

(a) Within 180 days after an application has been filed pursuant to §514.1, if the Commissioner determines that none of the grounds for denying approval specified in section 512(d) of the act applies:

(1) He shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which

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 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 warnings, 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) Within 180 days after an application has been filed pursuant to §514.1, if the Commissioner determines that none of the grounds for denying approval specified in section 512(d) of the act applies:

(1) He shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which

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 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 warnings, 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) Within 180 days after an application has been filed pursuant to §514.1, if the Commissioner determines that none of the grounds for denying approval specified in section 512(d) of the act applies:

(1) He shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which

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 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.
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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.

(2) He shall notify the applicant by sending him a copy of the proposed publication as described in paragraph (a)(1) of this section.

(b) Within 90 days after an application filed pursuant to § 514.2 if the Commissioner determines that none of the grounds for denying approval specified in section 512(m)(3) of the act applies, he shall notify the applicant that it is approvable by signing and mailing to the sponsor the original copy of the Form FDA 1900.

[40 FR 13825, Mar. 27, 1975, as amended at 51 FR 7392, Mar. 3, 1986]

§ 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 drug not exempted by § 514.8(a)(3)(i) and (a)(3)(ii).

(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 listed in § 514.8(d).

(xiv) Changes not requiring prior approval which are listed under § 514.8(a)(5) when submitted as supplemental applications.

(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,
§ 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 non-compliance.
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.

§ 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 consisting of one or more adequate and well-controlled studies by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the 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.

(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...
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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.

(b) The Commissioner shall within 90 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 an animal feed bearing or containing a new animal drug that:

(1) There is not in effect a regulation established pursuant to section 512(i) of the act (identified in such application) on the basis of which such application may be approved; or

(2) Such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to section 512(i) of the act (identified in such application), or that the purposes or conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications for use (including warnings) published pursuant to such section; or

(3) 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

(4) Based on a fair evaluation of all the material facts, such labeling is false or misleading in any particular.

(c) 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.


Effective Date Note: At 63 FR 10770, Mar. 5, 1998, §514.111 was amended by revising paragraph (a)(5), effective Apr. 6, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(5)(i) 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 consisting of adequate and well-controlled investigations, including clinical (field) investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the 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.

(ii) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical (field) investigations. They provide the basis for the determination whether there is substantial evidence to support the claims of effectiveness for new animal drugs.

(a) The plan or protocol for the study and the report of the results of the effectiveness study must include the following:

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(1) A clear statement of the objectives of the study.

(2) A method of selection of the subjects that—
   (i) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired;
   (ii) Assigns the subjects to test groups in such a way as to minimize bias; and
   (iii) Assures comparability in test and control groups of pertinent variables, such as species, age, sex, duration and severity of disease, management practices, and use of drugs other than those being studied. 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 (a)(5)(ii)(a)(i), (ii), or (iii) of this section.

(3) An explanation of the methods of observation and recording of the animal response variable studied and the means of excluding bias or minimizing bias in the observations.

(4) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of "blinding," if used, are to be documented. Generally, four types of comparisons are recognized:
   (i) No treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated animals.
   (ii) Placebo control: Comparison of the results of use of the new animal drug entity with an inactive preparation designed to resemble the test drug as far as possible.
   (iii) Active treatment control: An effective regimen of therapy may be used for comparison, e.g., where the condition treated is such that no treatment or administration of a placebo would be contrary to the well-being of the animals.
   (iv) Historical control: In some circumstances involving diseases with high and predictable mortality (leukemia or tetanus) or with signs and symptoms of predictable duration or severity (some forms of parasitism, bovine hypocalcemia, canine eclampsia) or in the case of prophylaxis where morbidity is predictable, the results of use of a new animal drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable animals with no treatments or with a regimen (therapeutic, diagnostic, prophylactic) whose effectiveness is established.

(5) A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

(6) Any of the criteria in this paragraph (a)(5)(ii) may be waived in whole or in part, either before the investigation or in the evaluation of a completed study, by the Director of the Center for Veterinary Medicine with respect to a specific clinical (field) investigation. A petition for such a waiver may be filed by any person who would be adversely affected by application of the criteria to a particular clinical investigation. The petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be or have been followed, the results of which will yield or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical (field) investigation, what alternative procedures, if any, are to be or have been employed, what results have been obtained, and the basis on which it can be or has been concluded that the clinical (field) investigation will yield or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(b) Standardized test drug: For such an investigation to be considered adequate for consideration for approval of a new animal drug, the test drug must be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(c) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.
§ 514.112 Return of applications for animal feeds bearing or containing new animal drugs.

Applications submitted pursuant to §514.2 will be returned to the applicant if such applications are incomplete or inaccurate or do not contain an identification of the applicable regulation(s). These regulations include those published pursuant to section 512(i) of the act, and are found in part 558 of this chapter. In addition, §510.515 of this chapter may also provide a basis on which approval of the application relies, as required by §514.2(b)(10). All reasons for the return of the application will be made known to the applicant.

[51 FR 7392, Mar. 3, 1986]

§ 514.115 Withdrawal of approval of applications.

(a) The Secretary may suspend approval of an application approved pursuant to section 512(c) or (m)(2) 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) or (m)(2) 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) or (m)(2) 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) or (m)(5)(A) 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) or (m)(5)(B) 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 or animal feed, 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) or (m)(2) 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. An application providing for the manufacture of animal feeds bearing or containing such drug and approved pursuant to section 512(m)(2) of the act shall be deemed as withdrawn upon publication in the Federal Register of the order revoking the corresponding regulation.

§ 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.
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(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...
§ 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 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 to refuse to approve an application or to withdraw the approval of an application will specify the grounds upon which he proposes to issue his order. On request of the applicant, the Commissioner will explain the reasons for his 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 he 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, his 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, he 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 should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he 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 data in the application and from the reasons and a 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 withdrawal of
approval of the application (for example, no adequate and well-controlled clinical investigations to support the claims of effectiveness have been identified), the Commissioner will enter an order on this data, stating his 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 he 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 his appearance.

[40 FR 13825, Mar. 27, 1975, as amended at 43 FR 1941, Jan. 13, 1978]

§ 514.201 Procedure for hearings.

Hearings relating to new animal drugs under section 512 (d), (e), (m)(3), and (m)(4) of the act shall be governed by part 12 of this chapter.

[42 FR 4717, J an. 25, 1977]

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, J an. 25, 1977]
Pt. 520

520.154a Soluble bacitracin methylene disalicylate.
520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.
520.154c Bacitracin zinc soluble powder.
520.182 Bicyclohexylammonium fumagillin.
520.222 Bunamidine hydrochloride.
520.246 Butorphanol tartrate tablets.
520.260 n-Butyl chloride capsules.
520.300 Cambendazole oral dosage forms.
520.300a Cambendazole suspension.
520.300b Cambendazole pellets.
520.300c Cambendazole paste.
520.309 Carprofen caplets.
520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.
520.312 Carnidazole tablets.
520.314 Cefadroxil tablets.
520.315 Cefadroxil powder for oral suspension.
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.
520.445 Chlortetracycline oral dosage forms.
520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.
520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).
520.445c Chlortetracycline tablets and boluses.
520.446 Clindamycin hydrochloride capsules.
520.447 Clindamycin hydrochloride liquid.
520.462 Clorsulon drench.
520.530 Cythioate oral liquid.
520.531 Cythioate tablets.
520.540 Dexamethasone oral dosage forms.
520.540a Dexamethasone powder.
520.540b Dexamethasone tablets and boluses.
520.540c Dexamethasone chewable tablets.
520.550 Dextroseglycine/electrolyte.
520.563 Diatriozate meglumine and diatrizoate sodium oral solution.
520.580 Dichlorophene and toluene capsules.
520.581 Dichlorophene tablets.
520.600 Dichlorvos.
520.608 Dicloxacillin sodium monohydrate capsules.
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.
520.622d Diethylcarbamazine citrate capsules.
520.623 Diethylcarbamazine citrate, oxibendazole chewable tablets.
520.640 Difloxacin.
520.763 Dithiazanine iodide oral dosage forms.
520.763a Dithiazanine iodide tablets.
520.763b Dithiazanine iodide powder.
520.763c Dithiazanine iodide and piperazine citrate suspension.
520.784 Doxylamine succinate tablets.
520.804 Enalapril tablets.
520.812 Enrofloxacin tablets.
520.813 Enrofloxacin oral solution.
520.816 Epistarlan tablets.
520.829 Erythromycin phosphate.
520.853 Ethylisobutrazine hydrochloride tablets.
520.903 Febantel oral dosage forms.
520.903a Febantel paste.
520.903b Febantel suspension.
520.903c Febantel-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.
520.960 Flumethasone tablets.
520.970 Flunixin oral dosage forms.
520.970a Flunixin meglumine granules.
520.970b Flunixin meglumine paste.
520.1010 Furosemide oral dosage forms.
520.1010a Furosemide tablets or boluses.
520.1010b Furosemide powder.
520.1010c Furosemide syrup.
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 soluble powder.
520.1100 Griseofulvin.
520.1120 Haloxon oral dosage forms.
520.1120a Haloxon drench.
520.1120b Haloxon boluses.
520.1130 Hetacillin oral dosage forms.
520.1130a Hetacillin potassium capsules.
520.1130b Hetacillin potassium oral suspension.
520.1130c Hetacillin potassium tablets.
520.1157 Iodinated casein tablets.
520.1158 Iodochlorhydroxyquin boluses.
520.1182 Iron dextran oral suspension.
520.1192 Ivermectin paste.
520.1193 Ivermectin tablets and chewables.
520.1194 Ivermectin drench.
520.1195 Ivermectin liquid.
520.1196 Ivermectin and prantel pamoate chewable tablet.
520.1197 Ivermectin sustained-release bolus.
520.1204 Kanamycin sulfate, aminopentamidine hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.
520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgite tablets.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>520.1242</td>
<td>Levamisole hydrochloride oral dosage forms.</td>
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<td>520.1242a</td>
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<td>520.1326c</td>
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<td>520.1326e</td>
<td>Mebendazole and trichlorfon with phenothiazine suspension.</td>
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<td>Promazine hydrochloride.</td>
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<td>Pyrantel pamoate paste.</td>
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<td>520.2100</td>
<td>Selenium, vitamin E capsules.</td>
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<tr>
<td>520.2122</td>
<td>Spectinomycin dihydrochloride oral solution.</td>
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</table>
§ 520.23

520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.
520.2123a Spectinomycin dihydrochloride pentahydrate tablets.
520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.
520.2150 Stanozolol oral dosage forms.
520.2150a Stanozolol tablets.
520.2150b Stanozolol chewable tablets.
520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.
520.2158a Streptomycin sulfate oral solution.
520.2158b Dihydrostreptomycin tablets.
520.2158c Dihydrostreptomycin oral suspension.
520.2160 Styrylpyridinium, diethylcarbamazine oral dosage forms.
520.2170 Sulfabromomethazine sodium boluses.
520.2184 Sodium sulfachloropyrazine monohydrate.
520.2200 Sulfachloropyridazine oral dosage forms.
520.2200a Sulfachloropyridazine bolus.
520.2200b Sulfachloropyridazine medicated milk and drinking water.
520.2200c Sulfachloropyridazine tablets.
520.2220 Sulfadimethoxine oral dosage forms.
520.2220a Sulfadimethoxine oral solution and soluble powder.
520.2220b Sulfadimethoxine tablets and boluses.
520.2220c Sulfadimethoxine oral suspension.
520.2220d Sulfadimethoxine-ornitroprim tablets.
520.2240 Sulfaethoxypyridazine.
520.2240a Sulfaethoxypyridazine drinking water.
520.2240b Sulfaethoxypyridazine tablets.
520.2260 Sulfamethazine oral dosage forms.
520.2260a Sulfamethazine oblets and boluses.
520.2260b Sulfamethazine sustained-release boluses.
520.2260c Sulfamethazine sustained-release tablets.
520.2261 Sulfamethazine sodium oral dosage forms.
520.2261a Sulfamethazine sodium drinking water solution.
520.2261b Sulfamethazine sodium soluble powder.
520.2280 Sulfamethizole and methenamine mandelate tablets.
520.2320 Sulfanitran and aklomide in combination.
520.2325 Sulfadiflouoxine oral dosage forms.
520.2325a Sulfadiflouoxine drinking water.
520.2325b Sulfadiflouoxine drench.
520.2330 Sulfafoxazole tablets.
520.2345 Tetracycline oral dosage forms.
520.2345a Tetracycline hydrochloride soluble powder.
520.2345b Tetracycline tablets.
520.2345c Tetracycline boluses.
520.2345d Tetracycline hydrochloride soluble powder.
520.2345e Tetracycline oral liquid.
520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.
520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.
520.2362 Thenium closylate tablets.
520.2380 Thiabendazole oral dosage forms.
520.2380a Thiabendazole top dressing and mineral protein feed block.
520.2380b Thiabendazole drench or oral paste.
520.2380c Thiabendazole bolus.
520.2380d Thiabendazole, piperazine citrate suspension.
520.2380e Thiabendazole with trichlorfon.
520.2380f Thiabendazole, piperazine phosphate powder.
520.2455 Tiamulin soluble powder.
520.2456 Tiamulin liquid concentrate.
520.2460 Ticarbodine oral dosage forms.
520.2460a Ticarbodine tablets.
520.2460b Ticarbodine capsules.
520.2473 Tioxdazole oral dosage forms.
520.2473a Tioxdazole granules.
520.2473b Tioxdazole paste.
520.2480 Triamcinolone acetonide tablets.
520.2482 Triamcinolone acetonide oral powder.
520.2520 Trichlorfon oral dosage forms.
520.2520a Trichlorfon oral.
520.2520b Trichlorfon and atropine.
520.2520c Trichlorofon boluses.
520.2520d Trichlorofon granules.
520.2520e Trichlorofon granules.
520.2520f Trichlorofon granules.
520.2520g Trichlorfon, phenothiazine, and piperazine dihydrochloride powder.
520.2582 Triflupromazine hydrochloride tablets.
520.2604 Trimeprazine tartrate and prednisolone tablets.
520.2605 Trimeprazine tartrate and prednisolone capsules.
520.2610 Trimethoprim and sulfadiazine tablets.
520.2611 Trimethoprim and sulfadiazine oral paste.
520.2612 Trimethoprim and sulfadiazine oral suspension.
520.2613 Trimethoprim and sulfadiazine powder.
520.2640 Tylosin.


Source: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine maleate tablets.

(a) Sponsors. See drug labeler codes in §510.600(c) of this chapter for identification of sponsors as follows:
Food and Drug Administration, HHS

§ 520.45a Albendazole suspension.

(a)(1) Specifications. The product contains 11.36 percent albendazole.
(2) Sponsor. See No. 000069 in §510.600 of this chapter.
(3) Related tolerances. See §556.34 of this chapter.
(4)(i) Conditions of use in cattle—(1) Amount. 4.54 milligrams per pound of body weight (10 milligrams per kilogram).
(ii) 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 stage larvae of intestinal worms (thread-necked intestinal worm (Nematodirus spathiger, N. helveticus), 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. Administer as a single oral dose using dosing gun or dosing syringe. 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.
(b)(1) Specifications. The product contains 4.55 percent albendazole.
(2) Sponsor. See No. 000069 in §510.600(c) of this chapter.
(3) Related tolerances. See §556.34 of this chapter.
(4) Conditions of use in sheep—(i) Amount. 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).
(ii) Indications for use. For removal and control of the following internal parasitic...
parasites of sheep: Adult liver flukes (Fasciola hepatica, Fascioloides magna); heads and segments of common tape-worms (Moniezia expansa) and fringed tapeworm (Thysanosoma actinioideis); adult and fourth stage larvae of stomach worms (brown stomach worm (Ostertagia circumcinta and Marshallagia marshallii), barberpole worm (Haemonchus contortus), small stomach worm (Trichostrongylus axei)); adult and fourth stage 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 (Buonostomum phlebotomum), bankrupt worm (Trichostrongylus colubriformis), nodular worm (Oesophagostomum radiatum), and large-mouth bowel worm (Dictyocaulus viviparum). (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.

§ 520.48 Altrenogest solution.

(a) Specifications. Each milliliter of altrenogest solution contains 2.2 milligrams of altrenogest.

(b) Sponsor. See No. 012579 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer orally at the rate of 1 milliliter per 110 pounds body weight (0.044 milligram per kilogram body weight). Give one dose daily for 15 consecutive days.

(2) Indications for use. For suppression of estrus in mares.

(3) Limitations. For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. The drug is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or smoldering uterine inflammation into a fulminating uterine infection in some instances. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) Chemical name. 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.
(b) Specifications. Each tablet contains 0.2 milligram of the drug.
(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.
(d) Conditions of use. (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.
(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Dosage in milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>0.1</td>
</tr>
<tr>
<td>11 to 20</td>
<td>0.2</td>
</tr>
<tr>
<td>21 to 50</td>
<td>0.3</td>
</tr>
<tr>
<td>51 to 100</td>
<td>0.4</td>
</tr>
<tr>
<td>Over 100</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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.
(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) Specifications. The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.
(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.
(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.
(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 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 of amoxicillin.
(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.
(c) Conditions of use. (1) Dogs—(i) Amount. 5 milligrams per pound of body weight, twice a day.
(ii) Indications for use. Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) Specifications. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(1) Conditions of use—(i) Dogs—(A) Amount. 5 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment of bacterial dermatitis due to S. aureus, Streptococcus spp., and P. mirabilis and soft tissue infections (abscesses, wounds, lacerations) due to S. aureus, Streptococcus spp., and P. mirabilis and Staphylococcus spp.

(iii) Limitations. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(b) Sponsor. See Nos. 000031 and 000093 in §510.600(c) of this chapter.

(1) Conditions of use. Dogs—(i) Amount. 5 milligrams per pound of body weight twice daily.

(iii) Limitations. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) Specifications. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(1) Conditions of use—(i) Dogs—(A) Amount. 5 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment of bacterial dermatitis due to S. aureus, Streptococcus spp., and P. mirabilis and soft tissue infections (abscesses, wounds, lacerations) due to S. aureus, Streptococcus spp., and P. mirabilis and Staphylococcus spp.

(iii) Limitations. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.88c Amoxicillin trihydrate oral suspension.

(a) Specifications. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.510 of this chapter.

(d) Conditions of use. Swine—(1) Amount. 40 milligrams orally, twice a day using a dosing pump.

(2) Indications for use. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by Escherichia coli susceptible to amoxicillin.

(3) Limitations. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. 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.

§ 520.88d Amoxicillin trihydrate soluble powder.

(a) Specifications. Each gram contains amoxicillin trihydrate equivalent to 115.4 milligrams of amoxicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.38 of this chapter.

(d) Conditions of use. Preruminating calves including veal calves—(1) Amount. 400 milligrams per 100 pounds of body weight twice daily.

(2) Indications for use. Treatment of bacterial enteritis when due to susceptible Escherichia coli in preruminating calves including veal calves.

(3) Limitations. For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. 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.

§ 520.88e Amoxicillin trihydrate boluses.

(a) Specifications. Each bolus contains the equivalent of 400 milligrams of amoxicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.38 of this chapter.

(d) Conditions of use. Preruminating calves including veal calves—(1) Amount. 400 milligrams per 100 pounds of body weight twice daily.

(2) Indications for use. Treatment of bacterial enteritis when due to susceptible Escherichia coli in preruminating calves including veal calves.

(3) Limitations. For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days. 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.

§ 520.88f Amoxicillin trihydrate tablets.

(a) Specifications. Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams of amoxicillin.

(b) Sponsor. See Nos. 000031 or 000093 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 5 milligrams per pound of body weight twice a day.

(ii) Indications for use. 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.


§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

(a) Specifications. Each tablet contains amoxicillin trihydrate and clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.

(b) Sponsor. See No. 000069 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.

(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 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. Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. 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.

(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 Staphylococcus aureus, nonbeta-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. Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


§ 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. 000069 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.

(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. Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. 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 of amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(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. Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and reevaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. 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]

§ 520.90b Ampicillin trihydrate tablets.

(a) Specifications. Each tablet contains 50 or 100 milligrams of ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. 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
§ 520.90c  Ampicillin trihydrate capsules.

(a) Specifications. Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

(b) Sponsor. See No. 055529 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. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. 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.

(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. The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. 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 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]
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 (septicaemia) 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. 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. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


(iii) Limitations. 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. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.90e Ampicillin trihydrate 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. For use in swine only. Not for use in other animals which are raised for food production. 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.

§ 520.90f Ampicillin trihydrate boluses.

(a) Specifications. Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

(b) Sponsor. See No. 055529 in § 510.600(c) of this chapter for use as in paragraph (d)(1), 000089 for use as in paragraph (d)(2).

(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.


(ii) Limitations. Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) Chemical name. 1-(4-Amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolininium chloride hydrochloride.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.50 of this chapter.

(d) Conditions of use. It is used in drinking water as follows:

(1) Chickens and turkeys—(i) Amount. 20 percent soluble powder.

(ii) Indications for use. Treatment of coccidiosis.

(iii) Limitations. Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-mediated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) Calves—(i) Amount. 9.6 percent solution or 20 percent soluble powder.

(a) Indications for use. As an aid in the treatment of coccidiosis caused by Eimeria bovis and E. zurnii.

(b) Limitations. Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) Amount. 9.6 percent solution or 20 percent soluble powder.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria bovis and E. zurnii.

(b) Limitations. Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

§ 520.100b Amprolium drench.

(a) Chemical name. 1-(4-Amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolininium chloride hydrochloride.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.50 of this chapter.

(d) Conditions of use. It is used for calves as follows:

(1) Calves—(i) Amount. 9.6 percent solution or 20 percent soluble powder.

(a) Indications for use. As an aid in the treatment of coccidiosis caused by Eimeria bovis and E. zurnii.

(b) Limitations. Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment;
when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) Amount. 9.6 percent solution or 20 percent soluble powder.

(i) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria bovis and E. zurnii.

(ii) Limitations. Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.100c Amprolium crumbles.

(a) Specifications. Amprolium crumbles contain 1.25 percent amprolium.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.50 of this chapter.

(d) Conditions of use. It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) Amount. 1.6 ounces of crumbles per 250 pounds of body weight per day (5 milligrams per kilogram of body weight).

(ii) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria bovis and E. zurnii.

(ii) Limitations. Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) Amount. 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

(i) Indications for use. As an aid in the treatment of coccidiosis caused by Eimeria bovis and E. zurnii.

(ii) Limitations. Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination should be done by a veterinarian or diagnostic laboratory before treatment. When treating outbreaks, the drug should be administered promptly after diagnosis is determined. Withdraw 24 hours before slaughter. Use as sole source of amprolium.


§ 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. 000986 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.52 of this chapter.

(d) Conditions of use. (1) In swine for control of porcine colibacillosis (weanling pig scours) caused by strains of E. coli sensitive to apramycin.

(2) It is administered for 7 days in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day. Swine will normally consume 1 gallon per day of medicated water containing 375 milligrams of apramycin for each 66 pounds of body weight. Water consumption should be monitored to determine that the required amount of apramycin is being consumed. The drug concentration should be adjusted according to water consumption which varies depending on ambient temperature, humidity, and other factors.

(3) Prepare fresh medicated water daily.

(4) Do not slaughter treated swine for 28 days following treatment.


§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Soluble bacitracin methylene disalicylate.

(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
§ 520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.

(a) Specifications. Each gram contains 200 units of soluble bacitracin methylene disalicylate, streptomycin sulfate equivalent to 20 milligrams of streptomycin, and 850 milligrams of carob flour.

(b) Sponsor. See No. 062925 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs—(1) Amount. 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. Treatment of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin zinc. See §510.154c of this chapter.

§ 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. 010042 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]

§ 520.154b Bacitracin activity for use as in paragraph (d)(3) of this section.

(b) Sponsor. See No. 046573 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 per gallon in drinking water.

(ii) Indications for use. Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) Limitations. Prepare a fresh solution daily.

(2) Broiler chickens—(i) Amount. 100 milligrams per gallon in drinking water.

(A) Indications for use. Aid in the prevention of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin methylene disalicylate.

(B) Limitations. Prepare a fresh solution daily.

(ii) Amount. 200 to 400 milligrams per gallon in drinking water.

(A) Indications for use. Aid in the control of necrotic enteritis caused by C. perfringens susceptible to bacitracin methylene disalicylate.

(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 Treponema hydysenteriae. 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.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]
§ 520.182 Bicyclohexlammonium fumagillin.

(a) Specifications. The drug is a soluble powder containing bicyclohexlammonium fumagillin and appropriate phosphate buffers.

(b) Sponsor. See No. 059620 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the prevention of nosema in honey bees.1

(2) It is administered usually in a 2:1 sugar syrup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar syrup.1

(3) Colonies used for package production should be fed medicated syrup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.1

(4) The medicated syrup should not be fed immediately before or during the honey flow.


§ 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 taeniaformis.

(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.


§ 520.246 Butorphanol tartrate tablets.

(a) Specifications. Each tablet contains 1, 5, or 10 milligrams of butorphanol base activity as butorphanol tartrate.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is used for the treatment of dogs as follows:

(1) Amount. 0.25 milligram of butorphanol base activity per pound of body weight.

(2) 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.

(3) Limitations. For oral use in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to a maximum of 0.5 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 14702, Apr. 6, 1982, as amended at 53 FR 28851, July 25, 1988]

§ 520.260 n-Butyl chloride capsules.

(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...
§ 520.260

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1 These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.

cat) 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 $\frac{1}{2}$ 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. 000115 or 012983 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 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 $\frac{1}{2}$ 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 1$\frac{1}{4}$ 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 2$\frac{1}{2}$ pounds body weight. Capsules containing 884 or 1,768 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. 

(c)(1) Specifications. n-Butyl chloride capsules, veterinary contain 884 or 1,768 milligrams or 4.42 grams of n-butyl chloride in each capsule.
(2) Sponsor. See No. 000115 in §510.600(c) of this chapter.

(3) Conditions of use. (i) It is used for the removal of ascarids (Toxocara canis and Toxascarls leonina) and hookworms (Anyclostoma caninum, Anyclostoma braziliense, and Uncinarls 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 rations may be resumed 4 to 8 hours after treatment.

(b) The drug is administered orally to dogs. Capsules containing 884 milligrams of n-butyl chloride are administered to dogs as follows: weighing under 5 pounds, 1 capsule; weighing 5-10 pounds, 2 capsules; weighing 10-20 pounds, 3 capsules; weighing 20-40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 miliograms of n-butyl chloride are administered at a dosage level of 1 capsule per dog to dogs weighing 5-10 pounds and 2 capsules per dog to dogs weighing 20-40 pounds. Capsules containing 4,42 grams of n-butyl chloride are administered at dosage level of 1 capsule per dog to dogs weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.


§ 520.300b Cambendazole oral dosage forms.

§ 520.300a 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. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascarls); pinworms (Oxyuris); and threadworms (Strongyloides).

(2) It is administered 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).

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(b) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascarls); pinworms (Oxyuris); and threadworms (Strongyloides).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(c) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascarls); pinworms (Oxyuris); and threadworms (Strongyloides).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 520.300c Cambendazole paste.

(a) Specifications. The drug is a paste containing 45 percent cambendazole.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used in horses 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).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 520.309 Carprofen caplets.

(a) Specifications. Each caplet contains 25, 75, or 100 milligrams of carprofen.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Amount. One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.

(2) Indications for use. For relief of pain and inflammation in dogs. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs.


[43 FR 55385, Nov. 28, 1978]
Food and Drug Administration, HHS

§ 520.315 Cefadroxil powder for oral suspension.

(a) Specifications. Cefadroxil powder is reconstituted to form a 50 milligram-per-milliliter aqueous suspension.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) For use in dogs as follows:

(i) Indications for use. For treating genitourinary tract infections (cystitis) caused by susceptible strains of Escherichia coli, Proteus mirabilis, and Staphylococcus aureus; and skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses caused by susceptible strains of Staphylococcus aureus.

(ii) Amount. 10 milligrams per pound of body weight, twice daily.

(2) For use in cats as follows:

(i) Indications for use. For treating skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of Pasteurella multocida, Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus spp.

(ii) Amount. 10 milligrams per pound of body weight, once daily.

(3) Limitations. Discard unused portion of reconstituted product after 14 days. Treatment should continue for 48 hours after animal is afebrile or asymptomatic. If no response after 3 days, discontinue treatment and re-evaluate therapy. Not for use in animals raised for food production. Safe use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 FR 27344, July 20, 1988]
§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) Specifications. Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) Sponsor. In §510.600(c) of this chapter: No. 0000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-, and 500-milligram tablets; No. 017030 for 100-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) Conditions of use. Dogs—(i) Amount. 25 milligrams per pound of body weight every 6 hours.


(iii) Limitations. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis. Not for animals that are raised for food production. Chloramphenicol should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery. Chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.390b Chloramphenicol capsules.

(a) Specifications. Each capsule contains 50, 100, 250, or 500 milligrams of chloramphenicol.

(b)(1) Sponsor. (1) For chloramphenicol capsules containing 50, 100, 250, or 500 milligrams of chloramphenicol see Nos. 000069, 000185, and 027454 in §510.600(c) of this chapter.

(2) For chloramphenicol capsules containing 100 or 250 milligrams of chloramphenicol see No. 058034 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs—(1) Amount. 25 milligrams per pound of body weight every 6 hours.


(3) Limitations. Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. This product 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.

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) Specifications. Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

(b) Sponsor. See No. 000856 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.\footnote{These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.}

§ 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.\footnote{[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]}


(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.\footnote{[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]}

(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.\footnote{[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]}

(ii) Indications for use. For use in cattle as an aid in reduction of postparturient udder edema.\footnote{[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]}

(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.\footnote{[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]}

§ 520.434 Chlorphenesin carbamate tablets.

(a) Specifications. Each tablet contains 400 milligrams of chlorphenesin carbamate.

(b) Sponsor. See No. 000009 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.

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§ 520.445  Chlortetracycline oral dosage forms.

§ 520.445a  Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.

(a) Specifications. Each pound contains chlortetracycline bisulfate equivalent to 102.4 grams of chlortetracycline hydrochloride with sulfamethazine bisulfate equivalent to 102.4 grams of sulfamethazine.

(b) Sponsor. See No. 010042 in §510.600(c) of this chapter.

(c) Related tolerances. See §§556.150 and 556.670 of this chapter.

(d) Conditions of use. Swine—Used in drinking water as follows:

(1) Amount. 250 milligrams of chlortetracycline with 250 milligrams of sulfamethazine per gallon.

(2) Indications for use. Prevention and treatment of bacterial enteritis; aid in the reduction of the incidence of cervical abscesses; aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) Limitations. Not to be used for more than 28 consecutive days; withdraw 15 days before slaughter; as sole source of chlortetracycline and sulfonamide.

[57 FR 37323, Aug. 18, 1992]

§ 520.445b  Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).

(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) Sponsor. See No. 053389 in §510.600(c) of this chapter for conditions of use as in paragraphs (d)(1)(i)(A) and (d)(2)(ii)(A) of this section; No. 010042 for conditions of use as in paragraph (d)(4) of this section; No. 000010 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) through (iv) of this section; Nos. 017519 and 059130 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) and (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.


(2) Limitations. Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 5 days of treatment.

(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...
A. pleuropneumoniae

fever) associated with Pasteurella spp., A. pleuropneumoniae (Hemophilus 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.

(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.

(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.

(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.

(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.

(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 (Hemophilus spp.), and Klebsiella spp.

(C) Limitations. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days; for 012286, 053389, and 054273 do not slaughter animals for food within 5 days of treatment; for 010042 do not slaughter animals for food within 24 hours of treatment.

(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 (Hemophilus 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.

3070.618-11

§ 520.445b

Food and Drug Administration, HHS

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§ 520.445c Chlorotetracycline tablets and boluses.

(a) Specifications. Each tablet/bolus contains 25, 250, or 500 milligrams of chlortetracycline hydrochloride.

(b) Sponsors. See No. 000010 in §510.600(c) of this chapter for the 250-milligram chlortetracycline hydrochloride bolus; see No. 010042 for the 25-milligram tablet and the 500 milligram bolus.

(c) Related tolerances. See §556.150 of this chapter.

(d) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use specified in this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter but may require bioequivalency and safety information.

(e) Conditions of use. Calves—(1) Amount. One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.


(ii) Limitations. Administer bolus 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.

(2) Amount. One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.


(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.

(3) Amount. One 25 milligram tablet per 5 pounds of body weight every 12 hours daily for 3 to 5 days.


(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; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

§ 520.446 Clindamycin hydrochloride capsules.

(a) Specifications. Each capsule contains the equivalent of 25, 75, or 150 milligrams of clindamycin as the hydrated hydrochloride salt.

(b) Sponsor. No 000009 in §530.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) Indications for use. For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of Staphylococcus aureus, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum, and Clostridium perfringens.

(3) Limitations. Wound infections, abscesses, and dental infections: Do not
use more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, and horses. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian. (d) Conditions of use in cats—(1) Amount. 5.0 to 10.0 milligrams per pound of body weight every 24 hours for a maximum of 14 days (11 to 22 milligrams per kilogram of body weight per day). (2) Indications for use. Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of Staphylococcus aureus, S. intermedius, and Streptococcus spp. Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of Clostridium perfringens and Bacteroides fragilis. (3) Limitations. Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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).

§ 520.447 Clindamycin hydrochloride liquid.

(a) Specifications. Each milliliter of 8.64 percent alcoholic solution contains the equivalent of 25 milligrams of clindamycin (as the hydrochloride).
(b) Sponsor. See No. 000009 in §510.600(c) of this chapter for use as in paragraphs (c) and (d) of this section. See No. 059130 for use as in paragraph (c) of this section.
(c) Conditions of use in dogs—(1) Amount. Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.
(2) Indications for use. For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of Staphylococcus aureus and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum, and Clostridium perfringens.
(3) Limitations. Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.530 Cythioate oral liquid.

(a) Specifications. Each milliliter contains 15 milligrams of cythioate.

(b) Sponsor. See Nos. 000059 and 010042 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. For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.531 Cythioate tablets.

(a) [Reserved]

(b) Sponsors. See No. 000059 in §510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 010042 in §510.600(c) of this chapter for use of 30-mg tablet.

(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. 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. For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) Specifications. Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Special considerations. Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy 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.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) Clinical and experimental data have 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) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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.
Conditions of use. (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (cushingoid syndrome), except for emergency therapy.

(v) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection 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.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Sponsors. See Nos. 000061 and 050604 in §510.600(c) of this chapter.

Conditions of use—(1) Amount. Dogs: Administer orally at 0.25 to 1.25 milligrams per day for up to 7 days. Cats: 0.125 to 0.5 milligram per day for up to 7 days.

(ii) Indications for use. In treatment of dogs and cats as an anti-inflammatory agent.

(iii) Limitations. (a) Clinical and experimental data have 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 they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers, except for emergency therapy.

(c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 520.550  
(iv) 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]

§ 520.550 Dextrose/glycine/electrolyte.  
(a) Specifications. The product is distributed in packets each of which contains the following ingredients: sodium chloride 8.82 grams, potassium phosphate 4.20 grams, citric acid anhydrous 0.5 gram, potassium citrate 0.12 gram, aminoacetic acid (glycine) 6.36 grams, and dextrose 44.0 grams.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Dextrose/glycine/electrolyte is indicated for use in the control of dehydration associated with diarrhea (scours) in calves. It is used as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(2) Dissolve each packet in two 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.

(3) The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. Oral therapy in these cases is too slow. Animals which cannot drink after initial intravenous therapy may need to be dosed with a stomach tube or enema. Adequate colostrom intake during the first 12 hours is essential for healthy, vigorous calves.

Antibacterial therapy is often indicated in bacterial scours due to E. coli and/or Salmonella. The product does not contain antibacterial agents. A veterinarian should be consulted in severely scouring calves or cases requiring antibacterial therapy. 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.


§ 520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.  
(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. 053501 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats.

(2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(3) 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]

§ 520.580 Dichlorophene and toluene capsules.  
(a) Specifications. Each soft gelatin capsule contains 50 milligrams of dichlorophene and 60 milligrams of toluene or multiples thereof.

(b) Sponsor. (1) For single dose only, see 000010, 000015, 000842, 011615, 015563, 017135, 023851, 049968, 050906, and 058670 in §510.600(c) of this chapter.

(2) For single and multiple dose, see 000010, 000061, and 038782 in §510.600(c) of this chapter.

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
§ 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—(1) Amount. Single dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per pound of body weight.1

(ii) Divided dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per 5 pounds of body weight (20 and 24 milligrams per pound) daily for 6 days.1

(2) Indications for use. It is used 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.1

(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 re-infection.1

[45 FR 10332, Feb. 15, 1980]

EDITORIAL NOTE: For Federal Register citations affecting §520.580, see the List of CFR Sections Affected in the Table of Federal Register Sections Affected resulting from the enactment of the Government Printing Office. VerDate 09<APR>98 11:31 Apr 28, 1998 Jkt 179071 PO 00000 Frm 00111 Fmt 8010 Sfmt 8010 Y:\SGML\179071.TXT 179071-3

§ 520.600 Dichlorvos.

(a) Chemical name. 2,2-Dichlorovinyl dimethyl phosphate.

(b) [Reserved]

(c) Sponsor. See No. 000010 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:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Pounds of feed to be mixed with each 0.08 ounce of dichlorvos</th>
<th>Pounds of mixed feed to be administered to each pig as a single treatment</th>
<th>Number of pigs to be treated per 0.08 ounce of dichlorvos</th>
</tr>
</thead>
<tbody>
<tr>
<td>20±30</td>
<td>4</td>
<td>0.33</td>
<td>12</td>
</tr>
<tr>
<td>31±40</td>
<td>5</td>
<td>0.56</td>
<td>9</td>
</tr>
<tr>
<td>41±60</td>
<td>6</td>
<td>1.00</td>
<td>6</td>
</tr>
<tr>
<td>61±80</td>
<td>5</td>
<td>1.00</td>
<td>5</td>
</tr>
<tr>
<td>81±100</td>
<td>4</td>
<td>1.00</td>
<td>4</td>
</tr>
<tr>
<td>Adult Gilts, Sows, and Boars</td>
<td>16</td>
<td>4.00</td>
<td>4</td>
</tr>
</tbody>
</table>

(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 scour 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 *Trichuris 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*, *Clycloecercus*, *Clycloccyclus*, *Clycoidontophorus*, *Triodontophorus*, *Poteriomum*, *Gyalocephalus*), pinworms (*Oxyurus equi*), and large roundworms (*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 bots (Gastrophilus intestinalis and *G. nasalis*), large strongyles (*Strongylus vulgaris*, *S. equinus*, and *S. edentatus*), small strongyles (of the genera *Cyathostomum*, *Clycloecercus*, *Clycloccyclus*, *Clycoidontophorus*, *Triodontophorus*, *Poteriomum*, *Gyalocephalus*), pinworms (*Oxyurus equi*), and large roundworms (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(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 severely 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 cats and puppies.

(1) It is indicated for the removal and control of roundworms (Toxocara canis, Toxocara cati, Toxascaris leonina) and hookworms (Ancylostoma caninum, Ancylostoma tubaeforme, Uncinaria stenocephala) occurring in the intestinal tracts of cats and puppies.

(2) The drug is in tablet form and is administered orally at a dosage level of 5 mg of the active ingredient per pound of body weight.

(3) Do not administer to puppies or cats showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or to animals recently exposed to or showing signs of infectious disease. The drug 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.

(4) Do not use in animals under 10 days of age or under 1 pound of body weight.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) Sponsors. (1) See 015579 in §510.600(c) of this chapter for use of 50, 200, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(2) See 053501 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 050604 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 and as an aid in the treatment of ascarid infections in dogs.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.608 Dicloxacillin sodium monohydrate capsules.

(a) Specifications. Each capsule contains dicloxacillin sodium monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin.

(b) Sponsor. See No. 008856 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs—(1) Amount. 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. Treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to the drug.

(3) Limitations. For the treatment of dogs only. Continue treatment for 24 to 48 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours before feeding to ensure maximum absorption. 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.

[57 FR 37325, Aug. 18, 1992]
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.

(3) See §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.

(4) See §510.600(c) of this chapter for use of 50, 100, 200, 300, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(5) See 000081 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 000010 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 and indications for use. (i) The drug is administered immediately after feeding.

(ii) Three milligrams per pound of body weight preferably 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 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.

(2) Sponsor. See No. 017030 for use as in paragraphs (b)(3)(ii)(a) and (b)(3)(iii)(c) of this section.

(ii) See No. 017030 for use as in paragraphs (b)(3)(ii)(a) and (c) of this section.

(3) Conditions of use—(i) Amount. 3 milligrams per pound of body weight
per day for prevention of heartworm disease and as an aid in control of large roundworms; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(ii) Indications for use. (a) For prevention of heartworm disease (Dirofilaria immitis) in dogs.
(b) As an aid in control of large roundworms (T. canis) in dogs.
(c) As an aid in treatment of ascarid infections in dogs (T. canis) and cats (T. canis and T. leonina).

(iii) Limitations. The drug may be placed on the daily ration or given directly by mouth. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestines from the lungs after the first dose. Older dogs should be proven negative for presence of Dirofilaria immitis infections before administering the drug. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start 1 month before the mosquito season and be continued daily throughout the mosquito season and for 2 months thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 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) For 015579, use of 30 or 120 milligram tablets as in paragraph (c)(2)(i) of this section.

(2) For 000069, 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 050604, 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.

(7) [Reserved]

(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. Tablets are administered orally or pulverized and given in the feed. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion or shock. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. 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 in the Finding Aids section of this volume.

§ 520.622d Diethylcarbamazine citrate capsules.

(a)(1) Specifications. Each capsule contains either 12.5, 50, 200, or 400 milligrams of diethylcarbamazine citrate.

(2) Sponsor. See 011014 in §510.600(c) of this chapter.

(3) Conditions of use—(i) Amount/indications for use. 3 milligrams per pound of body weight daily for prevention of heartworm disease (Dirofilaria immitis) in dogs.

(ii) Limitations. Administer orally directly or added to the daily ration. For ascarid infections, repeat treatment in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.623 Diethylcarbamazine citrate, 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 000069 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).

(d) Limitations. Orally administer daily during heartworm season. For free-choice feeding or broken and placed on or mixed with feed. Do not use in dogs that may harbor adult heartworms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.645 Difloxacin.

(a) Specifications. Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Dogs—(i) Amount. 5 to 10 mg per kilogram (2.3 to 4.6 mg/pound) of body weight.

(ii) Indications for use. For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) Limitations. Use once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days. 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]

§ 520.763a Dithiazanine iodide tablets.

§ 520.763a Dithiazanine iodide tablets.

(a) Chemical name. 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene) - 1,3 - pentadienyl]-benzothiazolium iodide.

(b) Specifications. Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

(c) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

<table>
<thead>
<tr>
<th>Parasites</th>
<th>Milligrams per pound of body weight</th>
<th>Length of treatment—days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large roundworms (Toxocara canis, Toxascaris leonina)</td>
<td>10</td>
<td>3–5</td>
</tr>
<tr>
<td>Hookworms (Ancylostoma caninum, Uncinaria stenocephala)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Whipworms (Trichuris vulpis)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Strongylodes (Strongylodes canis, Strongylodes stercoralis)</td>
<td>10</td>
<td>10–12</td>
</tr>
<tr>
<td>Heartworm microfilariae (Dirofilaria immitis)</td>
<td>3–5</td>
<td>7–10</td>
</tr>
</tbody>
</table>

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongylodes as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111
§ 520.763b Dithiazanine iodide powder.

(a) Chemical name. 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinylidene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) Specifications. Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(d) Conditions of use. (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

<table>
<thead>
<tr>
<th>Parasite</th>
<th>Milligrams per pound of body weight</th>
<th>Length of treatment—days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large roundworms (Toxocara canis, Toxascaris leonina)</td>
<td>10</td>
<td>3-5</td>
</tr>
<tr>
<td>Hookworms (Ancylostoma caninum, Uncinaria stenocephala)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Whipworms (Trichuris vulpis)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Strongyloides (Strongyloides canis, Strongyloides stercoralis)</td>
<td>10</td>
<td>10-12</td>
</tr>
<tr>
<td>Heartworm microfilariae (Dirofilaria immitus)</td>
<td>3-5</td>
<td>7-10</td>
</tr>
</tbody>
</table>

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) Specifications. Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams of piperazine base (as piperazine citrate).

(b) Sponsor. See 000010 in §510.600(c) of this chapter.

(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use—(1) Amount. 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; ¼ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10 1/4 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.”

§ 520.784  Doxylamine succinate tablets.

(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) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹


§ 520.804  Enalapril tablets.

(a) Specifications. Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.

(ii) Indications for use. Treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

(iii) Limitations. Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2-week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvar disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


§ 520.812  Enrofloxacin tablets.

(a) Specifications. Each tablet contains either 5.7, 22.7, or 68.0 milligrams of enrofloxacin.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Amount. 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(ii) Indications for use. Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(iii) Limitations. Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.813  Enrofloxacin oral solution.

(a) Specifications. Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.228 of this chapter.

(d) Conditions of use. It is used in drinking water as follows:

(1) Chickens and turkeys—(i) Amount. 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) Indications. Chickens: Control of mortality associated with Escherichia coli susceptible to enrofloxacin. Turkeys: Control of mortality associated with E. coli and Pasteurella multocida (fowl cholera) susceptible to enrofloxacin.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.
(iii) Limitations. Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 520.816 Epsiprantel tablets.

(a) Specifications. Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 2.5 milligrams per pound of body weight.


(2) Cats—(i) Amount. 1.25 milligrams per pound of body weight.


(3) Limitations. For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.823 Erythromycin phosphate.

(a) Specifications. Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of Streptomyces erythreus or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) Sponsor. See No. 050604 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. 0.500 gram per gallon.

(ii) Indications for use. As an aid in the control of chronic respiratory disease due to Mycoplasma gallisepticum susceptible to erythromycin.

(iii) Limitations. Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(2) Replacement chickens and chicken breeders—(i) Amount. 0.500 gram per gallon.

(ii) Indications for use. As an aid in the control of infectious coryza due to Hemophilus gallinarum susceptible to erythromycin.

(iii) Limitations. Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) Growing turkeys—(i) Amount. 0.500 gram per gallon.

(ii) Indications for use. As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) Limitations. Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980]
§ 520.863 Ethylisobutrazine hydrochloride tablets.

(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. (1) It is administered orally to dogs as a tranquilizer.\(^1\)

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.\(^1\)

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.\(^1\)

(d) Federal law restricts this drug to use by or on the order of a licensed veterinarian.\(^1\)


§ 520.903b Febantel suspension.

(a) Specifications. The suspension contains 9.3 percent (2.75 grams per ounce) febantel.

(b) Sponsor. See 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Six milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight).

(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 the various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

(3) Limitations. 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. Not for use in horses intended for food. 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
§ 520.903c  Febantel-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) and ascarids (Toxocara cati) and tapeworms (Dipylidium caninum and Taenia taeniaeformis).

(3) Limitations. Do not use in pregnant animals. Consider alternative therapy or use with caution in animals with preexisting liver or kidney dysfunction. Administer to puppies and kittens on a full stomach. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 50655, Oct. 8, 1991]

§ 520.905 Fenbendazole oral dosage forms.

§ 520.905a Fenbendazole suspension.

(a) Chemical name. Carbamic acid, [5-(phenylthio)-1H-benzoimidazol-2-yl]-methyl ester.

(b) Specifications. The drug is a suspension containing 10 percent (100 milligrams per milliliter) fenbendazole.

(c) Sponsor. See No. 012799 in §510.600(c) of this chapter.

(d) Conditions of use—(1) Horses—(i) Amount. 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram 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 orally by dose syringe or suitable plastic syringe. Do not use in horses intended for
food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) Beef and dairy cattle—(i) Amount. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(A) Indications for use. For the removal and control of lungworm (Dictyocaulus viviparous); 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 (Bushonstomum phlebotomum), threadnecked intestinal worm (Nematodirus helvetianus), small intestinal worm (Cooperia punctata and C. oncophora), bankrupt worm (Trichostrongylus colubriformis), and nodular worm (Oesophagostomum radiatum).

(B) Limitations. Treatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii) Amount. Administer orally 10 milligrams per kilogram of body weight.

(A) For the removal and control of stomach worm (4th-stage inhibited larvae) (type II ostertagiasis), Ostertagia ostertagi, and tapeworm, Moniezia benedeni.

(B) Limitations. Treatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Goats—(i) Amount. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) Indications for use. For the removal and control of stomach and intestinal worms Haemonchus contortus and Ostertagia circumcincta.

(iii) Limitations. Treatment may be needed after 4 to 6 weeks. Goats must not be slaughtered for food within 6 days following last treatment. Do not use in lactating goats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Special considerations. Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (d) 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.

§520.905b Fenbendazole granules.

(a) Specifications. The drug is in granular form containing 22 percent (222 milligrams per gram) fenbendazole.

(b) Sponsor. See No. 012799 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Horses—(i) Amount. 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram for the control of 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 (Parasascaris equorum).

(iii) Limitations. For the control of infections of stomach bot as provided in §520.2520, have been shown to be compatible and not to interfere with one another.

§ 520.905c Fenbendazole paste.

(a) Specifications. The product is an aqueous paste containing 10 percent fenbendazole.

(b) Sponsor. See No. 012799 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.275 of this chapter.

(d) Conditions of use—(1) Horses—(i) Amount. 2.3 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 1,100-pound horse). For foals and weanlings (less than 18 months of age), 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for each 550 pounds of body weight).

(ii) Indications for use. For control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris), small strongyles, pinworms (Oxyuris equi), and ascarids (Parascaris equorum) in horses.

(c) Limitations. Retreatment at intervals of 6 to 8 weeks may be required. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii)(a) Amount. 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 550-pound horse) daily for 5 days.

(d) Indications for use. For control of arteritis caused by the fourth stage larvae of Strongylus vulgaris.

(c) Limitations. Treatment should be initiated in the spring and repeated in 6 months. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of fourth stage larvae of S. vulgaris.

(2) Beef and dairy cattle—(i) Amount. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) Indications for use. For the removal and control of lungworm (Dictyocaulus viviparus), barberpole worm (Haemonchus contortus), brown stomach worm (Ostertagia ostertagi), small stomach worm (Trichostrongylus axei), hookworm (Bunostomum phlebotomum), thread-necked intestinal worm (Nematodirus helvetianus), small intestinal worms (Cooperia punctata and C. oncophora), bankrupt worm (Trichostrongylus colubriformis), and nodular worm (Oesophagostomum radiatum).

(iii) Limitations. Re-treatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(e) Special considerations. Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (d)(1)(i) of this section.
section and for treating infections of stomach bots as provided in §520.2520.


§ 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. 012799 in §510.600(c) of this chapter for use of the 4-percent product.

(2) See No. 017800 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—(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.


§ 520.960 Flumethasone tablets.

(a) Specifications. Each tablet contains 0.0625 milligram of flumethasone.

(b) Sponsor. See No. 000856 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.

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§ 520.970 Flunixin oral dosage forms.

§ 520.970a Flunixin meglumine granules.

(a) Specifications. Each 10-gram packet contains flunixin meglumine equivalent to 250 milligrams of flunixin.

(b) Sponsor. No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.5 milligram of flunixin per pound of body weight (one packet per 500 pounds) per day.

(2) Indications for use. For alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

(3) Limitations. Administer daily dose for up to 5 days by sprinkling on small amount of feed. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.970b Flunixin meglumine paste.

(a) Specifications. Each 30-gram syringe contains flunixin meglumine equivalent to 1,500 milligrams of flunixin.

(b) Sponsor. No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.5 milligram of flunixin per pound of body weight daily.

(2) Indications for use. For alleviation of inflammation and pain associated with musculoskeletal disorders.

(3) Limitations. For oral use only. Treatment should not exceed 5 consecutive days. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1010 Furosemide oral dosage forms.

§ 520.1010a Furosemide tablets or boluses.

(a) Specifications. Each tablet contains 12.5 or 50 milligrams of furosemide. Each bolus contains 2 grams of furosemide.

(b) Sponsor. See No. 012799 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (c) (1) and (2) of this section; see No. 000010 in § 510.600(c) of this chapter for use in dogs as provided for in paragraph (c)(1) of this section; see No. 000093 in § 510.600(c) of this chapter for use of a 12.5- and 50-milligram tablet for conditions of use provided for in paragraph (c)(3) of this section.

(c) Conditions of use. It is used as follows:

(1) Dogs and cats—(i) Amount. 1 to 2 milligrams per pound of body weight, once or twice daily, with a 6- to 8-hour interval between successive daily doses.

(ii) Indications for use. It is used for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute non-inflammatory tissue edema.

(iii) Limitations. The dosage should be adjusted to the animal’s response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound.
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of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema, or when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. The drug, if given in excessive amounts or over extended periods of time, may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1010b Furosemide powder.
(a) Specifications. Furosemide powder is packaged in packets containing 2 grams of furosemide plus other inert ingredients.
(b) Sponsor. See No. 012799 in §510.600(c) of this chapter.
(c) Conditions of use.
(1) Amount. 1 to 2 milligrams per pound of body weight, but not to exceed one packet per animal, per day.
(2) Indications for use. The drug is used for the treatment of physiological parturient edema of the mammary gland and associated structures.
(3) Limitations. Treatment not to exceed 48 hours post-parturition. For oral use only. The individual dose is one packet administered once daily; when treatment is initiated with an injectable, at least a 12-hour interval must follow before oral administration. 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. The drug, if given in excessive amounts or over extended periods of time, may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1010c Furosemide syrup.
(a) Specifications. Each milliliter of syrup contains 10 milligrams of furosemide.
(b) Sponsor. See No. 012799 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Amount. 1 to 2 milliliters orally (10 to 20 milligrams)
per 10 pounds of body weight (approximately 2.5 to 5 milligrams per kilogram), once or twice daily, with a 6 to 8-hour interval between successive daily doses.

(2) Indications for use. It is used in dogs for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(3) Limitations. The dosage should be adjusted to the animal’s response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema or, when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. If given in excessive amounts or over extended periods of time, the drug may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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 051259 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.

§ 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 059130 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.

§ 520.1044c Gentamicin sulfate soluble powder.

(a) Specifications. Each gram of gentamicin sulfate soluble powder contains gentamicin sulfate equivalent to 16.7, 66.7, or 333.3 milligrams of gentamicin.

(b) Sponsor. See Nos. 000061 and 057561 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 swine dysentery associated with T. hyodysenteriae.

(3) Limitations. For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 3 days following treatment.

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(gentamicin per gallon of drinking water for 3 consecutive days, to provide 0.5 milligram per pound of body weight per day; swine dysentery: gentamicin sulfate equivalent to 50 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 1 milligram per pound of body weight per 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. For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 10 days following treatment.

§ 520.1100 Griseofulvin.

(a) Chemical name. 7-Chloro-2',4,6-trimethoxy-6-methylspiro [benzofuran-2(3H), 1'-[2-cyclohexene]-3,4'-dione.

(b) Specifications. Complies with U.S.P. for griseofulvin microsize.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) Conditions of use. (1) As a soluble powder for horses, it is administered as a drench or as a top dressing on feed. It is used for equine ringworm infection caused by Trichophyton equinum or Microsporum gypseum. Administer for not less than 10 days a daily dose as follows: Adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

(2)(i) Boluses containing 2.5 grams of griseofulvin are used in horses for treating ringworm infection caused by Trichophyton equinum. It is administered to adult horses at a level of one bolus per day, to yearlings at one-half to one bolus per day, and to foals at one-half bolus per day. All three dosage levels should be administered for a period of not less than 10 days. In responsive cases, treatment should be continued until all infected areas are proven negative by appropriate culture. Not for use in horses intended for food.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Dogs and cats: (i) Amount. 125- and 500-milligram tablets administered orally as follows:

<table>
<thead>
<tr>
<th>Body weight (pounds)</th>
<th>Dosage (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 6</td>
<td>62.5</td>
</tr>
<tr>
<td>6 to 18</td>
<td>125</td>
</tr>
<tr>
<td>18 to 36</td>
<td>250</td>
</tr>
<tr>
<td>36 to 48</td>
<td>375</td>
</tr>
<tr>
<td>48 to 75</td>
<td>500</td>
</tr>
</tbody>
</table>

(ii) 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 x body weight x number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.


(iii) Limitations. For satisfactory diagnosis, a microscopic tissue examination or culture is recommended prior to treatment. Treatment should be continued for 3 to 4 weeks in skin and hair infections, and up to 4 months for infections involving nails or claws. Clipping of hair, nails, and claws to help remove any remaining viable fungi is indicated. Safety for use of griseofulvin for pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) Chemical name. 3-Chloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) Specifications. Haloxon assay of not less than 96 percent by infrared spectrum at 6.92 microns.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) 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.

(e) Related tolerances. See §556.310 of this chapter.

(f) Conditions of use. It is used as a drench as follows:

(i) Amount. 141.5 grams per packet.

(ii) Indications for use. Control of gastrointestinal roundworms of the genera Haemonchus, Ostertagia, Trichostrongylus, and Cooperia.

(iii) Limitations. (a) Dissolve each packet in 32 fluid ounces of water and administer as follows:

<table>
<thead>
<tr>
<th>Weight of animal (pounds)</th>
<th>Dose (fluid ounces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 100</td>
<td>1/2</td>
</tr>
<tr>
<td>100 to 150</td>
<td>1/5</td>
</tr>
<tr>
<td>150 to 200</td>
<td>2</td>
</tr>
<tr>
<td>200 to 300</td>
<td>3</td>
</tr>
<tr>
<td>300 to 450</td>
<td>4</td>
</tr>
<tr>
<td>450 to 700</td>
<td>5</td>
</tr>
<tr>
<td>700 to 1,000</td>
<td>6</td>
</tr>
<tr>
<td>1,000 to 1,200</td>
<td>7</td>
</tr>
<tr>
<td>Over 1,200</td>
<td>8</td>
</tr>
</tbody>
</table>

(b) Do not treat within 1 week of slaughter; do not treat dairy animals of breeding age; animals should be retreated in 3 to 4 weeks.


§ 520.1120b Haloxon boluses.

(a) Chemical name. 3-Chloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) Specifications. Each bolus contains 10.1 grams of haloxon.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) Related tolerances. See §556.310 of this chapter.

(e) Conditions of use. (1) Haloxon bolus is an anthelmintic used in cattle for the control of gastrointestinal roundworms of the genera Haemonchus, Ostertagia, Trichostrongylus and Cooperia.

(2) It is administered by giving one bolus per approximately 500 pounds body weight (35 to 50 milligrams per kilogram of body weight).

(3) For most effective results, retreat animals in 3 to 4 weeks. If reinfection is likely to occur, additional retreatments may be necessary.

(4) Do not use any drug, pesticide or other chemical having cholinesterase inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(5) Do not treat animals within one week of slaughter.

(6) Do not treat dairy animals of breeding age or older.


§ 520.1130 Hetacillin oral dosage forms.

§ 520.1130a Hetacillin potassium capsules.

(a) Specifications. Each capsule contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Dogs—(i) Amount. 5 milligrams per pound of body weight, twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) Limitations. For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1
to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals raised for food production. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

(2) Cats—(i) Amount. Administer 50 milligrams twice daily.

(ii) Indications for use. Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) Limitations. For use in cats only. Not for use in animals raised for food production. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992]

§ 520.1130c Hetacillin potassium tablets.

(a) Specifications. Each tablet contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 5 milligrams per pound of body weight twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment against strains of organisms susceptible to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) Limitations. For use in dogs only. Not for use in animals raised for food production. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals which are raised for food production.
§ 520.1157  
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cats—

(i) Amount. 50 milligrams twice daily.

(ii) Indications for use. Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) Limitations. For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. 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.

[57 FR 37326, Aug. 18, 1992]

§ 520.1157 Iodinated casein tablets.  
(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. ½ 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. If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 75199, Nov. 14, 1980]

§ 520.1158 Iodochlorhydroxyquin boluses.  
(a) Specifications. Each bolus contains 10 grams of iodochlorhydroxyquin.

(b) Sponsor. See No. 050604 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. For horses only; not to be administered to food-producing animals. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1182 Iron dextran oral suspension.

(a) Specifications. Each 1.8 milliliter contains 100 milligrams of elemental iron as ferric hydroxide in complex with a low molecular weight dextran and 0.2 percent phenol as a preservative.

(b) Sponsor. See 017800 in §510.600(c) of this chapter.

(c) Conditions of use—

(1) Amount. 100 milligrams of elemental iron to each pig.

(2) Indications for use. Prevention of iron deficiency anemia in baby pigs.

(3) Limitations. Treat each pig within 24 hours of farrowing. Administer 1.8 milliliters orally by automatic dose dispenser.

[45 FR 75199, Nov. 14, 1980]

§ 520.1192 Ivermectin paste.  
(a) Specifications—

(1) Horses. Paste contains 1.87 percent ivermectin.

(2) Cattle. Paste contains 0.153 percent ivermectin.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use—

(1) Horses—

(i) Amount. 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) Indications for use. It is used in horses for the treatment and control of large strongyles (adult) (Strongylus equinus), (adult and arterial larval stages) (Strongylus vulgaris), (adult and migrating tissue stages) (Strongylus edentatus), (adult) (Triodontophorus spp.); small strongyles, including those resistant to some benzimidazole class
compounds (adult and fourth stage larvae) (Cyathostomum spp., Cyclicoclyclus spp., Cyclicodentobrus spp., Cyclicostephanus spp.); pinworms (adult and fourth stage larvae and adults) (Parascaris equorum); hairworms (adult) (Trichostrongylus axei); large mouth stomach worms (adult) (Habronema muscae); stomach bots (oral and gastric stages) (Gastrophilus 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; and dermatitis caused by neck threadworm microfilariae (Onchocerca spp.).

(iii) Limitations. For oral use only. Do not use in horses intended for food purposes. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 520.1193 Ivermectin tablets and chewables.

(a) Specifications—(1) Dogs. Each tablet or chewable contains 68, 136, or 272 micrograms of ivermectin.

(2) Cats. Each chewable contains 55 or 165 micrograms of ivermectin.

(b) Sponsor. See 050604 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. 6.0 micrograms per kilogram body weight (2.72 micrograms per pound), minimum. For dogs up to 25 pounds, 68 micrograms; dogs 26 to 50 pounds, 136 micrograms; dogs 51 to 100 pounds, 272 micrograms; dogs over 100 pounds, a combination of the appropriate tablets. The drug is administered at monthly dosing intervals.

(2) 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.

(3) Limitations. Use once-a-month. Recommended for dogs 6 weeks of age and older. Initial use within 1 month after first exposure to mosquitoes. Final use within 1 month after last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) Conditions of use in cats—(1) Amount. Up to 2.3 kilograms (up to 5 pounds), 55 micrograms; 2.3 to 6.8 kilograms (5 to 15 pounds), 165 micrograms; over 6.8 kilograms (15 pounds), a combination of the appropriate chewables (recommended minimum dose of 24 micrograms of ivermectin per kilogram of body weight (10.9 micrograms per pound).

(2) 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.

(3) Limitations. For use in cats 6 weeks of age and older. Administer once a month. The initial dose must be given within a month after cats first exposure to mosquitoes. The final dose must be given within a month after the
§ 520.1194 Ivermectin drench.

(a) Specifications. Each milliliter of 0.08 percent (weight per volume) micellar solution contains 0.08 milligram 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—(1) Amount. 3.0 milliliters (2.4 milligrams of ivermectin) per 26 pounds of body weight (or 200 micrograms per kilogram of body weight).

(2) Indications for use. It is used in sheep for the treatment and control of the adult and fourth-stage larvae of the following parasites of sheep: gastrointestinal roundworms (Haemonchus contortus, H. placei (adults only), Oesophagostomum columbianum, O. venulosum (adults only), Nematodirus battus, N. pathiger, Strongylus papillosus (adults only), Chabertia ovina (adults only), Trichuris ovis (adults only)), lungworms (Dictyocaulus filaria); and all larval stages of the nasal bot Oestrus ovis.

(3) Limitations. It is used as a drench in sheep only. Do not treat sheep within 11 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 520.1195 Ivermectin liquid.

(a) Specifications. Each milliliter contains 10 milligrams of ivermectin.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 200 micrograms per kilogram of body weight as a single dose.

(2) Indications for use. It is used in horses for the treatment and control of large strongyles (adult) (Strongylus equinus), (adult and arterial larval stages) (Strongylus vulgaris), (adult and migrating tissue stages) (Strongylus endentatus), (adult) (Triodontophorus spp.); small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (Cyathostomum spp., Cylicocyclus spp., Cylicodontophorus spp., Cystocystus spp.); pinworms (adult and fourth stage larvae) (Oxyuris equi); hairworms (adult) (Trichostrongylus axei); large mouth stomach worms (adult) (Habronema muscae); stomach bots (oral and gastric stages) (Gastrophilus 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; and dermatitis caused by neck threadworm microfilariae (Onchocerca spp.).

(3) Limitations. Administer by stomach tube or as an oral drench. Do not use in horses intended for food purposes. Federal law restricts this drug to us by or on the order of a licensed veterinarian.


§ 520.1196 Ivermectin and pyrantel pamoate chewable tablet.

(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) Sponsor. See 050604 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. A minimum of 6 µg of ivermectin and 5 mg of pyrantel (as pamoate salt) per kilogram (2.72 µg and 2.27 mg per pound) of body weight.

(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. Use monthly. Recommended for dogs 6 weeks of age and older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 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 135 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.

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.

(a) Specifications. Each five milliliters of suspension of the drug contains: 100 milligrams of kanamycin as the sulfate (the kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30 of this chapter), 0.033 milligram of aminopentamide hydrogen sulfate, 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) It is administered orally to dogs for the symptomatic relief of acute bacterial diarrhea caused by kanamycin-susceptible organisms.

(2) The drug is recommended for use at the rate of one teaspoonful (5 milliliters) of suspension per 20 pounds of body weight every 8 hours. Animals weighing under 10 pounds should be given one-half the above amount every 8 hours. The initial dose should be twice the amount of a single dose. Maximum dosage should not exceed three times the recommended dose.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgite tablets.

(a) Specifications. Each tablet contains 100 milligrams of kanamycin (as the sulfate), 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. One tablet per 44 kilograms (20 pounds) of body weight every 8 hours. For animals under 22 kilograms (10 pounds) ½
tablet every 8 hours. The 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 associated diarrhea in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 8710, Mar. 1, 1991]

§ 520.1242 Levamisole hydrochloride oral dosage forms.

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) Chemical name. (-)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazole monohydrochloride.

(b) Specifications. Assay of not less than 98 percent by nonaqueous titration with 0.1N potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) Sponsor. (1) See No. 043781 in §510.600(c) of this chapter for conditions of use provided for in paragraph (f) of this section.

(2) See 000061 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (f)(1) and (2)(ii), and (f)(3) for 16.15 grams per bottle, of this section.

(d) [Reserved]

(e) Related tolerances. Section 556.350 of this chapter.

(f) Conditions of use. It is used as follows:

(1) Cattle—(i) Amount. 46.8 grams per packet.

(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. Dissolve in water to provide 32 fluid ounces of drench solution and administer as a single oral dose by syringe; conditions of constant helminth exposure may require retreatment 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. 46.8 grams per packet.

(a) 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).

(b) Limitations. Dissolve in 1 gallon (128 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight; 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 veterinarian before using in severely debilitated animals.

(ii) Amount. 11.7 grams per packet.

(a) Indications for use. See paragraph (f)(2)(ii)(a) of this section.

(3) Swine—(i) Amount. 9.075 or 18.15 grams per bottle.

(ii) Indications for use. Anthelmintic 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. Dissolve in water to provide 9.075 grams per 250 milliliters or 18.15 grams per 500 milliliters. Add 10 milliliters (2 teaspoons) of this concentrate solution to each gallon of drinking water. Allow 1 gallon of medicated drinking water for each 100 pounds of 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 exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. 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.

§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

(a) Chemical name. (\(-\)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-b]thiazole monohydrochloride.

(b) Specifications. Assay of not less than 98 percent by nonaqueous titration with 0.1 N potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) Sponsor. See Nos. 000061 and 043781 in §510.600(c) of this chapter.

(d) Required labeling. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(e) Related tolerances. See §556.350 of this chapter.

(f) Conditions of use. (1) It is used in an oblet for cattle as follows:
   (i) Amount. 2.19 grams per oblet.
   (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. Administer as a single dose as follows: 250 to 450 pounds, \(1/2\) oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, 1½ oblets; 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) It is used in a tablet for sheep as follows:
   (i) Amount. 0.184 gram per tablet.
   (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. Administer one tablet for each 50 pounds of body weight; 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.

§ 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.


§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) Specifications. Each tablet contains 907 milligrams 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. 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 2 1/2 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.


§ 520.1242f Levamisole hydrochloride gel.

(a) Specifications. The drug is a gel containing 11.5 percent levamisole hydrochloride.
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§ 520.1263a Lincomycin hydrochloride monohydrate oral dosage forms.

(a) Specifications. The lincomycin hydrochloride monohydrate of the tablet meets the specifications prescribed by §531.130(a)(1) of this chapter. The sirup meets the specifications prescribed by §531.130(a)(1) of this chapter.

(b) Sponsor. See No. 00009 in §510.600(c) of this chapter.

§ 520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.

(a) Specifications. The lincomycin hydrochloride monohydrate of the tablet meets the specifications prescribed by §531.30(a)(1) of this chapter. The sirup meets the specifications prescribed by §531.30(a)(1) of this chapter.

(b) Sponsor. See No. 00009 in §510.600(c) of this chapter.
§ 520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.

(a) Specifications. The lincomycin hydrochloride monohydrate meets the specifications prescribed by § 453.30(a)(1) of this chapter. The spectinomycin sulfate tetrahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of Streptomyces spectabilis or the same antibiotic substance produced by any other means. The quantity of total antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drugs. Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate are present in the drug in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base.

(b) Sponsor. See No. 000009 in § 510.600(c) of this chapter.

(c) Related tolerances. See §§ 556.600 and 556.360 of this chapter.

(d) Conditions of use. (1) It is administered in the drinking water of chickens up to 7 days of age as an aid in the control of airsacculitis caused by either Mycoplasma synoviae or Mycoplasma gallisepticum susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by Escherichia coli and M. gallisepticum susceptible to lincomycin-spectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) Specifications. Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin.

(b) Sponsor. See Nos. 000009 and 017144 in § 510.600(c) of this chapter.

(c) Tolerances. See § 556.360 of this chapter.

(d) Conditions of use—(1) It is used in drinking water for swine as follows:

(A) Dosage. 3.8 milligrams per pound of body weight per day.

(B) Indications for use. Treatment of swine dysentery (bloody scours).

(C) 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. Not for use in swine weighing more than 250 pounds. Do not slaughter swine for 6 days following last treatment.

(ii) [Reserved]

(2) It is used in drinking water for broiler chickens as follows:

(A) Indications for use. For the control of necrotic enteritis caused by Clostridium perfringens susceptible to lincomycin.

(B) 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.

(ii) [Reserved]
§ 520.1284 Sodium liothyronine tablets.

(a) Specifications. Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram 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 per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(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 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1288 Lufenuron tablets.

(a) Specifications—(1) Dogs. Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron.

(2) Cats. Each regular tablet contains either 90 or 204.9 mg lufenuron, each flavor tablet contains 135 or 270 mg lufenuron.

(b) Sponsor. See No. 058198 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. 10 milligrams of lufenuron per kilogram (4.5 milligrams per pound) of body weight.

(2) Indications for use. For use in dogs, 6 weeks of age and older, for the prevention and control of flea populations.

(3) Limitations. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. 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.


§ 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 mg lufenuron per pound (lb) of body weight (30 mg per kilogram). Recommended 90 mg regular tablet for cats up to 6 lb of body weight, 204.9 mg regular tablet for 7 to 15 lb, 135 mg flavor tablet for up to 10 lb, 270 mg flavor tablet for 11 to 20 lb. Cats over 15 lb (regular tablet) or over 20 lb (flavor tablet) are provided the appropriate combination of tablets.

(2) Indications for use. For control of flea populations.

(3) Limitations. For oral use in cats or kittens 6 weeks of age or older, once a month, directly or broken and mixed with wet 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.

§ 520.1320 Mebendazole oral.

(a) Chemical name. Methyl 5-benzoylbenezimidazole-2-carbamate.

(b) Specifications. As oral powder: Each gram contains either 40 or 166.7 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. As oral suspension: Each milliliter contains 33.3 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. Each milliliter contains 33.3 milligrams of mebendazole.

(c) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(d) 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. It is used in horses 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—(a) Oral powder. The drug is given by sprinkling directly on the grain portion of the ration or dissolving in 2 to 4 pints of water and administering by stomach tube. The drug is compatible with carbon disulfide, which can be used concurrently for both control (Gastrophilus spp.). Routine cautions regarding the use of carbon disulfide must be observed. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) Oral paste. The drug is given by dosing gun (syringe), inserting the tip of the gun at the interdental space in the horse's mouth and depositing the paste on the animal's tongue. The hand is placed under the animal's jaw, and the head is raised to assure that the paste is deposited on the roof of the mouth. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(c) Oral suspension. The drug is administered by stomach tube. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Dogs—(i) Amount. One hundred milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder.

(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. Administer as an oral powder by mixing with a small quantity of food, preferably before the regular meal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1326a Mebendazole and trichlorfon oral dosage forms.

(a) Specifications. Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorfon.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use. 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 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. Administer orally as an individual dose by stomach tube or thoroughly mixed in the ground grain portion of the ration to be consumed in one feeding. Discard treated feed not consumed. 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 horses intended for food use.
use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 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—

(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.


§ 520.1330 Meclofenamic acid granules.

(a) Chemical name. N-(2,6-Dichloromethyl) anthranilic acid.

(b) Specifications. The drug is in granular form containing 5 percent meclofenamic acid.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is used in horses for the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(2) It is administered orally at a dosage of 1 milligram per pound of body weight (1 gram per 1,000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(3) Treatment beyond the initial 5- to 7-day period may be indicated. A maintenance dosage level should be individualized for each animal.

(4) This drug should not be administered to horses with active gastrointestinal, hepatic, or renal disease.

(5) Not for use in horses intended for food.

§ 520.1331 Meclofenamic acid tablets.

(a) Specifications. Each tablet contains either 10 or 20 milligrams of meclofenamic acid.

(b) Sponsor. See No. 000856 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. For oral use only. Should not be administered to animals with congestive heart failure or active gastrointestinal, hepatic, or renal disease. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1341 Megestrol acetate tablets.

(a) Specifications. Each tablet contains 5 or 20 milligrams of megestrol acetate.

(b) Sponsor. No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in female dogs for the postponement of estrus and the alleviation of false pregnancy.

(2) It is administered orally, intact, or crushed and mixed with food as follows:
§ 520.1380 Methocarbamol tablets.

(a) Chemical name. 3-(O-Methoxyphenoxy)-1,2-propanediol 1-carbamate.

(b) Specifications. Each tablet contains 500 milligrams of methocarbamol.

(c) Sponsor. See No. 000031 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is administered to dogs and cats as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

(2) Dosage is based upon severity of symptoms and response noted. The usual initial dose in 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1408 Methylprednisolone tablets.

(a) Specifications. Each tablet contains 1, 2, or 4 milligrams of methylprednisolone.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter for use of 1- and 4-milligram tablets; see No. 000010 for use of 1- and 2-milligram tablets.

(c) NAS/NRC status. The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Special consideration. (1) Clinical and experimental data have 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.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, or cushingoid syndrome. The presence of active tuberculosis, diabetes, osteoporosis, chronic psychotic reactions, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids. Some of these conditions occur only rarely in dogs and cats but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) Conditions of use—(1) Amount. Dogs and cats: 5 to 15 pounds, 2 milligrams; 15 to 40 pounds, 2 to 4 milligrams; 40 to 80 pounds, 4 to 8 milligrams.

(2) Indications for use. For use in dogs and cats as an anti-inflammatory agent.

(3) Limitations. 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. Hazardous for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1409 Methylprednisolone, aspirin tablets.

(a) Specifications. Each tablet contains 0.5 milligrams of methylprednisolone and 300 milligrams of aspirin.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) NAS/NRC status. The conditions of use have been NAS/NRC reviewed and found effective. New animal drug applications for approval of drugs for these conditions of use need not include effectiveness data specified by §514.111 of this chapter, but may require bioequivalence and safety information.

(d) Special considerations. (1) Clinical and experimental data have 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.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with tuberculosis, chronic nephritis, peptic ulcer, or Cushingoid syndrome. The presence of diabetes mellitus, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) Conditions of use—(1) Amount. Dogs under 15 pounds, 1 to 4 tablets daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily.

(2) Indications for use. As an anti-inflammatory and analgesic agent in dogs.

(3) Limitations. 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. Do not administer to cats. Do not overdose. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21566, May 13, 1983]

§ 520.1422 Metoserpate hydrochloride.

(a) Chemical name. Methyl-o-methyl-18-epireserpate hydrochloride.

(b) Sponsor. See No. 000003 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.

§ 520.1430 Mibolerone.

(a) Specifications. Each milliliter contains 100 micrograms of mibolerone.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 30 micrograms for animals weighing 1 to
§ 520.1445 Milbemycin oxime tablets.

(a) Specifications. Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(b) Sponsor. See 058198 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.23 milligram per pound of body weight (0.5 milligram per kilogram).

(2) 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.

(3) Limitations. Do not use in puppies less than 4 weeks of age and less than 2 pounds in body weight. Administer once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1446 Milbemycin oxime/lufenuron tablets.

(a) Specifications. Tablets containing: 2.3 milligrams milbemycin oxime/46 milligrams lufenuron, 5.75 milligrams/115 milligrams, 11.5 milligrams/230 milligrams, and 23 milligrams/460 milligrams.

(b) Sponsor. See No. 058198 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.5 milligrams of milbemycin and 10 milligrams of lufenuron per kilogram of body weight.

(2) Indications for use. For use in dogs, 4 weeks of age and older and 2 pounds body weight or greater, for the prevention of heartworm disease caused by Dirofilaria immitis, for the prevention and control of flea populations, the control of adult Anyclostoma caninum (hookworm), and the removal and control of adult Toxocara canis, Toxascaris leonina (roundworm), and Trichuris vulpis (whipworm) infections.

(3) Limitations. Administer tablet(s) once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the Rf value must be comparable to a reference standard (the Rf value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60°C for 2 hours.

[55 FR 3586, Feb. 2, 1990]

§ 520.1448a Monensin blocks.

(a)(1) Specifications. Each pound of protein-mineral block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) Sponsor. See 036904 in §510.600(c) of this chapter.
(3) Related tolerances. See §556.420 of this chapter.

(4) Conditions of use—(i) Amount. 80 to 200 milligrams of monensin (0.2 to 0.5 pound of block) per head per day.

(ii) Indications for use. Increased rate of weight gain.

(iii) Limitations. Block to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide 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. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

(b) [Reserved]

(c)(1) Specifications. Each pound of protein block contains 175 milligrams of monensin (0.038 percent) as monensin sodium.

(2) Sponsor. See 021676 in §510.600(c) of this chapter.

(3) Related tolerances. See §556.420 of this chapter.

(4) Conditions of use—(i) Amount. 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day.

(ii) Indications for use. Increased rate of weight gain.

(iii) Limitations. Blocks to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy). Provide at least one block per five head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

[46 FR 19466, Mar. 31, 1981]

EDITORIAL NOTE: For Federal Register citations affecting §520.1448a, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§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. 000069 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).
§ 520.1450b 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.


§ 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. 000069 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.

[56 FR 13396, Apr. 2, 1991]

§ 520.1451 Moxidectin.

(a) Specifications. Each tablet contains 30, 68, or 136 micrograms of moxidectin.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) [Reserved]

(d) 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. Use once-a-month in dogs at 8 weeks of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1452 Moxidectin gel.

(a) Specifications. The gel contains 2 percent moxidectin (20 milligrams per milliliter).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

d) Conditions of use—(1) Amount. 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) Indications for use. Horses and ponies for treatment and control of large strongyles (Strongylus vulgaris (adults and L4/LS arterial stages), S. edentatus (adult and tissue stages), Triodontophorus brevicauda (adults), T. serratus (adults)); small strongyles (Cyathostomum spp. (adults), Cylcoclyclus spp. (adults), Cylcocephalus capitatus (adults), undifferentiated luminal 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)). One dose also suppresses small strongyle egg production for 84 days.

(3) Limitations. For horses and ponies including breeding mares and stallions. Not for use in horses and ponies intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 520.1468 Naproxen granules.

(a) Specifications. Naproxen granules contain 50 percent naproxen.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

c) Conditions of use—(1) Horses. The drug is used 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.

(2)(i) For oral maintenance therapy following initial intravenous dosage, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as top dressing in the animal’s feed for up to 14 consecutive days. The initial intravenous dosage is 5 milligrams per kilogram of body weight.

(ii) For oral dosage only, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as a top dressing in the animal’s feed for up to 14 consecutive days.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1484 Neomycin sulfate soluble powder.

(a) Specifications. The drug contains 20.3 grams of neomycin sulfate per ounce which is equivalent to 14.2 grams of neomycin base.

(b) Sponsors. See Nos. 000009, 000069, 046573, 050604, and 059130 in §510.600(c) of this chapter.

c) Conditions of use—(1) Amount. 10 milligrams of neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

(2) Indications for use. For the treatment and control of colibacillosis (bacterial enteritis) caused by Escherichia coli susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

(3) Limitations. Add to drinking water or milk; not for use in liquid supplements. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: For sponsor 059130—cattle and goats, 30 days; swine, 20 days; for sponsors 000009, 000069, 046573, 050604—cattle (not for use in veal.
§ 520.1485 Neomycin sulfate oral solution.

(a) Specifications. Each milliliter contains 200 milligrams of neomycin sulfate (equivalent to 140 milligrams of neomycin base).

(b) Sponsors. See Nos. 000009, 050604, and 059130 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.430 of this chapter.

(d) Conditions of use—(1) Amount. 10 milligrams of neomycin sulfate per pound of body weight in divided doses for a maximum of 14 days.

(2) Indications for use. For the treatment and control of colibacillosis (bacterial enteritis) caused by Escherichia coli susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats.

(3) Limitations. Administer undiluted or in drinking water. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: For sponsor 059130: 30 days for cattle and goats, and 20 days for swine and sheep; for sponsors 000009 and 050604: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

§ 520.1616 Orbifloxacin tablets.

(a) Specifications. Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Dogs and cats—(i) Amount. 2.5 to 7.5 milligrams per kilogram body weight.

(ii) Indications for use. For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) Limitations. Administer orally once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs and cats during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 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. 000856 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
Food and Drug Administration, HHS

§ 520.1630 Oxfendazole suspension.

(a) Specifications. Each milliliter contains 90.6 or 225.0 milligrams oxfendazole (9.06 or 22.5 percent).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.495 of this chapter.

(d) Conditions of use—(1) Horses (9.06 percent suspension only).

(i) Amount. 10 milligrams per kilogram (2.2 pounds) of body weight.

(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. Administer 9.06 percent suspension by stomach tube or dose syringe. 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.


§ 520.1630 Oxfendazole suspension.

(a) Specifications. Each milliliter contains 90.6 or 225.0 milligrams oxfendazole (9.06 or 22.5 percent).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.495 of this chapter.

(d) Conditions of use—(1) Horses (9.06 percent suspension only).

(i) Amount. 10 milligrams per kilogram (2.2 pounds) of body weight.

(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. Administer 9.06 percent suspension by stomach tube or dose syringe. 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.

(Trichostrongylus axei—adult), brown stomach worms (Ostertagia ostertagi—adult, L4, inhibited L4); intestinal worms; nodular worms (Oesophagostomum radiatum—adult), small intestinal worms (Cooperia punctata, C. oncophora, and C. mcmasteri—adult, L4), and tape-worms (Moniezia benedeni—adult).

(iii) Limitations. For use in cattle only. Administer 9.06 percent suspension orally only with a dose syringe, and 22.5 percent suspension either orally with a dose syringe or intraruminally with a rumen injector. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle. For use of 9.06 percent suspension orally: Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism. For use of 22.5 percent suspension orally or intraruminally: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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 000856 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. equinus, S. vulgaris); small strongyles (genera Cylcistephanus, Cylcoclyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyaloccephalus); large roundworms (Parascaris equorum), pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

(3) Limitations. Administer orally by syringe. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 520.1638 Oxibendazole paste.

(a) Specifications. The paste contains 22.7 percent oxibendazole.

(b) Sponsor. See 000069 in §510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (genera Cylcistephanus, Cylcoclyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyaloccephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

(2) Indications for use. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (genera Cylcistephanus, Cylcoclyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyaloccephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

§ 520.1640 Oxibendazole suspension.

(a) Specifications. The suspension contains 10 percent oxibendazole.

(b) Sponsor. See 000069 in §510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (genera Cylcistephanus, Cylcoclyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyaloccephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).
milligrams of oxibendazole per kilogram of body weight; for threadworms, 15 milligrams per kilogram of body weight.

(2) Indications for use. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (species of the genera Cylicostephanus Cylicoclyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyalocephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

(3) Limitations. Administer 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. Prepare individual doses to ensure that each animal receives the correct amount. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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. 000069 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, tonsillitis 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 organism. These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
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.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

§ 520.1660c Oxytetracycline hydrochloride tablets.

(a) Specifications. Each tablet contains 250 or 500 milligrams of oxytetracycline hydrochloride.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) NAS/NRC status. The conditions of use of oxytetracycline hydrochloride in paragraph (b)(2) of this section have been reviewed by NAS/NRC and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter but may require bioequivalency and safety information.

(d) Tolerances. See §556.500 of this chapter.

(e) 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 (coli bacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by Pasteurella multocida.

(2)(i) Amount. 500 milligrams per 100 pounds 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 (coli bacillosis) 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). Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle.


§ 520.1660d Oxytetracycline hydrochloride soluble 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.;

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz; 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.).

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (pails: 2 and 5 lb).

(8) Each 3.5 gram packet (4.78 ounce) contains 102.4 grams of OTC HCl.

(b) Sponsor. See sponsor numbers in §510.600(c) of this chapter as follows:

(1) No. 000069 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) Nos. 017144 and 047015 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

(3) No. 000100 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. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, and sheep.

(6) No. 053389 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

(c) [Reserved]

(d) Related tolerances. See §556.500 of this chapter.

(1) Conditions of use. (1) It is used in drinking water as follows: Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(i) Chickens—(A) Amount per gallon. 200 to 400 milligrams.

(ii) Turkeys—(C) Amount per gallon. 400 to 800 milligrams.

(2) Indications for use. Control of infectious synovitis caused by Mycoplasma synoviae susceptible to oxytetracycline.

(3) Limitations. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(B) Amount per gallon. 400 to 800 milligrams.

(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) Limitations. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(2) Indications for use. Control of hexamitiasis caused by Hexamita meleagridis susceptible to oxytetracycline.

(3) Limitations. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 017144, 057561, and 059130 in §510.600(c) of this chapter. Withdraw 4 days prior to slaughtering those products sponsored by Nos. 000069 and 059130 in §510.600(c) of this chapter.
§ 520.1696  
059130. Administer up to 5 days; do not use for more than 5 consecutive days; withdraw 13 days prior to slaughter those products sponsored by Nos. 017144 and 057561.

(iv) Calves, beef cattle, and nonlactating dairy cattle—(A) Amount. 10 milligrams per pound of body weight daily.

(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) Limitations. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. 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.

(v) Sheep—(A) Amount. 10 milligrams per pound of body weight daily.

(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) Limitations. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Withdraw 5 days prior to slaughter.

(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.

(ii) Indications for use. Control and treatment of American and European foul brood caused by Bacillus larvae susceptible to oxytetracycline.

(iii) Limitations. 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.


§ 520.1696c Penicillin oral dosage forms.

§ 520.1696a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.

(a) Specifications. When reconstituted, each milliliter contains penicillin G procaine equivalent to 20,000, 25,000, 40,000, 50,000, 80,000, or 100,000 units of penicillin G.

(b) Sponsor. [Reserved]

(c) Related tolerances. See § 556.510 of this chapter.

(d) Conditions of use. Chickens—It is used in drinking water as follows:

(1) Amount. 100,000 units per gallon.

(i) Indications for use. Treatment of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) Limitations. As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

(2) Amount. 50,000 to 100,000 units per gallon.

(i) Indications for use. Prevention of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) Limitations. As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

[57 FR 37326, Aug. 18, 1992]

§ 520.1696b Penicillin G potassium in drinking water.

(a) Specifications. When reconstituted, each milliliter contains penicillin G potassium equivalent to 20,000, 25,000,
§ 520.1720a Phenylbutazone oral dosage forms.

(a) Specifications. Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) Sponsor. See sponsor numbers in §510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-milligram tablets or 1-gram tablets, in dogs and horses.

(2) No. 000010 for use of 100- or 200-milligram tablets or 1-gram tablets in dogs and horses.

(3) Nos. 000031, 000591, 000856, 000864, and 015579 for use of 100-milligram tablets in dogs and horses.

(4) No. 055246 for use of 100-milligram tablets in dogs.

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1696d Penicillin V potassium tablets.

(a) Specifications. Each tablet contains penicillin V potassium equivalent to 25 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

(b) Sponsor. See Nos. 017144, 050604, and 053501 in §510.600(c) of this chapter.

(c) National Academy of Sciences/National Research Council (NAS/NRC) status. These conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use. 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. Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1696c Penicillin V potassium for oral solution.

(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) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use. 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. Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1696 Phenylbutazone tablets and boluses.

(a) Specifications. Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) Sponsor. See Nos. 000031, 000591, 000856, 000864, and 015579 for use of 100-milligram tablets in dogs and horses.

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) Specifications. Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) Sponsor. See sponsor numbers in §510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-milligram tablets or 1-gram tablets, in dogs and horses.

(2) No. 000010 for use of 100- or 200-milligram tablets or 1-gram tablets in dogs and horses.

(3) Nos. 000031, 000591, 000856, 000864, and 015579 for use of 100-milligram tablets in dogs and horses.

(4) No. 055246 for use of 100-milligram tablets in dogs.
§ 520.1720b

(c) Conditions of use—(1) Dogs—(i) Amount. Twenty milligrams per pound of body weight daily.¹

(ii) Indications for use. The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.¹

(iii) Limitations. Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(2) Horses—(i) Amount. One to two grams per 500 pounds weight daily.¹

(ii) Indications for use. This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.¹

(iii) Limitations. Do not exceed a daily dosage of 4 grams per day. Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in animals intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹


§ 520.1720c Phenylbutazone paste.

(a) Specifications. The paste contains 20 percent phenylbutazone.

(b) Sponsor. See 000061 and 010797 in §510.600(c) of this chapter.

(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use in horses—(1) Amount. 1 to 2 grams 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. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹


¹See footnote 1 to §520.1660b.
§ 520.1720d Phenylbutazone gel.

(a) Specifications. Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) Sponsor. See 050604 in §510.600(c) of this chapter.

(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.

(d) 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. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.1802b Piperazine-carbon disulfide complex boluses.

(a) Specifications. Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) Sponsor. See 000009 in §510.600(c) of this chapter.

(c) Conditions of use: 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 and 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 52781, Aug. 8, 1980]
§ 520.1802c Piperazine-phosphate capsules.
(a) Specifications. Each capsule contains 120, 300, or 600 milligrams of piperazine phosphate monohydrate.
(b) Sponsor. See No. 050906 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Amount. 60 milligrams of piperazine phosphate monohydrate per pound of body weight.¹
(2) Indications for use—(i) Dogs. It is used for the removal of large roundworms (ascarids) Toxocara canis and Toxascaris leonina.¹
(ii) Cats. It is used for the removal of large roundworms (ascarids) Toxocara mystax and Toxacaris leonina.¹
(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.¹

§ 520.1805 Piperazine-phosphate with theminium closylate tablets.
(a) Specifications. Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams theminium (as theminium closylate) or 500 milligrams piperazine hexahydrate (as piperazine phosphate) and 250 milligrams theminium (as theminium 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:

<table>
<thead>
<tr>
<th>Animal weight (lb)</th>
<th>375 mg</th>
<th>750 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 but less than 5</td>
<td>½</td>
<td></td>
</tr>
<tr>
<td>5 but less than 10</td>
<td>1</td>
<td>½</td>
</tr>
<tr>
<td>10 or heavier</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
Indications for use.

For removal of immature (fourth stage larvae) and adult hookworms (Ankylostoma caninum, A. braziliense, and Uncinaria stenocephala) and ascarids (Toxocara canis) from weaned pups and adult dogs.

Limitations.

Do not use this product to treat dogs weighing less than 2 pounds, unweaned pups, or pups under 5 weeks of age. Maximum efficacy against hookworms necessitates two doses in 1 day of treatment. The interval between the doses should be not less than 4 hours or more than 24 hours. Administer the first dose in the morning before feeding. Do not permit dog to chew tablet. Feed the dog between doses. Do not feed milk or other fatty foods during treatment. Retreatment may be needed in 7 to 28 days as determined by laboratory fecal examinations or in animals kept in known contaminated quarters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1806 Piperazine monohydrochloride liquid.

Indications for use.

For dogs for the removal of roundworms (Toxocara canis and Toxascaris leonina).

Dosage.

Administer 20 to 30 milligrams of piperazine base per pound of body weight as a single dose.

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 three weeks of age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 520.1840 Poloxalene.

(a) Chemical name. Polyoxypolyethylene-polyoxyethylene glycol nonionic block polymer.

(b) Specifications.

(1) Molecular weight range: 2,850 to 3,150.

(2) Hydroxyl number: 35.7 to 39.4.

(3) Cloud point (10 percent solution): 42 °C.±46 °C.

(4) Structural formula:

(c) Sponsor.

(1) See No. 000069 in §510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(1) of this section.

(2) See No. 000069 in §510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(3) of this section.

(3) See No. 036904 in §510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(2) of this section.

(4) See No. 017800 in §510.600(c) of this chapter for sponsor of the usage provided by paragraph (d)(4) of this section.

(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.
§ 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. 050112 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]

§ 520.1870 Praziquantel tablets.

(a) Specifications. Each dog tablet contains 34 milligrams (mg) of praziquantel; each cat tablet contains 11.5 or 23 mg of praziquantel.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Indications for use. For removal of canine cestodes Dipylidium caninum and Taenia pisiformis. If labeled for use by or on the order of a licensed veterinarian, for removal of the canine cestode Echinococcus granulosus, and for removal and control of the canine cestode Echinococcus multilocularis.

(ii) Dosage. Dogs 5 pounds and under, ½ tablet (17 mg); 6 to 10 pounds, 1 tablet (34 mg); 11 to 15 pounds, 1½ tablets (51 mg); 16 to 30 pounds, 2 tablets (68 mg); 31 to 45 pounds, 3 tablets (102 mg); 46 to 60 pounds, 4 tablets (136 mg); over 60 pounds, 5 tablets maximum (170 mg).

(iii) Limitations. Administer directly by mouth or crumbled and in feed. Not intended for use in puppies less than 4 weeks of age. For over-the-counter (OTC) use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism. For prescription use: 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.


§ 520.1871 Praziquantel/pyrantel pamoate tablets.

(a) Specifications. Each cat tablet contains 18.2 milligrams (mg) praziquantel with 72.6 mg pyrantel (as pyrantel pamoate).

(b) Sponsor. See 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Cats—(i) Dosage. 1.5 to 1.9 pounds, ¼ tablet; 2 to 3 pounds, ½ tablet; 4 to 8 pounds, 1 tablet; 9 to 12 pounds, 1 1/2 tablets; 13 to 16 pounds, 2 tablets.

(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.
Food and Drug Administration, HHS

(iii) Limitations. Not for use in kittens less than 1 month of age or weighing less than 1.5 pounds. 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. Consult your veterinarian before giving to sick or pregnant animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) [Reserved]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) Specifications. Each tablet contains either:

(1) Tablet No. 1: 22.7 milligrams praziquantel, 22.7 milligrams pyrantel base, and 113.4 milligrams febantel;

(2) Tablet No. 2: 68 milligrams praziquantel, 68 milligrams pyrantel base, and 340.2 milligrams 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:

<table>
<thead>
<tr>
<th>Weight of animal (Kilograms)</th>
<th>Number of tablets per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tablet no. 1</td>
</tr>
<tr>
<td>0.9 to 1.8</td>
<td>2 to 4</td>
</tr>
<tr>
<td>2.3 to 3.2</td>
<td>5 to 7</td>
</tr>
<tr>
<td>3.6 to 5.4</td>
<td>8 to 12</td>
</tr>
<tr>
<td>5.9 to 8.2</td>
<td>13 to 18</td>
</tr>
<tr>
<td>8.6 to 11.4</td>
<td>19 to 25</td>
</tr>
<tr>
<td>11.6 to 13.6</td>
<td>26 to 30</td>
</tr>
<tr>
<td>14.1 to 20.0</td>
<td>31 to 44</td>
</tr>
<tr>
<td>20.4 to 27.2</td>
<td>45 to 60</td>
</tr>
<tr>
<td>27.7 to 33.6</td>
<td>61 to 74</td>
</tr>
<tr>
<td>34.0 to 40.9</td>
<td>75 to 90</td>
</tr>
<tr>
<td>41.3 to 47.2</td>
<td>91 to 104</td>
</tr>
<tr>
<td>47.7 to 54.5</td>
<td>105 to 125</td>
</tr>
</tbody>
</table>

(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 33008, July 1, 1994, as amended at 61 FR 29651, June 12, 1996]

§ 520.1880 Prednisolone tablets.

(a) Specifications. Each tablet contains 5 or 20 milligrams prednisolone.

(b) Sponsor. See No. 061690 in § 510.600(c)(2) of this chapter.

(c) Special considerations. (1) Clinical and experimental data have 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 parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Do not use in viral infections. Systemic therapy with prednisolone is contraindicated in animals with peptic ulcer, corneal ulcer, and Cushingoid syndrome. The presence of diabetes, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, renal insufficiency, and active tuberculosis necessitates carefully controlled use. Some of the above conditions occur only rarely in dogs but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(d) Conditions of use—(1) Amount. Dogs: 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 in dogs as an anti-inflammatory agent.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1900 Primidone tablets.

(a) Specifications. Each tablet contains 50 or 250 milligrams of primidone.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter for use of 250 milligram tablets; see No. 000856 in §510.600(c) of this chapter 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.\(^1\)

(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.\(^1\)

(3) Limitations. The tablets may be administered whole or crushed and mixed with the food. When convulsions are frequent, the dosage should be divided and administered at intervals. Reduction in dosage should be made gradually and never be abruptly discontinued. Do not use in feline species, as primidone appears to have a specific neurotoxicity in cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.\(^1\)

\(^{1}\)These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.1920 Prochlorperazine, isopropamide sustained release capsules.

(a) Specifications. Prochlorperazine, isopropamide sustained release capsules contain 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. 000069 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer capsules orally twice daily to dogs as follows:

<table>
<thead>
<tr>
<th>Animal weight (pounds)</th>
<th>Number of capsules per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsule No. 1</td>
</tr>
<tr>
<td>10 to 20</td>
<td>1</td>
</tr>
<tr>
<td>20 to 30</td>
<td>1</td>
</tr>
<tr>
<td>Over 30</td>
<td>2</td>
</tr>
<tr>
<td>Over 60</td>
<td>2</td>
</tr>
</tbody>
</table>

(2) Indications for use. For treatment of dogs in which infectious bacterial
Food and Drug Administration, HHS § 520.2041

(3) Limitations. Do not continue medication longer than 5 days. Overdosage or prolonged administration may produce nephrotoxicity as manifested by albuminuria, presence of granular casts and depressed urinary output. If it is desirable to administer a vasoconstrictor, norepinephrine is the drug of choice. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1962 Promazine hydrochloride.

(a)(1) Chemical name. 10-[(3-Dimethylamino)propyl]phenothiazine monohydrochloride.

(2) Specifications. Conforms to N.F. XII.

(3) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(4) [Reserved]

(5) Conditions of use. (i) The drug is used for quieting excitable, unruly, or intractable horses. It is administered at a dosage level of 0.45 to 0.9 milligrams of promazine hydrochloride per pound of body weight mixed with an amount of feed that will be readily consumed.

(ii) Do not use in horses intended for food.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]


§ 520.2002 Propiopromazine hydrochloride.

(a) Chemical name. 1-Propanone, 1-[10-(3-dimethylamino)propyl]phenothiazine-2-yl]-monohydrochloride.

(b) Specifications. The drug is administered in a chewable tablet containing 10 to 20 milligrams of propiopromazine hydrochloride.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is intended for oral administration to dogs as a tranquilizer. It is used 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.

(2) It is administered at the rate of 0.5 to 2 milligrams of propiopromazine hydrochloride per pound of body weight once or twice daily depending upon the degree of tranquilization desired.

NOTE: Not for use with organophosphates and/or procaine hydrochloride, as phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Overdosage may produce significant depression.

(3) For use only by or on the order of a licensed veterinarian.


§ 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 No. 017135 in §510.600(c) of this chapter.

(c) Sponsor. See No. 017135 in §510.600(c) of this chapter.

(d) Conditions of 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.

(iii) In adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 55386, Nov. 28, 1978; 59 FR 5705, Feb. 8, 1994]
§ 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.

§ 520.2043 Pyrantel pamoate suspension.

(a)(1) Specifications. Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 50 milligrams of pyrantel base per milliliter.

(2) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(b)(1) Specifications. Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 2.27 or 4.54 milligrams of pyrantel base per milliliter.

(2) Sponsors. See Nos. 000069 and 011615 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 023851 for use of 4.54 milligrams per milliliter product.

(c) Conditions of use. It is used in puppies and dogs as follows:

(i) Amount. Equivalent of 2.27 milligrams of pyrantel base per pound of body weight.

(ii) Indications for use. For the removal of large roundworms (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum and Uncinaria stenocephala).

(iii) Limitations. Administer in the animal’s feed bowl as a single dose mixed with the usual grain ration, or by stomach tube, or by dose syringe. Not for use in horses and ponies to be slaughtered for food purposes. 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.” When the drug is not for administration by stomach tube, it shall be labeled: “Consult your veterinarian for assistance in the diagnosis, control, and treatment of parasitism.”
§ 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

(a) Specifications. (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.

(2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.

(b) Sponsor. (1) See No. 000069 in §510.600(c) of this chapter for conditions of use provided for in paragraphs (d) (1) and (2) of this section.

(2) See No. 060594 in §510.600(c) of this chapter, for conditions of use provided for in paragraph (d)(3) of this section.

(c) Related tolerances. See §556.560 of this chapter.

(d) Conditions of use. It is used in: (1) Horses and colts:

(i) For the removal and control of infections from the following parasites: Strongyles (Strongylus vulgaris, S. edentatus, S. equinus), nodular worm (Oesophagostomum), pinworms (Oxyuris equi), and large roundworms (Parasarcis).

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (Ascaris suum) and nodular worm (Oesophagostomum) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted 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.

(iii) Fast pigs overnight for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (Strongylus

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.
§ 520.2087 Roxarsone soluble powder.

(a) Specifications. Each ounce (avoirdupois) of soluble powder contains 21.7 grams of roxarsone (monosodium 3-nitro-4-hydroxyphenylarsonate).

(b) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.60 of this chapter.

(d) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.2088 Roxarsone tablets.

(a)(1) Specifications. Each tablet contains 36 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(3) Related tolerances. See §556.60 of this chapter.

(4) NAS/NRC status. The weight gain, feed efficiency, and pigmentation claims are NAS/NRC reviewed and found effective. NADA’s for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(5) Conditions of use—(i) Growing chickens and growing turkeys—(a) Amount. Dissolve 2 tablets in each gallon of drinking water (0.002 percent roxarsone).

(b) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(c) Limitations. Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) Growing chickens—(a) Amount. Dissolve 8 tablets in each gallon of drinking water (0.008 percent roxarsone).

(b) Indications for use. As an aid in the prevention of coccidiosis due to Eimeria tenella.

(c) Limitations. Administer for not more than 10 consecutive days. Treatment may be repeated after 5 days off medication. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(b)(1) Specifications. Each tablet contains 400 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(3) Related tolerances. See §556.60 of this chapter.

(4) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses need not
include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(5) Conditions of use—(i) Swine—(a) Amount. 1 tablet (400 milligrams) per gallon of drinking water for no more than 6 days, or 1 tablet (400 milligrams) per 2 fluid ounces of warm water per 50 pounds of body weight as a drench once daily for 1 to 2 days.

(b) Indications for use. As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).

(c) Limitations. Treatment may be repeated after 5 days off medication. If no improvement is observed, consult a veterinarian. Treated animals must consume enough medicated water to provide a therapeutic dose. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) [Reserved]

(c)(1) Specifications. Each tablet contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) Sponsor. See No. 017144 in §510.600(c) of this chapter.

(3) Related tolerances. See §556.60 of this chapter.

(4) Conditions of use in growing chickens and growing turkeys—(1) Amount. 1 tablet in each gallon of drinking water (0.002 percent roxarsone).

(ii) Indications for use. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) Limitations. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

§ 520.2089 Roxarsone liquid.

(a) Specifications. Each teaspoon (5 milliliters) of solution contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(b) Sponsor. See No. 017144 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.60 of this chapter.

§ 520.2095 Sarafloxacin soluble powder.

(a) Specifications. Each 145 grams (5.1 ounces) pouch contains sarafloxacin hydrochloride equivalent to 14.5 grams of sarafloxacin base.

(b) Sponsor. See No. 000074 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.594 of this chapter.

(d) Conditions of use in growing chickens and growing turkeys—(1) Amount. 1 teaspoon (5 milliliters) to each gallon of drinking water (0.002 percent sarafloxacin).

(2) Indications for use. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) Limitations. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[58 FR 65665, Dec. 16, 1993]

§ 520.2095 Sarafloxacin soluble powder.

(a) Specifications. Each 145 grams (5.1 ounces) pouch contains sarafloxacin hydrochloride equivalent to 14.5 grams of sarafloxacin base.

(b) Sponsor. See No. 000074 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.594 of this chapter.

(d) Conditions of use in growing chickens and growing turkeys—(1) Amount. 1 teaspoon (5 milliliters) to each gallon of drinking water (0.002 percent sarafloxacin).

(2) Indications for use. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) Limitations. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[58 FR 65665, Dec. 16, 1993]
§ 520.2098 Selegiline hydrochloride tablets.

(a) Specifications. Each tablet contains either 2, 5, 10, 15, or 30 milligrams of selegiline hydrochloride.

(b) Sponsor. See No. 063248 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—Dogs—(1) Dosage. 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(2) Indications for use. For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(3) Limitations. Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.2100 Selenium, vitamin E capsules.

(a) Specifications. The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium) and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to 0.25 milligram of selenium) and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate).

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.2122 Spectinomycin dihydrochloride oral solution.

(a) Specifications. The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of Streptomyces flavopersicus (var. Abbott) or the same antibiotic substance produced by any other means. The drug is packaged as an aqueous solution containing 50 milligrams of spectinomycin activity per millilitre.

(b) Sponsors. (1) See No. 050604 in §510.600(c) of this chapter.

(2) See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used for the treatment and control of infectious bacterial enteritis (white scours) associated with E. coli in pigs under 4 weeks of age.

(2) It is administered orally at the rate of 50 milligrams per 10 pounds body weight twice daily for 3 to 5 days.

(3) Do not administer to pigs over 15 pounds body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

§ 520.2123   Spectinomycin dihydrochloride pentahydrate oral dosage forms.
§ 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.
(a) Specifications. The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of Streptomyces flavopersicus (var. Abbott) or the same antibiotic substance produced by any other means.
(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.
(c) Special considerations. The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.
(d) Conditions of use. (1) The tablets are administered orally to dogs in the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.
   (2) The drug is administered orally to provide 10 milligrams per pound of body weight twice daily. The tablets may be placed in the animal’s mouth or crushed and administered in milk or in the feed. Dosage may be continued for 4 consecutive days. Should no improvement be observed, discontinue drug and redetermine diagnosis.
   (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 47 FR 14149, Apr. 2, 1982]

§ 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.
(a) Specifications. The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of Streptomyces flavopersicus (var. Abbott) or the same antibiotic substance produced by any other means.
(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.
(c) Special considerations. The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.
(d) Related tolerances. See §556.600 of this chapter.
(e) Conditions of use. (1) It is administered in the drinking water of growing chickens at 2 grams of spectinomycin 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. It is administered as an aid in the prevention or control of losses due to CRD associated with M. gallisepticum (PPLO). Do not administer to laying chickens. Do not administer within 5 days of slaughter.
   (2) It is administered in the drinking water of floor-raised broiler chickens at 0.5 gram of spectinomycin 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. It is administered for increased rate of weight gain and improved feed efficiency. Do not administer to laying chickens. Do not administer within 5 days of slaughter.
   (3) It is administered in drinking water of broiler chickens at 1 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 to 5 days of life as an aid in controlling infectious synovitis due to Mycoplasma synoviae. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980]

§ 520.2150 Stanozolol oral dosage forms.
§ 520.2150a Stanozolol tablets.
(a) Specifications. Each tablet contains 2 milligrams of stanozolol.
(b) Sponsor. No. 000009 in §510.600(c) of this chapter.
(c) Conditions of use. (1) Used as an anabolic steroid treatment in dogs and cats.
   (2) Administered orally to cats and small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.
(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2150b Stanozolol chewable tablets.

(a) Specifications. Each chewable tablet contains 2 milligrams of stanozolol.

(b) Sponsor. No. 000009 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) Used as an anabolic steroid treatment in dogs.

(2) Administered orally to small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.

§ 520.2158a Streptomycin sulfate oral solution.

(a) Specifications. Solution containing 25 percent streptomycin sulfate.

(b) Sponsor. See No. 033008 in § 510.600(c) of this chapter.

(c) Related tolerances. See §§ 556.610 and 556.200 of this chapter.

(d) Conditions of use. Use in drinking water as follows:

(1) Calves and swine—(i) Amount. 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon).

(ii) Indications for use. Treatment of bacterial enteritis caused by Escherichia coli and Salmonella spp. susceptible to streptomycin.

(iii) Limitations. Calves: Do not administer for more than 5 days. Swine: Do not administer for more than 4 days. Prepare fresh solution daily. Calves: Withdraw 2 days before slaughter. As sole source of streptomycin.

(b) Related tolerances. See §§ 556.120 and 556.200 of this chapter.

(2) Chickens—(i) Amount. 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon).

(ii) Indications for use. Treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.

(iii) Limitations. Chickens: Do not administer for more than 5 days. Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Prepare fresh solution daily. As sole source of streptomycin.

(c) Conditions of use. Calves—(1) Amount. 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.

(2) Indications for use. Treatment of bacterial scour in calves.

(3) Limitations. Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[57 FR 37327, Aug. 18, 1992, as amended at 58 FR 47111, Sept. 8, 1993]
§ 520.2160 Styrylpyridinium, diethylcarbamazine oral dosage forms.

§ 520.2170 Sulfabromomethazine sodium boluses.
(a) Specifications. Each bolus contains 15 grams of sulfabromomethazine sodium.
(b) Related tolerance. See § 556.620 of this chapter.
(c) Sponsor. See No. 050604 in § 510.600(c) of this chapter.
(d) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.
(e) Conditions of use. Cattle—(1) Amount. 90 milligrams per pound body weight.
(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. Administer orally; repeat in 48 hours if necessary; 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; discontinue use if hematuria, crystalluria or severe depression are noticed; if signs persist after 2 or 3 days consult a veterinarian.


§ 520.2184 Sodium sulfachloropyrazine monohydrate.
(a) Chemical name. 2-Sulfamido-6-chloropyrazine, sodium.
(b) Sponsor. See Nos. 010042 and 053501 in § 510.600(c) of this chapter.
(c) Related tolerances. See § 556.625 of this chapter.
(d) Conditions of use. It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:
(1) Amount. 0.03 percent.
(2) Indications for use. Treatment of coccidiosis.
(3) Limitations. Administer in drinking water for 3 days as sole source of drinking water and sulfonamide medication; withdraw 4 days prior to slaughter; not to be administered to chickens producing eggs for human consumption.


§ 520.2200 Sulfachlorpyridazine oral dosage forms.

§ 520.2200a Sulfachlorpyridazine bolus.
(a) Chemical name. N’-6-(Chloro-3-pyridazinyl) sulfanilamide.
(b) Specifications. Melting point range: 190° C to 191°C.
(c) Sponsor. See No. 053501 in § 510.600(c) of this chapter.
(d) Related tolerances. See § 556.630 of this chapter.
(e) Conditions of use. It is used in calves as follows:
(1) Amount. 30 to 45 milligrams per pound body weight per day.
(2) Indications for use. Treatment of diarrhea caused or complicated by E. coli (colibacillosis).
(3) Limitations. Administer in a bolus containing 2 grams of sulfachlorpyridazine for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 7 days after the last treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2200b Sulfachlorpyridazine medicated milk and drinking water.
(a) Chemical name. N’-6-(Chloro-3-pyridazinyl) sulfanilamide.
(b) Specifications. Melting point range: 190° C to 191°C.
(c) Sponsor. See No. 053501 in § 510.600(c) of this chapter.
(d) Related tolerances. See § 556.630 of this chapter.
(e) Conditions of use. It is used as follows:
(1) Calves—(i) Amount. 30 to 45 milligrams per pound body weight per day.
§ 520.2200c Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) Specifications. (1) The oral solution contains 12.5 percent (3.75 grams per ounce) sulfadimethoxine.

(2) Each packet of powder contains the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt).

(b) Sponsors. See Nos. 000010, 000069, and 057561 in § 510.600(c) of this chapter.

(c) Special considerations. Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders.

(d) Related tolerances. See § 556.640 of this chapter.

(e) Conditions of use. The oral solution is administered as a cattle drench or diluted as directed to prepare drinking water. The powder is used to prepare a drench or drinking water. The concentrations and uses of the various solutions are as follows:

(1) Broiler and replacement chickens only. (i) Amount. 1.875 (0.05 percent) grams per gallon.

(ii) Indications for use. Treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) Limitations. Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(2) Meat-producing turkeys only—(i) Amount. 0.938 (0.025 percent) grams per gallon.

(ii) Indications for use. Treatment of disease outbreaks of coccidiosis and fowl cholera.

(ii) Limitations. Administer for 6 consecutive days; do not administer to
turkeys over 24 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(3) Dairy calves, dairy heifers, and beef cattle only—(i) Amount. 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.

(ii) Indications for use. Treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

(iii) 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; in drinking water or drench; available as a sulfadimethoxine soluble powder or a 12.5 percent sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat beyond 5 days; withdraw 7 days before slaughter.


§ 520.2220c Sulfadimethoxine tablets and boluses.

(a) Chemical name. N’-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) Sponsors. Firms identified by numbers in §510.600(c) of this chapter have been granted approvals for specific conditions of use as indicated in paragraph (e) of this section as follows:

(1) To 000069: approval for use as in paragraphs (e) (1) and (3) of this section.

(2) [Reserved]

(3) To 000061: approval for use as in paragraph (e)(2)(ii) of this section.

(c) [Reserved]

(d) Related tolerances. See §556.640 of this chapter.

(e) It is used as follows:

(1) Cattle—(i) Amount. 1.25 to 2.5 grams per 100 pounds body weight.

(ii) Indications for use. Treatment of foot rot, bacterial pneumonia, shipping fever, and calf diphtheria.

(iii) Limitations. 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 from 4 to 5 days; 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.

(2) Dogs and cats—(i) [Reserved]

(ii) Amount. 12.5 to 25 milligrams per pound body weight.

(a) Indications for use. Treatment of sulfadimethoxine-susceptible bacterial infections.

(b) Limitations. Administer 25 milligrams per pound body weight for first day followed by 12.5 milligrams per pound body weight per day until the animal is free of symptoms for 48 hours, for use only by or on the order of a licensed veterinarian.

(3) Beef cattle and nonlactating dairy cattle—(i) Amount. 12.5-gram-sustained-release bolus.

(ii) Indications for use. Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as Pasteurella spp. sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with Sphaerophorus necrophorus sensitive to sulfadimethoxine.

(iii) Limitations. Administer one 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. Do not use in lactating dairy cattle. Do not administer within 12 days of slaughter. During treatment make certain that animals maintain adequate water intake. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.2220d Sulfadimethoxine oral suspension.

(a) Chemical name. N’-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) Specifications. Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) Sponsor. See Nos. 000061 and 000069 in §510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.
§ 520.2220d Sulfadimethoxine–ormetoprim tablets.

(a) Specifications. Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or 1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. On the first day of treatment, administer 25 milligrams per pound (55 milligrams per kilogram) of body weight. Then follow with a daily dosage of 12.5 milligrams per pound (27.5 milligrams per kilogram) of body weight.

(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 Escherichia coli, Staphylococcus spp., and Proteus mirabilis susceptible to ormetoprim-potentiated sulfadimethoxine.

(3) Limitations. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during the treatment period.


§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) Chemical name. N′-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) Specifications. Melting point range of 180° C. to 186° C.

(c) Sponsor. See No. 010042 in §510.600(c) of this chapter.

(d) Related tolerances. See §556.650 of this chapter.

(e) Conditions of use. It is used as follows:

(1) Swine—(i) Amount. 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).

(ii) Indications for use. Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying Salmonella cholerasuis infection.

(iii) Limitations. 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 as sodium sulfaethoxypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) Cattle—(i) Amount. 2.5 grams per gallon (0.066 percent).

(ii) Indications for use. Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) Limitations. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

§ 520.2240b Sulfaethoxypyridazine tablets.

(a) Chemical name. N′-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) Specifications. Melting point range of 180° C to 186° C.

(c) Sponsor. See No. 010042 in §§510.600(c) of this chapter.

(d) Related tolerances. See §556.650 of this chapter.

(e) Conditions of use. It is used for cattle as follows:
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§ 520.2260a Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblets and boluses.

(a)(1) Sponsor. See No. 010042 in §510.600(c) of this chapter for use of 2.5, 5, or 15 gram sulfamethazine oblet.

(b)(1) Sponsor. See No. 053501 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 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. Not for use in lactating dairy animals. Do not treat cattle within 10 days of slaughter. Not to be used in horses intended for food.

(4) NAS/NRC status. The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(1) Sponsor. See No. 053501 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 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 (colibacillosis) 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 recommended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

§ 520.2260b Sulframethazine sustained-release boluses.

(a)(1) Sponsor. See No. 000859 in §510.600(c) of this chapter for use of a 22.5-gram sulframethazine 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 sulframethazine.

(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. 053501 in §510.600(c) of this chapter for use of a 27-gram sulframethazine 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 sulframethazine 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. 050604 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.1

(ii) Indications for use. For beef and nonlactating dairy cattle for the treatment of diseases caused by sulframethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by Pasteurella spp., colibacillosis (bacterial scour) 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.1

(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

1These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
the 3-day therapy. Do not use in lactating dairy cattle. Do not treat animals within 12 days of slaughter.

(d)(1) Sponsor. See 000059 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 scour) (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. 050004 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 scour) (E. coli), and calf diphtheria (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. 000010 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 Pasteurella spp.; necrotic pododermatitis (foot rot) and calf diphtheria caused by Fusobacterium necrophorum; colibacillosis (bacterial scour) caused by Escherichia coli; coccidiosis caused by Eimeria bovis and E. zuernii; 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 scour) 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.


§ 520.2261c Sulfamethazine sustained-release tablets.

(a) Sponsor. See No. 053501 in §510.600(c) of this chapter for use of an 8-gram sulfamethazine sustained-release tablet.

(b) 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 scour) caused by Escherichia coli; and calf diphtheria caused by Fusobacterium necrophorum.

(3) Limitations. If there is no response within 2 to 3 days, reevaluate therapy. Do not crush tablets. 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.


§ 520.2261 Sulfamethazine sodium oral dosage forms.

§ 520.2261a Sulfamethazine sodium drinking water solution.

(a) Sponsor. See Nos. 017800 and 010042 in §510.600(c) of this chapter for use of a 12.5-percent sulfamethazine sodium solution.

(b) Related tolerances in edible products. See §556.670 of this chapter.

(c) 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 scour) (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 scour) (Escherichia coli), and bacterial pneumonia (Pasteurella spp.).

(iii) Chickens and turkeys. In chickens for control of infectious coryza (Haemophilus gallinarum), 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;
Sulfamethazine sodium soluble powder.

(a) Sponsor. See No. 010042 in §510.600(c) of this chapter for use of a soluble powder composed of 100 percent sulfamethazine sodium.

(b) Related tolerances in edible products. See §556.670 of this chapter.

(c) Conditions of use—(1) Amount. Administer in drinking water to provide: Chickens 58 to 85 milligrams of sulfamethazine sodium per pound of body weight per day; turkeys 50 to 124 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. Administer to cattle and swine in drinking water, or as a drench, to provide 108 milligrams of sulfamethazine sodium per pound of body weight on the first day and 54 milligrams of sulfamethazine sodium per pound of body weight per day on the second, third, and fourth days of administration.

(2) Indications for use. For treatment and control of disease 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 (Haemophilus gallinarum), coccidiosis (Eimeria tenella, Eimeria necatrix), acute fowl cholera (Pasteurella multocida), and pullorum disease (Salmonella pullorum). In turkeys for control of coccidiosis (Eimeria meleagrimitis, Eimeria adenoides). 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 for 2 days, then reduce drug concentration 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 prior to slaughter for food. Not for use in lactating dairy cattle. 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.

§520.2261b 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 prior to slaughter for food. Not for use in lactating dairy cattle. 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.

(d) NAS/NRC status. The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

[47 FR 25322, June 11, 1982]

§ 520.2280 Sulfamethizole and methenamine mandelate tablets.

(a) Specifications. Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use.

(1) The drug is indicated for the treatment of urinary tract infections in dogs and cats such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. It is also used 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.

(2) It is administered at a dosage level of one tablet for each 20 pounds of body weight given three times per day. The drug should be given until all signs are alleviated. To reduce the possibility of a relapse, it is suggested that therapy be continued for a further period of a week to 10 days.

(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 50 FR 13561, Apr. 5, 1985]

§ 520.2320 Sulfaquinoxaline oral dosage forms.

§ 520.2325a Sulfaquinoxaline drinking water.

(a) Sponsor. See §510.600(c) of this chapter for identification of the sponsors.

(1) To No. 050749 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 No. 060594 for use of 3.44- and 12.85-percent sulfaquinoxaline sodium solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) To No. 017144 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.

(4) No. 053501 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. adenoides.
(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. Consult a veterinarian or poultry pathologist for diagnosis. 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.

§520.2325b Sulfaquinoxaline drench.

(a)-(b) [Reserved]

(c) Sponsor. See No. 050749 in §510.600 (c) of this chapter.

(d) NAS/NRC status. The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses
need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency information. Applications for these uses must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) Conditions of uses. As a 25-percent sulfaquinoxaline soluble powder.

(1) For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by Eimeria bovis or E. zuernii.

(2) Give one teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(f) Limitations. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

§ 520.2330 Sulfisoxazole tablets.

(a) Specifications. Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—

(1) Amount. Administer one tablet orally per 4 pounds of body weight.\textsuperscript{1}

(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.\textsuperscript{1}

(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.\textsuperscript{1}

\textsuperscript{1}These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) Specifications. Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) Sponsor. See §510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

(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 Escherichia 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 the 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.


§ 520.2345b Tetracycline tablets.

(a) Specifications. Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) Sponsor. For 100, 250, or 500 milligrams per tablet, see No. 000069 in §510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 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]

§ 520.2345c Tetracycline boluses.

(a) Specifications. Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

(b) Sponsors. See No. 010042 in §510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No. 000009 in §510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

(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.


(iii) 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.

(iv) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use specified in paragraph (d)(1) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.

(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]

§ 520.2345d Tetracycline hydrochloride soluble powder.

(a) Sponsors. The following sponsors listed in §510.600(c) of this chapter hold approvals for the drug concentrations (i.e., grams of tetracycline hydrochloride per pound) and conditions of use indicated:

(1) 046573, 051259, 054273, 057561, and 059130 102.4 and 324 grams per pound as in paragraph (d) of this section.

(2) 000009, 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(3) 010042, 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) 046573, 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(b) Related tolerances. See §556.720 of this chapter.

(c) [Reserved]

(d) Conditions of use in drinking water—(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 (Hemophilus 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 sponsor 010042 and within 5 days of treatment for sponsors 046573 and 000009; prepare a fresh solution daily; use as the sole source of tetracycline.

(2) Swine—(i) Amount. 10 milligrams per pound of body weight per day in divided doses.


(iii) Limitations. Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor
§ 520.2345e Tetracycline oral liquid.

(a) Specifications. Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

(b) Sponsor. See No. 000009, in §510.600(c) of this chapter for use of 25 or 100 milligrams per milliliter liquid in dogs as in paragraph (c)(1) of this section; see No. 000009 in §510.600(c) of this chapter for use of 100 milligrams per milliliter liquid in dogs and cats as in paragraph (c)(2).

(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.

(iv) National Academy of Sciences/National Research Council (NAS/NRC) status. These conditions were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(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, 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]

§ 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. 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. Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. 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. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Administer for 48 hours only. Continue treatment if needed with tetracycline/novobiocin alone. The product is contraindicated in animals with tuberculosis, hyperadrenocorticalism, or peptic ulcers. Clinical and experimental data have 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]
§ 520.2362 Thenium closylate tablets.

(a) Chemical name. (N,N-Dimethyl-N-2-phenoxyethyl-N-2-thenylammonium)-p-chlorobenzene-sulfonate.

(b) Specifications. Thenium closylate tablets contain thenium closylate equivalent to 500 milligrams thenium as base in each tablet.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The tablets are administered orally to dogs as a single day treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms). Dogs weighing 10 pounds and over are administered 1 tablet as a single dose. Dogs weighing 5 to 10 pounds are administered one-half tablet twice during a single day. All dosages are given for 1 day only. The treatment should be repeated after 2 or 3 weeks.

(2) Suckling puppies or recently weaned puppies weighing less than 5 pounds should not be treated with the drug. Animals that are severely infected, exhibiting evidence of intestinal hemorrhage, debilitation, and anemia, should be given supportive treatment.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 520.2380 Thiabendazole oral dosage forms.

§ 520.2380a Thiabendazole top dressing and mineral protein feed block.

(a) Chemical name. 2-(4-Thiazolyl)benzimidazole.

(b) Specifications. Conforms to N.F. XI.

(c) Sponsor. (1) See No. 017800 in §510.600(c) of this chapter for the sponsor of the usage provided for by paragraph (e)(1)(ii) of this section.

(2) See No. 050604 in §510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e)(1)(iii) of this section.

(3) See No. 021930 in §510.600(c) of this chapter for the sponsor of the usage provided for by paragraph (e)(2) of this section.

(d) Related tolerances. See §556.730 of this chapter.

(e) 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, *Strongylus*, and pinworms of the genera *Strongylus*, *Cyathostomum*, and *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) 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
§ 520.2380b Thiabendazole drench or oral paste.

(a) Chemical name. 2-(4-Thiazolyl)benzimidazole.

(b) Specifications. Conforms to N.F. XII.

(c) Sponsor. See No. 050604 in §510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e) of this section.

(d) Related tolerances. See §556.730 of this chapter.

(e) Conditions of use. It is used as follows:

(i) Horses. As a single liquid oral dose, administered as a drench or by stomach tube; or as an oral paste.

(ii) Amount. 2 grams per 100 pounds of body weight.

(iii) Indications for use. For the control of infections of large strongyles (Strongylus vulgaris, Strongylus endentatus), small strongyles (Cyathostomum, 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 the 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.

(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 retreated 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)(ii)(a) of this section.

(b) Limitations. For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be retreated 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.


(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.

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§ 520.2380c Thiabendazole bolus.

(a) Chemical name. 2-(4-Thiazolyl) benzimidazole.

(b) Specifications. Conforms to N.F. XII.

(c) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(d) Related tolerances. See §556.730 of this chapter.

(e) Conditions of use. It is used as follows:

(1) Cattle. In a bolus.

(i) Amount. 3 grams per 100 pounds of body weight.


(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 (genera Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp., Cooperia 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 Oesophagostomum spp.).

§ 520.2380f Thiabendazole, piperazine phosphate powder.

(a) Specifications. Each ounce of water dispersible powder contains 6.67 grams of thiabendazole and 2.5 grams of piperazine phosphate. (b) Sponsor. See No. 017135 in § 510.600(c) of this chapter. (c) Conditions of use. (1) It is administered to horses by stomach tube or as a drench at the rate of 1 fluid ounce of suspension per 100 pounds of body weight 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.). (2) Do not use in horses intended to be used for food purposes. (3) For 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]

§ 520.2380g Thiabendazole, piperazine citrate suspension.

(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. (1) It is administered to horses by stomach tube or as a drench at the rate of 1 fluid ounce of suspension per 100 pounds of body weight 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.). (2) Do not use in horses intended to be used for food purposes.
§ 520.2455

Tiamulin soluble powder.

(a) Specifications. A water-soluble powder containing 45 percent tiamulin used to make a medicated drinking water containing 227 or 677 milligrams of tiamulin per gallon.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.738 of this chapter.

(d) Conditions of use in swine—

(1) Amount. 3.5 milligrams of tiamulin per pound of body weight for 5 days.

(i) Indications for use. For treatment of swine dysentery associated with Treponema hydysenteriae and swine pneumonia due to Actinobacillus pleuropneumoniae susceptible to tiamulin.

(ii) Limitations. Use for 5 consecutive days. When a dose is 3.5 milligrams per pound of body weight daily, withdraw medication 3 days before slaughter. Prepare fresh medicated water daily. Not for use in swine over 250 pounds body weight.

(2) Amount. 10.5 milligrams of tiamulin per pound of body weight for 5 days.

(i) Indications for use. For treatment of swine pneumonia due to Actinobacillus pleuropneumoniae susceptible to tiamulin.

(ii) Limitations. Use for 5 consecutive days. Withdraw 7 days before slaughter. Prepare fresh water daily. Not for use in swine over 250 pounds body weight. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin or salinomycin) as adverse reactions may occur.

§ 520.2456

Tiamulin liquid concentrate.

(a) Specifications. A liquid concentrate containing 12.3 percent tiamulin used to make a medicated drinking water containing 227 milligrams or 681 milligrams of tiamulin per gallon.

(b) Sponsor. See 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.738 of this chapter.

(d) Conditions of use in swine—

(1) Amount. Dysentery: 3.5 milligrams of tiamulin per pound of body weight daily. Pneumonia: 10.5 milligrams of tiamulin per pound of body weight daily.

(2) Indications for use. For treatment of swine dysentery associated with Treponema hydysenteriae and swine pneumonia due to Actinobacillus pleuropneumoniae susceptible to tiamulin.

(3) Limitations. Use for 5 consecutive days. When a dose is 3.5 milligrams per pound of body weight daily, withdraw medication 3 days before slaughter. Prepare fresh medicated water daily. Not for use in swine over 250 pounds body weight. Do not allow consumption of feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin or salinomycin) as adverse reactions may occur.
monensin, lasalocid, narasin, or salinomycin) as adverse reactions may occur.


§ 520.2460 Ticarbodine oral dosage forms.

§ 520.2460a Ticarbodine tablets.

(a) Specifications. Ticarbodine tablets, veterinary contain 90, 225, or 900 milligrams of ticarbodine per tablet.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs for the removal of roundworms (Toxocara canis), hookworms (Ancylostoma caninum and Uncinia stenocephala), and tapeworms (Dipylidium caninum and Taenia pisiformis).

(2) Dosage is administered at 45 milligrams of the drug per pound of body weight in a single dose. Dosage may be repeated in 21 days.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2460b Ticarbodine capsules.

(a) Specifications. Each capsule contains 90, 225, 450, or 900 milligrams of ticarbodine.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs for removal of roundworms (Toxocara canis), hookworms (Ancylostoma caninum and Uncinia stenocephala), and tapeworms (Dipylidium caninum and Taenia pisiformis).

(2) Dosage is administered orally as a single dose at 45 milligrams per lb. of body weight. Dosage may be repeated in 21-day intervals.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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]

§ 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
§ 520.2481 Triamcinolone acetonide tablets.

(a) Specifications. Each tablet contains either 0.5 milligram or 1.5 milligrams of the drug.
(b) Sponsor. See Nos. 000010 and 053501 in §510.600(c) of this chapter.
(c) NAS/NRC status. The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(d) Conditions of use. (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.
   (2) An initial daily dosage of 0.05 milligram per pound of body weight is usually sufficient to control symptoms, although up to 0.1 milligram per pound of body weight may be given daily if response to the smaller dose is inadequate. As soon as feasible, and in any case within 2 weeks, dosage should be reduced gradually to maintenance levels of 0.0125 to 0.025 milligram per pound of body weight per day. Therapy should be discontinued by a gradual reduction in dosage after the condition has been controlled for several days.
   (3) The labeling shall comply with the requirements of §510.410 of this chapter.
   (4) Not for use in horses intended for food.
   (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2482 Triamcinolone acetonide oral powder.

(a) Specifications. Each 15 grams of triamcinolone acetonide oral powder contains 10 milligrams of triamcinolone acetonide.
(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.
(c) NAS/NRC status. The conditions of use specified in this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(d) Conditions of use. (1) The drug is used as an anti-inflammatory agent for horses.
   (2) It is administered at a dosage of 0.005 to 0.01 milligram triamcinolone acetonide per pound of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Treatment may be initiated with a single dose of sterile triamcinolone acetonide suspension USP followed after 3 or 4 days with the use of triamcinolone acetonide oral powder.
   (3) The labeling shall comply with the requirements of §510.410 of this chapter.
   (4) Not for use in horses intended for food.
   (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2520 Trichlorfon oral dosage forms.

(a) Chemical name. Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.
(b) Sponsor. See No. 017800 in §510.600(c) of this chapter.
(c) Special considerations. This drug 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.
(d) Conditions of use. (1) It is intended for use in horses for the removal of bots (Gasterophilus spp.), ascarids (Parascaris equorum), and pinworms (Oxyuris equi).
   (2) Mix the drug, either dry or dissolved in water, in feed and administer
at the rate of 4.5 grams of trichlorfon per 250 pounds of body weight. The drug is to be consumed at one feeding. Treatment should be repeated at 3-to 4-month intervals. Do not repeat treatment more frequently than every 30 days. Do not treat horses to be used for food. Do not treat sick or debilitated horses, colts under 4 months of age, mares in the last month of pregnancy, or animals other than horses. Do not administer intravenous anesthetics, especially muscle relaxants, for a period of 2 weeks after treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 63097, Nov. 2, 1979; 61 FR 34729, July 3, 1996]

§ 520.2520b Trichlorfon and atropine.

(a) Chemical name. (1) For trichlorfon: O,O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the treatment of Syphacia obvelata (pinworm) in laboratory mice.

(2) It is administered in distilled water as sole source of drinking water continuously for 7 to 14 days at 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter.

(3) Prepare fresh solution every 3 days. Do not use simultaneously with other drugs, insecticides, pesticides, or chemicals having cholinesterase activity, nor within 7 days before or after treatment with any other cholinesterase inhibitor.

(4) Restricted to use by or on the order of a licensed veterinarian.

§ 520.2520e Trichlorfon boluses.

(a) Specifications. Each bolus contains either 7.3, 10.9, 14.6, or 18.2 g of trichlorfon.

(b) Sponsor. See 000856 in §510.600(c) of this chapter.

(c) Special considerations. Trichlorfon is a cholinesterase inhibitor. Do not use this product on animals simultaneously with, or within 2 weeks before or after treatment with or exposure to, neuromuscular depolarizing agents (i.e., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) NAS/NRC status. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.

(e) Conditions of use—(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 fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48127, July 18, 1980]

§ 520.2520f Trichlorfon granules.

(a) Specifications. Each package contains either 18.2 or 36.4 g of trichlorfon.

(b) Sponsor. See 000856 in §510.600(c) of this chapter.

(c) Special considerations. Trichlorfon is a cholinesterase inhibitor. Do not use this product on animals simultaneously with, or within 2 weeks before or after treatment with or exposure to, neuromuscular depolarizing agents (i.e., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) NAS/NRC status. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter.

(e) Conditions of use—(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 fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe
§ 520.2520g 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. 000856 in §510.600(c) of this chapter.

(c) Special considerations. Labeling shall bear the following statements: The drug is a cholinesterase inhibitor. Do not use this product in horses simultaneously with, or within 2 weeks before or after treatment with, or exposure to, neuromuscular depolarizing agents (e.g., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) Conditions of use—(1) Amount. 18.2 milligrams of trichlorfon, 12.5 milligrams of phenothiazine, and 40.0 milligrams of piperazine base 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. Mix powder and vial contents together in warm water to form suspension. Administer by stomach tube. Do not fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 48128, July 18, 1980]

§ 520.2582 Triflupromazine hydrochloride tablets.

(a) Specifications. Each tablet contains either 10 milligrams or 25 milligrams of triflupromazine hydrochloride.

(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs and cats 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.

(2) The drug is administered orally to dogs and cats at a dosage level of 1 to 2 milligrams per pound of body weight daily; an initial dosage at the 2-milligram level is suggested followed by daily doses at the 1-milligram level. Frequently, the drug may be withdrawn after 4 to 5 days, with drug effect continuing after withdrawal.

(3) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) 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 41489, Oct. 11, 1985]

§ 520.2604 Trimeprazine tartrate and prednisolone tablets.

(a) Specifications. Each tablet contains: trimeprazine tartrate, 5 milligrams; and prednisolone, 2 milligrams.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is administered orally to dogs for the relief of itching regardless of cause; 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. It is also used in dogs as adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheoobronchitis, bronchitis including allergic bronchitis, in
Food and Drug Administration, HHS

§ 520.2605

Trimeprazine tartrate and prednisolone capsules.

(a) Specifications. Each capsule contains 3.75 milligrams of trimeprazine in sustained released form (as the tartrate) and 2 milligrams of prednisolone (capsule no. 2).

(b) Sponsor. See 000079 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer either capsule orally once daily to dogs as follows:

<table>
<thead>
<tr>
<th>Animal weight (pounds)</th>
<th>Number of capsules per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsule No. 1</td>
</tr>
<tr>
<td>Up to 10</td>
<td>1</td>
</tr>
<tr>
<td>11 to 20</td>
<td>2</td>
</tr>
<tr>
<td>21 to 40</td>
<td>4</td>
</tr>
<tr>
<td>Over 40</td>
<td>6</td>
</tr>
</tbody>
</table>

(2) Indications for use. For the relief of itching regardless of cause, 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). It is also used in dogs as adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, tonsillitis, acute upper respiratory infections, and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(3) Limitations. After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.

(4) Clinical and experimental data have 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.

(5) 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 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

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Trimsilatin, acute upper respiratory infections and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.1

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.

(4) Clinical and experimental data have 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.

(5) 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 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]
§ 520.2610 *Trimethoprim and sulfadiazine tablets.*

(a) Specifications. Each tablet contains 30 milligrams (5 milligrams of trimethoprim and 25 milligrams of sulfadiazine), 120 milligrams (20 milligrams of trimethoprim and 100 milligrams of sulfadiazine), 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine) or 960 milligrams (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine).

(b) Sponsor. See Nos. 000061 and 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) 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.

(2) The drug is given orally at 30 milligrams per kilogram of body weight per day (14 milligrams per pound per day), or as follows:

<table>
<thead>
<tr>
<th>Animal body weight (pounds) Number of tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>30 MG TABLETS</td>
</tr>
<tr>
<td>2.2 ........................................................................ 1</td>
</tr>
<tr>
<td>4.4 ........................................................................ 2</td>
</tr>
<tr>
<td>6.6 ........................................................................ 3</td>
</tr>
<tr>
<td>8.8 ........................................................................ 4</td>
</tr>
<tr>
<td>120 MG TABLETS</td>
</tr>
<tr>
<td>Up to 9 ................................................................. 1</td>
</tr>
<tr>
<td>10 to 19 ............................................................... 2</td>
</tr>
<tr>
<td>20 to 29 ............................................................... 3</td>
</tr>
<tr>
<td>30 to 40 ............................................................... 4</td>
</tr>
<tr>
<td>480 MG TABLETS</td>
</tr>
<tr>
<td>30 to 40 ............................................................... 1</td>
</tr>
<tr>
<td>40 to 60 ............................................................... 1 1/6</td>
</tr>
<tr>
<td>60 to 80 ............................................................... 2</td>
</tr>
<tr>
<td>80 to 110 ............................................................. 3</td>
</tr>
<tr>
<td>Over 110 .............................................................. 4</td>
</tr>
</tbody>
</table>

(3) The drug is given once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis.

(4) Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

(7) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2611 *Trimethoprim and sulfa-diazine oral paste.*

(a) Specifications. Each gram of oral paste contains 400 milligrams (67 milligrams of trimethoprim and 333 milligrams of sulfadiazine).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter for product to be dosed at 5 grams per 150 pounds of body weight per day. See No. 000061 in §510.600(c) of this chapter for product to be dosed at 3.75 grams per 110 pounds of body weight per day.

(c) Conditions of use—(1) Dosage. (i) 5 grams (335 milligrams of trimethoprim and 1,665 milligrams of sulfadiazine) per 150 pounds (68 kilograms) of body weight per day. (ii) 3.75 grams (250 milligrams of trimethoprim and 1,250 milligrams of sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) Indications for use. For horses 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. Administer orally, once a day, as a single dose for 5 to 7 days; daily dose may also be halved and given morning and evening; for acute infection therapy continue treatment 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count...
§ 520.2612 Trimethoprim and sulfadiazine oral suspension.

(a) Specifications. Each milliliter of oral suspension contains 60 milligrams of drug (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine).

(b) Sponsor. See No. 000061 in §510.600 of this chapter.

(c) Conditions of use. Dogs—(1) Dosage. 1 milliliter (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine) per 5 pounds of body weight.

(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. For oral use only. Administer the recommended dose once daily or one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. If no improvement is seen in 3 to 5 days, reevaluate diagnosis. A complete blood count should be done periodically with prolonged use. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2613 Trimethoprim and sulfadiazine powder.

(a) Specifications. Each gram of powder contains 67 milligrams of trimethoprim and 333 milligrams of sulfadiazine.

(b) Sponsor. See No. 058711 in §510.600(c) of this chapter.

(c) Conditions of use: Horses—(1) Dosage. 3.75 grams of powder per 110 pounds (50 kilograms) of body weight per day.

(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. Administer orally in a small amount of feed, as a single daily dose, for 5 to 7 days. Continue therapy for 2 to 3 days after clinical signs have subsided. If no improvement is seen in 3 to 5 days, reevaluate diagnosis. A complete blood count should be done periodically with prolonged use. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2640 Tylosin.

(a) Specifications. Tylosin is the antibiotic substance produced by growth of Streptomyces fradiae or the same antibiotic substance produced by any other means. Tylosin, present as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled “Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,” which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) Sponsor. See No. 000986 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 §556.740 of this chapter.

(e) Conditions of use. It is used in drinking water of animals as follows:

(i) Chickens—(i) Amount. 2 grams per gallon.

(ii) Indications for use. Aid in the treatment of chronic respiratory disease (CRD) caused by Mycoplasma gallisepticum sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) caused by Mycoplasma synoviae sensitive to tylosin in broiler chickens.

(iii) Limitations. Do not use in layers producing eggs for human consumption; administer from 1 to 5 days as sole source of drinking water; treated chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter.

(ii) Turkeys—(i) Amount. 2 grams per gallon.

(ii) Indications for use. Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by Mycoplasma gallisepticum sensitive to tylosin.

(iii) Limitations. Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter.

(2) Swine—(i) Amount. 0.25 gram per gallon.

(ii) Indications for use. For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) Limitations. As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated; mix fresh solution daily; medication must be withheld from animals 48 hours prior to slaughter.


PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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522.62 Amopropazine fumarate sterile solution injection.
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522.90b Ampicillin trihydrate for sterile suspension.
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522.234 Butamisole hydrochloride.
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522.314 Ceftiofur hydrochloride sterile suspension.
522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.
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522.480 Repository corticotropin injection.
522.518 Cupric glycate injection.
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522.540 Dexemethasone injection.
522.542 Dexemethasone-21-isonicotinate suspension.
522.563 Diatrizoate meglumine and diatrizoate sodium injection.
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522.575 Diazepam injection.
522.590 Dihydrostreptomycin sulfate injection.
522.650 Dinoprost tromethamine sterile solution.
522.690 Diprenorphine hydrochloride injection.
522.723 Doxycycline hyclate.
522.770 Doramectin.
522.775 Doxapram hydrochloride injection.
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522.784 Doxylamine succinate injection.
522.800 Droperidol and fentanyl citrate injection.
522.812 Enrofloxacin solution.
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522.840 Estradiol.
522.842 Estradiol benzoate and testosterone propionate in combination.
522.850 Estradiol valerate and norgestomet in combination.
522.863 Ethylisobutrazine hydrochloride injection.
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522.914 Fenprostalene solution.
522.940 Colloidal ferric oxide injection.
522.955 Florfenicol solution.
522.960 Flumethasone implantation or injectable dosage forms.
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522.970 Flunixin meglumine solution.
522.1002 Follicle stimulating hormone.
522.1004 Fomepizole.
522.1010 Furosemide injection.
522.1020 Gelatin solution.
522.1044 Gentamicin sulfate injection.
522.1055 Gleptoferron injection.
522.1066 Glycopyrrolate injection.
522.1077 Gonadorelin injectable.
522.1078 Gonadorelin diacetate tetrahydrate injection.
522.1079 Serum gonadotropin and chorionic gonadotropin.
522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
522.1085 Guaiifenesin sterile powder.
522.1086 Guaiifenesin injection.
522.1125 Hemoglobin glutamer-200 (bovine) solution.
522.1145 Hyaluronate sodium injection.
522.1150 Hydrochlorothiazide injection.
522.1155 Imidocarb dipropionate sterile powder.
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522.1182 Iron dextran complex injection.
522.1183 Iron hydrogenated dextran injection.
522.1192 Ivermectin injection.
522.1193 Ivermectin and clorsulon injection.
522.1204 Kanamycin sulfate injection.
522.1222 Ketamine hydrochloride injectable dosage forms.
522.1222a Ketamine hydrochloride injection.
522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamidie hydrogen sulfate injection.
522.1225 Ketoprofen solution.
522.1228 [Reserved]
522.1244 Levamisole phosphate injection.
522.1258 Lidocaine injection with epinephrine.
522.1260 Lincomycin injection.
522.1290 Luprostol sterile solution.
522.1335 Medetomidine hydrochloride injection.
522.1350 Melatonin implant.
522.1362 Melarsomine dihydrochloride for injection.
522.1372 Meipivacaine hydrochloride injection.
522.1380 Methocarbamol injection.
522.1410 Sterile methylprednisolone acetate suspension.
522.1452 Nalorphine hydrochloride injection.
522.1462 Naloxyone hydrochloride injection.
522.1465 Naltrexone hydrochloride injection.
522.1468 Naproxen for injection.
522.1484 Neomycin sulfate sterile solution.
522.1503 Neostigmine methylsulfate injection.
522.1610 Oleate sodium solution.
522.1620 Orgastein for injection.
522.1642 Oxyhomorphine hydrochloride injection.
522.1660 Oxytetracycline injection.
522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
522.1662a Oxytetracycline hydrochloride injection.
522.1662b Oxytetracycline hydrochloride with lidocaine injection.
522.1668 Oxytocin injection.
522.1696 Penicillin G procaine implantation and injectable dosage forms.
522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.
522.1696b Penicillin G procaine aqueous suspension.
522.1696c Penicillin G procaine in oil.
522.1698 Pentazocine lactate injection.
522.1704 Sodium pentobarbital injection.
522.1720 Phenylbutazone injection.
522.1850 Polysulfated glycosaminoglycan.
522.1852 Sterile pralidoxime chloride.
522.1870 Pretizanef quadrate solution.
522.1881 Sterile prednisolone acetate aqueous suspension.
522.1883 Prednisolone sodium phosphate injection, sterile.
522.1884 Prednisolone sodium succinate injection.
522.1885 Prednisolone tertiary butylacetate suspension.
522.1890 Sterile prednisone suspension.
522.1920 Prochlorperazine, isopropamide for injection.
522.1940 Progesterone and estradiol benzoate in combination.
522.1962 Promazine hydrochloride injection.
§ 522.23

Acrivastine injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 10 milligrams of acrivastine maleate.

(b) Conditions of use. See No. 000056 in §510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) Indications for use. It is used in dogs, cats, and horses as an antihistaminic agent.

(2) Amount. Dogs: 0.2 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) Conditions of use. See No. 000010 in §510.600(c) of this chapter for use in dogs as follows:

(1) Indications for use. It is used in dogs as an antihistaminic agent.

(2) Amount. Dogs: 2.0 to 4.0 milligrams per pound of body weight.

(3) Limitations. The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.44 Sterile sodium acetazolamide.

(a) Specifications. Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) Sponsor. See No. 010042 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.1

(3) For use only by or on the order of a licensed veterinarian.1

§ 522.46 Alfacaprost.

(a) Specifications. Each milliliter of sterile solution contains 1 milligram of alfacaprost.

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(b) Sponsor. No. 055882 in §510.600(c) of this chapter.

(c) Conditions of use. It is used in horses as follows:

(1) Amount. For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) Indications for use. To cause luteolysis in mares with active corpora lutea.

(3) Limitations. For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.56 Amikacin sulfate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) Sponsor. See Nos. 000856 and 059130 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 5 milligrams per pound of body weight twice daily.

(2) Indications for use. The drug is used in dogs 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. The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case re-evaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing acuity is required for functioning. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) Chemical name. 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) Specifications. It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Dosage in milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>0.1</td>
</tr>
<tr>
<td>11 to 20</td>
<td>0.2</td>
</tr>
<tr>
<td>21 to 50</td>
<td>0.3</td>
</tr>
<tr>
<td>51 to 100</td>
<td>0.4</td>
</tr>
<tr>
<td>Over 100</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) Specifications. Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
§ 522.88 Sterile amoxicillin trihydrate for suspension.

(a)(1) Specifications. Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 250 milligrams per milliliter for use as in paragraph (e).

(b) Sponsor. See 000069 in §510.600(c) of this chapter.

(c) Related tolerance. See §556.38 of this chapter.

(d) Conditions of use in dogs and cats—

(1) Amount. 5 milligrams per pound of body weight daily.

(2) Indications for use—(i) Dogs. 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., and P. mirabilis.


(3) Limitations. For use in dogs and cats only. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing susceptibility testing of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Condition of use. Cattle—

(1) Amount. 3 to 5 milligrams per pound of body weight once a day according to the animal being treated, the severity of infection, and the animal's response.

(2) Indications for use—Treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to P. multocida, P. haemolytica, Hemophilus spp., Staphylococcus spp., and Streptococcus spp. and acute necrotic pododermatitis (foot rot) due to Fusobacterium necrophorum.

(3) Limitations. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 to 72 hours after the

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1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
animal has become afebrile or asymptomatic. Do not continue treatment beyond 5 days. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Maximum volume per injection should not exceed 30 milliliters.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.90 Ampicillin implantation and injectible dosage forms.

§ 522.90a Ampicillin trihydrate sterile suspension.

(a) Specifications. Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams of ampicillin.

(1) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(2) Related tolerances. See §556.40 of this chapter.

(3) Conditions of use—(i) Calves. Amount. For enteritis: 3 milligrams per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 milligrams per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(B) Indications for use. Treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella spp. susceptible to ampicillin.

(C) Limitations. Not for use in other animals raised for food production. 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.

(ii) Dogs. Amount. 3 to 6 milligrams per pound of body weight intramuscularly, once or twice daily.

(B) Indications for use. 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.

(C) Limitations. Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) Cats. Amount. 5 to 10 milligrams per pound of body weight intramuscularly or subcutaneously, once or twice daily.

(B) Indications for use. Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to Staphylococcus spp., Streptococcus spp., and Pasteurella spp.

(C) Limitations. Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) Swine. Amount. 3 milligrams per pound of body weight, intramuscularly, once or twice daily, for up to 3 days.

(B) Indications for use. Treatment of bacterial enteritis (coli bacillosis) caused by E. coli and bacterial pneumonia caused by Pasteurella spp. susceptible to ampicillin.

(C) 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.

(b) Specifications. Each milliliter contains ampicillin trihydrate equivalent to 150 milligrams of ampicillin.

(1) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(2) Related tolerances. See §556.40 of this chapter.

(3) Conditions of use. Dogs—(i) Amount. 3 to 5 milligrams of ampicillin per pound of body weight, once a day for up to 4 days.
§ 522.90b Ampicillin trihydrate for sterile suspension

(ii) Indications for use. 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. Administer intramuscularly. If continued treatment is indicated, oral dosage is recommended. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment are recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 522.90c Ampicillin sodium for aqueous injection

(a) Specifications. When reconstituted, each milliliter contains ampicillin sodium equivalent to 300 milligrams of ampicillin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.40 of this chapter.

(d) Conditions of use. (1) Dogs—(i) Amount. 3 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment of respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) Limitations. Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cats—(i) Amount. 3 milligrams per pound of body weight twice daily.

(ii) Indications for use. Treatment against 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.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993]
Food and Drug Administration, HHS

§ 522.144 Arsenamide sodium aqueous injection.

(a) Chemical name. [(p-Carbamoylphenyl) arsylene]dithio diacetic acid, sodium salt.

(b) Specifications. The drug is a sterile aqueous solution and each milliliter contains 10.0 milligrams of arsenamide sodium.

(c) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(d) Conditions of use. (1) For the treatment and prevention of canine heartworm disease caused by Dirofilaria immitis.

(2) It is administered intravenously at 0.1 milliliter per pound of body weight (1.0 milliliter for every 10 pounds) twice a day for 2 days. For dogs in poor condition, particularly those with evidence of reduced liver function, a more conservative dosage schedule of 0.1 milliliter per pound of body weight daily for 15 days is recommended.

(3) Restricted to use only by or on the order of a licensed veterinarian.


§ 522.147 Atipamezole hydrochloride.

(a) Specifications. Each milliliter of sterile injectable solution contains 5.0 milligrams of atipamezole hydrochloride.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Amount. Inject intramuscularly the same volume as that of medetomidine used.

(2) Indications for use. To reverse clinical effects of the sedative and analgesic agent medetomidine hydrochloride.

(3) Limitations. For intramuscular use only. Not recommended for use in pregnant or lactating animals, or animals intended for breeding. Atipamezole has not been evaluated in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.


(b) Specifications. The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phosphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection q.s.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) Conditions of use. It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for
example, acute and traumatic lameness involving the carpel and fetlock joints. Administer from 2.5 to 5 cubic centimeters per dose. Dose may be repeated when necessary depending upon the duration of relief obtained. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

§ 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 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.

§ 522.204 Boldenone undecylenate injection.

(a) Specifications. Each milliliter contains 25 or 50 milligrams of boldenone undecylenate in a sesame oil base.

(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is intended for use as an aid in treating debilitated horses following disease or overwork and overexertion when an improvement in weight, hair coat, or general physical condition is desired. The drug is given only as adjunctive therapy to other specific and supportive therapy for diseases, surgical cases, and traumatic injuries. Optimal results can be expected only when good management and feeding practices are followed.

(2) It is administered intramuscularly at a dosage level of 0.5 milligram per pound of body weight. Treatment may be repeated at 3-week intervals.

(3) For use in horses only. Do not administer to horses intended for use as food. The effectiveness of the drug in stallions and pregnant mares has not been established, nor has the drug been shown not to be teratogenic in pregnant mares; therefore, this drug should not be used in stallions and pregnant mares.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.234 Butamisole hydrochloride.

(a) Specifications. The drug contains 11 milligrams of butamisole per milliliter in a solution consisting of 70 percent propylene glycol, 4 percent benzyl alcohol, and distilled water.

(b) Sponsor. See Nos. 000859 and 043781 in §510.600(c) of this chapter.
Conditions of use.

(1) The drug is administered by subcutaneous injection to dogs for the treatment of infections with whipworms (Trichuris vulpis), and the hookworm (Ancylostoma caninum).

(2) The drug is administered subcutaneously at the rate of 0.1 milliliter per pound of body weight. 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.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.246 Butorphanol tartrate injection.

(a) Specifications. Each milliliter of aqueous solution contains either 0.5, 2 or 10 milligrams of butorphanol (as butorphanol tartrate).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—

(1) Dogs—(i) Amount. 0.025 milligram of butorphanol base activity per pound of body weight (equivalent to 0.5 milliliter per 10 pounds), using 0.5 milligram per milliliter solution.

(ii) Indications for use. For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsilitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(iii) Limitations. For subcutaneous injection in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to maximum of 0.05 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Horses—(i) Amount. 0.05 milligram of butorphanol base activity per pound of body weight (0.1 milligram/kilogram) using 0.5 milligrams per milliliter solution.

(ii) Indications for use. For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) Limitations. For intravenous use in horses only. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Cats—(i) Amount. 0.2 milligram of butorphanol base activity per pound of body weight (0.4 milligram/kilogram), using 2 milligrams per milliliter solution.

(ii) Indications for use. For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.

(iii) Limitations. For subcutaneous injection in cats only. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days. Safety for use in pregnant female cats, breeding male cats or kittens less than 4 months of age has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.311 Carfentanil citrate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 3 milligrams of carfentanil citrate.

(b) Sponsor. See No. 053923 in §510.600(c) of this chapter.

(c) Conditions of use—

(1) Amount. 5 to 20 micrograms per kilogram (0.005 to 0.020 milligram per kilogram) of body weight.

(2) Indications for use. For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) Limitations. Inject into large muscle of neck, shoulder, back, or hindquarter. Avoid intrathoracic, intra-abdominal, or subcutaneous injection. To reverse effect, use 7 milligrams of diprenorphine for each milligram of carfentanil citrate, given intravenously or one-half intravenously and one-half intramuscularly or subcutaneously. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Do not use in animals that display clinical signs of severe cardiovascular
or respiratory disease. Available data are inadequate to recommend use in pregnant animals. Avoid use during breeding 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.

[53 FR 40057, Oct. 13, 1988]

§ 522.313 Ceftiofur sterile powder for injection.

(a) Specifications. Ceftiofur sodium sterile powder for injection is reconstituted to form an aqueous solution containing the equivalent of 50 milligrams ceftiofur per milliliter.

(b) Sponsor. See 000009 in §510.600 of this chapter.

(c) Related tolerances. See §556.113 of this chapter.

(d) Conditions of use—(1) Cattle—(i) Amount. 0.5 to 1.0 milligram of ceftiofur per pound of body weight intramuscularly.

(ii) Indications for use. Treatment of bovine respiratory disease (shipping fever, pneumonia) associated with Pasteurella hemolytica, P. multocida, and Haemophilus somnus in beef and dairy cattle. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus.

(iii) Limitations. Treatment should be repeated once every 24 hours for 3 days. Treat for an additional 2 days if animals do not show a satisfactory response. Do not use in animals previously found to be hypersensitive to the drug. Use of doses in excess of those indicated or route of administration other than that recommended may result in illegal residues in tissues. Safety of ceftiofur has not been determined in breeding swine. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Swine—(i) Amount. 3 to 5 milligrams per kilogram (1.36 to 2.27 milligrams per pound) of body weight.

(ii) Indications for use. For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis, and Streptococcus suis Type 2.

(iii) Limitations. For intramuscular use only. Treatment should be repeated at 24 hour intervals for a total of 3 consecutive days. Do not use in animals previously found to be hypersensitive to the drug. Use of dosages in excess of those indicated or route of administration other than that recommended may result in illegal residues in tissues. Safety of ceftiofur has not been determined in breeding swine. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Day-old chickens—(i) Amount. 0.08 to 0.20 milligram per chick.

(ii) Indications for use. For control of early mortality associated with Escherichia coli organisms susceptible to ceftiofur.

(iii) Limitations. For subcutaneous use in the neck of day-old chicks only. As a single dose only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Day-old turkey poults—(i) Amount. 0.17 to 0.5 milligram per poult.

(ii) Indications for use. For control of early mortality associated with E. coli organisms susceptible to ceftiofur.

(iii) Limitations. For subcutaneous use in the neck of day-old poults only. As a single dose only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) Horses—(i) Amount. 2.2 to 4.4 milligrams per kilogram (1.0 to 2.0 milligrams per pound) of body weight.

(ii) Indications for use. For treatment of respiratory infections in horses associated with Streptococcus zooepidemicus.

(iii) Limitations. For intramuscular use only. 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 milliliters should be administered per injection site. Not for use in horses intended for food. Do not use in animals previously found to be hypersensitive to the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(6) Dogs—(i) Amount. 1.0 milligrams per pound (2.2 milligrams per kilogram) of body weight.

(ii) Indications for use. Treatment of canine urinary tract infections associated with Escherichia coli and Proteus mirabilis.
(iii) Limitations. For subcutaneous use only. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared, for 5 to 14 days. Do not use in animals found to be hypersensitive to the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(7) Sheep—(i) Amount. 0.5 to 1.0 milligram per pound (1.1 to 2.2 milligrams per kilogram) of body weight.

(ii) Indications for use. For treatment of sheep respiratory disease (pneumonia) associated with Pasteurella haemolytica and/or P. multocida.

(iii) Limitations. For intramuscular use only. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in tissues. Safety of ceftiofur has not been determined in breeding swine. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

(a) [Reserved]

(b)(1) Specifications. Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.

(2) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(3) Conditions of use. (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.390 Chloramphenicol injection.

(a) Specifications. Each milliliter contains 100 milligrams of chloramphenicol.

(b) Sponsor. See Nos. 000069 and 050604 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs—(1) Amount. 5 to 15 milligrams per pound of
§ 522.460 Cloprostenol sodium.

(a)(1) Specifications. Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.

(2) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(3) Conditions of use. For intramuscular use in beef and dairy cattle to induce luteolysis.

(i) Amount. 2 milliliters (equivalent to 500 micrograms of cloprostenol).

(ii) Indications. (a) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(b) Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception, or for treating unobserved (non-detected) estrus, mummified fetus, and luteal cysts.

(c) Single cloprostenol injection for the treatment of pyometra.

(iii) Do not administer to pregnant animals where the calf is not to be aborted.

(iv) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(v) 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 131.5 micrograms of cloprostenol sodium (equivalent to 125 micrograms of cloprostenol).

(2) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(3) Special considerations. Labeling shall bear the statements prescribed in paragraphs (a)(3) (iii) and (iv) of this section.

(4) Conditions of use—(i) Amount. 3 milliliters (equivalent to 375 micrograms of cloprostenol) intramuscularly per animal as a single dose.

(ii) Indications for use. To induce abortion in pregnant feedlot heifers from 1 week after mating until 4 1/2 months of gestation.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 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 046573 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]

§ 522.480 Repository corticotropin injection.


(2) Sponsor. See No. 037990 in § 510.600(c) of this chapter.

(3) Special considerations. The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(4) Conditions of use. (i) It is used as an intramuscular or subcutaneous injection in cattle and small animals for stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH). It is also a therapeutic agent for primary bovine ketosis.

(ii) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(iii) For use only by or on the order of a licensed veterinarian.

(b) Specifications. The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. units per milliliter.

(2) Sponsor. See No. 000864 in § 510.600(c) of this chapter.

(3) Conditions of use. (i) For intramuscular injection in dogs as a diagnostic aid to test for adrenal dysfunction. For intramuscular or subcutaneous injection in dogs and cats for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(ii) For diagnostic use: Administer at one unit per pound of body weight intramuscularly. For therapeutic use: Administer at one unit per pound of body weight intramuscularly or subcutaneously, initially, to be repeated as indicated.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) National Academy of Sciences/National Research Council (NAS/NRC) status. The therapeutic indication for use has been reviewed by NAS/NRC and found to be effective. Applications for this use need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.


§ 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...
§ 522.535  Desoxycorticosterone pivalate.

(a) Specifications. Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) Sponsor. See No. 058198 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Dogs—(i) Amount. 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.

(ii) Indications for use. For replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) Limitations. For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]

§ 522.536  Detomidine hydrochloride injection.

(a)(1) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 2 mg of dexamethasone.

(b) Sponsor. See No. 000061 and 059130 in §510.600(c) of this chapter.

(c) Conditions of use—(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.

(ii) Indication for use. As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(iii) Limitations. For sedation administer intravenously (IV) or intramuscularly (IM); for analgesia by IV; for both sedation and analgesia by IV. Do not use in horses with pre-existing atrioventricular or sinoauricular block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in breeding animals. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50365, Dec. 6, 1989; 54 FR 51551, Dec. 15, 1989]

§ 522.540  Dexamethasone injection.

(a)(1) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 2 mg of dexamethasone.

(b)(1) Specifications. The drug is a sterile aqueous solution. Each milliliter contains either 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams dexamethasone).
These conditions are NAS/NRC-reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
§ 522.542 Dexamethasone sodium phosphate suspension

(a) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3 milligrams of dexamethasone).

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Conditions of use. (i) The drug is given for glucocorticoid and anti-inflammatory effect in dogs and horses. (ii) Administer intravenously as follows: Dogs—0.25 to 1 milligram initially; may be repeated for 3 to 5 days or until response is noted. Horses—2.5 to 5 milligrams. If permanent glucocorticoid effect is required, oral therapy may be substituted. When therapy is to be withdrawn after prolonged use, the daily dose should be reduced gradually over several days. (iii) Clinical and experimental data have 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 following by dystocia, fetal death, retained placenta, and metritis. (iv) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Except when used for emergency therapy, the product is contraindicated in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers. (v) Not for use in horses intended for food.

(vi) 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 in the Finding Aids section of this volume.

§ 522.542 Dexamethasone-21-isonicotinate suspension

(a) Specifications. Each milliliter of sterile suspension contains 1 milligram of dexamethasone-21-isonicotinate.

(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses. (2) It is recommended for intramuscular administration as follows: Dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—5 to 20 milligrams. Dosage may be repeated.

(3) Clinical and experimental data have 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 following by dystocia, fetal death, retained placenta, and metritis.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 37543, July 22, 1977, as amended at 47 FR 14703, Apr. 6, 1982]

§ 522.563 Diatrizoate meglumine and diatrizoate sodium injection

(a) Specifications. Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.

(b) Sponsor. See No. 053501 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter...
into the urethra to provide desired contrasts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catheter or intraventricular puncture. For cerebral angiography rapidly inject 3 to 10 milliliters via carotid artery. For periphereal arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 0.5 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter 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 milliliter per pound of body weight directly into the peritoneal cavity.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.575 Diazepam injection.

(a) Specification. Each milliliter of sterile solution contains 5 milligrams of diazepam.

(b) Sponsor. See 000004 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs—(1) Indications for use. As a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia.

(2) Dosage. Intravenously, 0.2 milligram per kilogram of body weight 3-5 minutes before anesthesia is to be induced using a short acting barbiturate.

(3) Limitations. Not for use in dogs with known sensitivity to benzodiazepines. Safety in animals intended for breeding and pregnant animals has not been established. 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]

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) Specifications. Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) Sponsor. See Nos. 000069 and 055529 in §510.600(c) of this chapter.

(c) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter but may require bioequivalency and safety information.

(d) Conditions of use—(1) Amount. 5 milligrams per pound of body weight every 12 hours.

(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. Administer by deep intramuscular injection only. Treatment should be continued for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination. Treatment with subtherapeutic dosages, excessive duration of therapy, or inappropriate use of this antibiotic may lead to the emergence of streptomycin or dihydrostreptomycin resistant organisms. 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]

§ 522.690 Dinoprost tromethamine sterile solution.

(a) Specifications. Each milliliter of sterile solution contains the equivalent of 5 milligrams of dinoprost.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) Special considerations. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily
§ 522.723 Absorption through the skin and can cause abortion and bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water. Use of this product in excess of the approved dose may result in drug residues. Do not administer intravenously; this may potentiate adverse reactions.

(d) Conditions of use—
(1) Mares—
(i) Amount. Equivalent of 1 milligram of dinoprost per 100 pounds of body weight.
(ii) Indications. 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. For use once as a single intramuscular injection. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cattle—
(i) Amount. 5 milliliters (equivalent to 25 milligrams of dinoprost).
(ii) Indications. For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.
(b) Limitations. For use in beef cattle and nonlactating dairy heifers, as follows: Inject a dose of 5 milliliters intramuscularly either once or twice at a 10- to 12-day interval. With a single injection, cattle should be bred at the usual time relative to estrus. With the two injections, cattle can be bred after the second injection either at the usual time relative to detected estrus or at about 80 hours after the second injection. Estrus is expected to occur 1 to 5 days after injection if a corpus luteum was present. Cattle that do not become pregnant to breeding at estrus on days 1 to 5 after injection will be expected to return to estrus in about 18 to 24 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii)(a) Indications. For treatment of pyometra (chronic endometritis).
(b) Limitations. For intramuscular use as a single injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Nonlactating cattle—
(i) Amount. Five milliliters intramuscularly as a single injection.
(ii) Indications. For its abortifacient effect in nonlactating cattle.
(iii) Limitations. For intramuscular use only, during first 100 days of gestation. Cattle that abort will abort within 35 days after injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Lactating dairy cattle—
(i) Amount. Five milliliters intramuscularly as a single injection.
(ii) Indications. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.
(iii) Limitations. Breed cattle as they are detected in estrus. If estrus has not been observed by 80 hours after injection, breed at 80 hours. If cattle return to estrus breed at the usual time relative to estrus. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) Swine—
(i) Amount. 2 milliliters (equivalent to 10 milligrams of dinoprost).
(ii) Indications. For parturition induction in swine when injected within 3 days of normal predicted farrowing.
(iii) Limitations. For use in swine as follows: Inject a dose of 2 milliliters intramuscularly within 3 days of predicted farrowing. The response to treatment varies by individual animals with a mean interval from administration to parturition of approximately 30 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.723 Diprenorphine hydrochloride injection.

(a) Chemical name. N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7-alpha-(1-hydroxy-1-methylethyl) - 6,14-endoethanonororipavine hydrochloride.
(b) Specifications. Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.
(c) Sponsors. See No. 010042 in §510.600(c) of this chapter.
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(d) Conditions of use. (1) 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.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) 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.

(4) 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.

§ 522.775 Doramectin.

(a) Specifications. Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) Sponsor. See No. 000069 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, 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.

§ 522.777 Doxapram hydrochloride injection.

(a) Specifications. The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) Sponsor. See No. 000031 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per 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.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.778 Doxycycline hyclate.

(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 063604 in §510.600(c) of this chapter.
(c) [Reserved]
(d) Conditions of use—(1) Dogs—(i) Amount. Apply subgingivally to periodontal pocket(s) of affected teeth.
(ii) Indications for use. For treatment and control of periodontal disease.
(iii) Limitations. Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
[63 FR 8349, Feb. 19, 1998]

§ 522.784 Doxylamine succinate injection.
(a) Specifications. Each milliliter of the drug contains 11.36 mg of doxylamine succinate.
(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.
(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.
(3) Not for use in horses intended for food.
(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.800 Droperidol and fentanyl citrate injection.
(a) Specifications. Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.
(b) Sponsor. See No. 000045 in §510.600(c) of this chapter.
(c) Conditions of use. (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.
(2) It is administered as follows:
(i) For analgesia and tranquilization administer according to response desired, as follows:
(1) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or
(2) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.
(ii) For general anesthesia administer according to response desired, as follows:
(1) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or
(2) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.
(3) For use only by or on the order of a licensed veterinarian.

§ 522.812 Enrofloxacin solution.
(a) Specifications. Each milliliter of sterile aqueous solution contains 22.7 milligrams of enrofloxacin.
(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.
(c) [Reserved]
§ 522.840 Estradiol.

(a) Specifications. Each silicone rubber implant contains 25.7 or 43.9 milligrams of estradiol.

(b) Sponsor. See 000986 in §510.600(c) of this chapter.

(c) Conditions of use. It is used for implantation in steers and heifers as follows:

(1) Amount. Insert one 25.7-milligram implant every 200 days; insert one 43.9-milligram 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.

(iii) Limitations. For subcutaneous ear implantation in steers and heifers only. A second implant may be used if desired. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-milligram implant or 400 days for the 43.9 milligram implant. Increased sexual activity
§ 522.842

(bulling, riding, and excitability) has been reported in implanted animals.


§ 522.842 Estradiol benzoate and testosterone propionate in combination.

(a) Chemical names.

(1) Estradiol benzoate: 1,3,5(10)-Estratriene-3,17β-diol 3-benzoate.

(2) Testosterone propionate: 17β-Hydroxyandrost-4-en-3-one propionate.

(b) Sponsor. See Nos. 000856 and 021641 in §510.600(c) of this chapter.

(c) Related tolerances. See §§ 556.240 and 556.710 of this chapter.

(d) Conditions of use. It is used for implantation in heifers as follows:

(1) Amount. 20 milligrams of estradiol benzoate and 200 milligrams of testosterone propionate per dose.

(2) Indications for use. Growth promotion 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.

(e) NAS/NRC status. These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety data.

§ 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 No. 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.


§ 522.863 Ethylisobutrazine hydrochloride injection.

(a) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 50 milligrams of ethylisobutrazine hydrochloride.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use—(1) It is used in dogs as a tranquilizer.

(2) It is administered intramuscularly at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight for profound tranquilization. It is administered intravenously at a dosage level of 1 to 2 milligrams of ethylisobutrazine hydrochloride per pound of body weight to effect.

(3) It is not to be used in conjunction with organophosphates and/or procaine

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
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hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹


§ 522.883 Etorphine hydrochloride injection.

(a) Chemical name. 6,7,8,14-tetrahydro-alpha-methyl-alpha-1-propyl-6,14-endoethenoopavine-alpha-methanol hydrochloride.

(b) Specifications. Each milliliter of etorphine hydrochloride injection, veterinary, contains 1 mg of etorphine hydrochloride in sterile aqueous solution.

(c) Sponsors. See No. 053923 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is used for the immobilization of wild and exotic animals.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, contains 1 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) Sponsors. See No. 053923 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is used for the immobilization of wild and exotic animals.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, contains 1 mg of diprenorphine hydrochloride in sterile aqueous solution.

(d) Conditions of use. (1) The drug is used for the immobilization of wild and exotic animals.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, contains 1 mg of diprenorphine hydrochloride in sterile aqueous solution.

(4) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use for 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(5) 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.


§ 522.900 Euthanasia solution.

(a) [Reserved]

(b)(1) Specifications. Each milliliter of nonsterile solution contains 390 milligrams of pentobarbital sodium and 50 milligrams of phenytoin sodium.

(c) Sponsors. See 000033 in §510.600(c) of this chapter.

(d) Conditions of use. (i) Indications for use. For the humane, painless, and rapid euthanasia of dogs.

(ii) Amount. One milliliter (390 milligrams of pentobarbital sodium and 50 milligrams of phenytoin sodium) for each 10 pounds of body weight.

(iii) Limitations. For intravenous injection or intracardiac injection when intravenous use is impractical. Do not use for therapeutic purposes. Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.914 Fenprostalene solution.

(a) Specifications. (1) Cattle. Each milliliter of sterile solution contains 0.5 milligram of fenprostalene.

(2) Swine. Each milliliter of sterile solution contains 0.25 milligram of fenprostalene.

(b) Sponsors. See 000856 in §510.600(c) of this chapter.

(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 bronchiapasm. Accidental spillage on the skin should be
§ 522.940 Colloidal ferric oxide injection.

(a) Specifications. Each milliliter of the drug contains colloidal ferric oxide equivalent to 100 milligrams of iron stabilized with a low-viscosity dextrin and contains 0.5 percent phenol as a preservative.

(b) NAS/NRC status. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(c) (1) Sponsor. See Nos. 010042 and 017800 in §510.600(c) of this chapter.

(2) Conditions of use. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an intramuscular injection of 1 milliliter of the drug to each animal at any time between 2 to 5 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of from 1 to 2 milliliters of the drug to each animal at any time between 5 to 28 days of age.


§ 522.955 Florfenicol solution.

(a) Specifications. Each milliliter of sterile solution contains 300 milligrams of florfenicol.

(b) Sponsor. See 000061 in §510.600(c) of this chapter.

(c) Related tolerance. See §556.283 of this chapter.

(d) Conditions of use—(1) Cattle—(i) Amount. 20 milligrams per kilogram body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later.

(ii) Indications for use. For treatment of bovine respiratory disease (BRD) associated with Pasteurella haemolytica, P. multocida, and Haemophilus somnus.

(iii) Limitations. For intramuscular use only. Do not inject more than 10 milliliters at each site. Injection should be given only in the neck musculature. Do not slaughter within 28 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. Not for use in veal calves, calves under 1 month of age, or calves being fed an all milk diet. Use may cause violative tissue residues to remain beyond the withdrawal time. Not for use in cattle of breeding age. The effect of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 522.960 Flumethasone implantation or injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) Chemical name. 6α,9α-Difluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione.

(b) Specifications. Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of
§ 522.960c Flumethasone acetate injection.

(a) Chemical name. 6-alpha,9-alpha-difluoro-16-alpha-methylprednisolone 21-acetate.

(b) Specifications. Flumethasone injection is sterile and contains per cubic centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; water for injection q.s.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) It is recommended in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Dosage in milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>1.0</td>
</tr>
<tr>
<td>10 to 25</td>
<td>2.0</td>
</tr>
<tr>
<td>25 and over</td>
<td>4.0</td>
</tr>
</tbody>
</table>

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 milligram per animal.

(3) For use only by or on the order of a licensed veterinarian.


§ 522.960c Flumethasone solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains 0.5 milligram flumethasone.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. It is used as follows:

(i) Horses—(i) Amount. 1.25 to 2.5 milligrams daily, intravenously, intramuscularly, or intra-articularly.

(ii) Indications for use. It is used for the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) Limitations—(a) Clinical and experimental data have 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.
(b) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(c) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(d) Flumethasone may be administered to animals with bacterial diseases provided appropriate antibacterial therapy is administered simultaneously.

(e) The drug is not to be used in horses intended for slaughter for food purposes.

(f) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Dogs—(i) Amount. 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intraleosionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) Indications for use. It is used for 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.

(iii) Limitations. See paragraph (c)(1)(iii) of this section.


§ 522.970 Flunixin meglumine solution.

(a) Specifications. The drug contains 50 milligrams of flunixin per milliliter of aqueous solution.

(b) Sponsors. See Nos. 000061, 000856, 057561, and 059130 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.5 milligram of flunixin per pound of body weight (1 milliliter per 100 pounds) per day.

(2) Indications for use. Horses: For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of pain associated with colic.

(3) Limitations. For musculoskeletal disorders, administer intravenously or intramuscularly for up to 5 days. For colic, administer a single dose intravenously—the single dose may be repeated if signs of colic recur. Caution: The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.995 Fluprostenol sodium injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) Sponsor. See 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 0.55 microgram fluprostenol per kilogram of body weight.

(2) Indications for use. The drug is used 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. Administer by intramuscular injection only. Warning: Not for use in horses intended for food.
For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. 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. Fluprostenol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

§ 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 059521 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.

§ 522.1004 Fomepizole.

(a) Specifications. Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) Sponsor. See 062161 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

(2) Indications for use. As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) Limitations. Administer intravenously. For use by or on the order of a licensed veterinarian.

§ 522.1010 Furosemide injection.

(a) Specifications. Each milliliter of sterile solution contains 50 milligrams of furosemide as the diethanolamine salt.

(b) Sponsor. See No. 012799 in §§510.600(c) of this chapter for use in dogs and cats as in paragraph (c)(1) of this section, horses as in paragraph (c)(2)(i) of this section, and cattle as in paragraph (c)(3) of this section. See Nos. 000010 and 000864 in §§510.600(c) for use in horses as in paragraph (c)(2)(ii) of this section. See No. 000010 in §§510.600(c) of this chapter for use in dogs as in paragraph (c)(1) of this section.

(c) Conditions of use—(1) Dogs and cats. (i) It is used for the treatment of edema (pulmonary congestion, ascites)
associated with cardiac insufficiency and acute noninflammatory tissue edema.

(ii) The drug is administered intramuscularly or intravenously at a dosage of 12.5 to 25 milligrams per 10 pounds of body weight; once or twice daily after a 6- to 8-hour interval. The lower dosage is suggested for cats. The dosage should be adjusted to the individual animal’s response. In refractory or severe edematous cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. The established effective dose should be administered once or twice daily on an intermittent daily schedule. Diuretic therapy should be discontinued after reduction of edema, or when necessary, maintained after determining a programmed dosage schedule to prevent recurrence.

(2) Horses. (i) It is used for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(a) Administer intramuscularly or intravenously at 250 to 500 milligrams per animal once or twice daily at 6- to 8-hours intervals until desired results are achieved.

(b) Do not use in horses intended for food.

(ii) It is used for treatment of acute noninflammatory tissue edema.

(a) Administer intramuscularly or intravenously at 0.5 milligram per pound of body weight; once or twice daily at 6- to 8-hour intervals.

(b) The dosage should be adjusted to the individual’s response. In refractory or severe edematous cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. The established effective dose should be administered once or twice daily on an intermittent daily schedule, i.e., every other day or 2 to 4 consecutive days weekly. Concurrent therapy for treatment of systemic conditions causing edema (pulmonary congestion, ascites, cardiac insufficiency) should be instituted.

(3) Cattle. (i) It is used for the treatment of physiological parturient edema of the mammary gland and associated structures.

(ii) The drug is administered intramuscularly or intravenously at a dosage of 500 milligrams per animal once daily or 250 milligrams per animal twice daily at 12-hour intervals, treatment not to exceed 48 hours postparturition.

(iii) Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food.

(iv) Cattle must not be slaughtered for food within 48 hours following last treatment.

(4) The drug if given in excessive amounts may result in dehydration and electrolyte imbalance.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1020 Gelatin solution.

(a) Specifications. It is sterile and each 100 cubic centimeters contains 8 grams of gelatin in an 0.85 percent sodium chloride solution.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(2) 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. It is administered intravenously at a rate of 10 cubic centimeters per minute in small animals and 20 to 30 cubic centimeters per minute in large animals. The solution is administered aseptically and must be between 50 to 70 °F. when injected.

(3) A few animals will exhibit signs of allergic reaction. This solution can cause transient reversible nephrosis.
This product is not intended to replace whole blood in cases of anemia and should not be used in the presence of renal dysfunction. Unused portions remaining in bottles should be discarded.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1044 Gentamicin sulfate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to either 5, 50, or 100 milligrams of gentamicin.

(b) Sponsors. (1) See No. 000061 in §510.600(c) of this chapter for use of: 5-milligrams-per-milliliter solution in dogs and cats as in paragraph (d)(1) of this section, 50- and 100-milligrams-per-milliliter solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) [Reserved]

(3) See No. 054273 for use of 50 milligrams-per-milliliter solution in dogs as in paragraph (d)(5) of this section.

(4) See No. 050604 for use of 100 milligrams-per-milliliter solution 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.

§ 522.1055  
(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.

§ 522.1055  Gleptoferron injection.

(a) Specifications. Each milliliter contains the equivalent of 200 milligrams of elemental iron as gleptoferron (complex of ferric hydroxide and dextran glucoheptonic acid), and 0.5 percent phenol as a preservative.

(b) Sponsor. See 062408 in § 510.600(c) of this chapter.

(c) Conditions of use. It is used in baby pigs as follows:
   (1) For prevention of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly on or before 3 days of age.
   (2) For treatment of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly.

§ 522.1066  Glycopyrrolate injection.

(a) Specifications. Each milliliter of aqueous solution contains 0.2 milligram of glycopyrrolate.

(b) Sponsor. See No. 000031 in §510.600(c) of this chapter.

(c) Conditions of use. It is indicated as a preanesthetic agent in dogs and cats.
   (1) It is administered intravenously, intramuscularly, or subcutaneously in dogs and intramuscularly in cats at a dosage level of 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight).
   (2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1077  Gonadorelin injectable.

(a) Specifications. Each milliliter sterile aqueous solution contains 50 micrograms of gonadorelin (as hydrochloride).

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use in cattle—(1) Amount. 100 micrograms per cow intramuscularly.
   (2) Indications for use. For the treatment of cystic ovaries (ovarian follicular cysts) in cattle to reduce the time to first estrus.
   (3) Limitations. For intramuscular use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1078  Gonadorelin diacetate tetrahydrate injection.

(a) Specifications. The drug contains 50 micrograms of gonadorelin diacetate tetrahydrate in each milliliter of sterile solution.

(b) Sponsor. See Nos. 050604 and 057926 in §510.600(c) of this chapter.

(c) Conditions of use. It is used in dairy cows as follows:
   (1) Amount. 100 micrograms per cow.
   (2) Indications for use. The drug is used for the treatment of ovarian cysts.
   (3) Limitations. Administer as a single intramuscular or intravenous injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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. 057926 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 5 1/2 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.

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
(a)(1) Specifications. Chorionic gonadotropin for injection is supplied in vials containing 5,000, 10,000 or 20,000 U.S.P. units of lyophilized powder for reconstitution with the accompanying sterile diluent to a 10 milliliter solution.
(b)(1) Specifications. Chorionic gonadotropin suspension, veterinary contains in each milliliter, 750 I.U. of chorionic gonadotropin suspended in white wax and sesame oil.
(c) Conditions of use—
   (i) Amount. (a) 10,000 U.S.P. units intramuscularly, and 2,500 to 5,000 U.S.P. units intravenously, and 500 to 2,500 U.S.P. units intrafollicularly.
   (b) 2,500 to 5,000 U.S.P. units intramuscularly.
   (iii) Limitations. Dosage may be repeated in 14 days if the animal’s behavior or rectal examination of the ovaries indicates the necessity for retreatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
(b)(1) Specifications. Chorionic gonadotropin suspension, veterinary contains in each milliliter, 750 I.U. of chorionic gonadotropin suspended in white wax and sesame oil.
(c) Conditions of use—
   (i) Amount. 2 milliliters (1,500 I.U.) subcutaneously, at the time of insemination, in the neck or shoulder region.
   (ii) Indications for use. The drug is used as an aid in increasing pregnancy rate of estrus-synchronized and normal cycling heifers.
   (iii) Limitations. The drug is not to be used to induce multiple ovulations. Doses higher than recommended may reduce pregnancy rate. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1085 Guaifenesin sterile powder.
(a) Specifications. It is a sterile powder containing guaifenesin.
(b) Sponsor. See No. 000031 and 037990 in §510.600(c) of this chapter.
(c) Conditions of use. (1) It is indicated for intravenous use as a muscle relaxant in horses.
   (2) 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. It is administered by rapid intravenous infusion at a fixed dosage of 1 milliliter of prepared solution per pound of body weight.
   (3) Not to be used in horses intended for food.
   (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Footnotes:
1 These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified as §514.111 of this chapter.
§ 522.1086  Guaiifenesin injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 50 milligrams of guaiifenesin and 50 milligrams of dextrose.

(b) Sponsor. See No. 037990 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used intravenously in horses as a skeletal muscle relaxant.

(2) Administer rapidly at a dosage of 1 milliliter per pound of body weight.

(3) No to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 27223, May 23, 1995]

§ 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 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 for at least 24 hours, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) Limitations. For intravenous use only. Overdosage or an excessive rate of administration (greater than 10 milliliters per kilogram per hour) may result in circulatory overload. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998]

§ 522.1145  Hyaluronate sodium injection.

(a)(1) Specifications. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) Sponsors. See 000009 and 060865 in §510.600(c) of this chapter.

(b)(1) Specifications. Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) Sponsor. See 053501 in § 510.600(c) of this chapter.

(c)(1) Specifications. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) Sponsor. See 000856 in § 510.600(c) of this chapter.

(3) Conditions of use—(i) Amount. Small and medium-size joints (carpal, fetlock)—20 milligrams; larger joint (hock)—40 milligrams.

(ii) Indications for use. Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) Limitations. For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. 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 5 milligrams of hyaluronate sodium.

(2) Sponsor. See 060856 in § 510.600(c) of this chapter.

(3) Conditions of use—(i) Amount. Small and medium-size joints (carpal, fetlock)—10 milligrams; larger joint (hock)—20 milligrams.

(ii) Indications for use. Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) Limitations. For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of four treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 27223, May 23, 1995]
Food and Drug Administration, HHS

§ 522.1150 Hydrochlorothiazide injection.

(a) Specifications. Each milliliter 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 postpartum uterine edema.1

(3) 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 (6 milkings) after the last treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.1


§ 522.1155 Imidocarb dipropionate sterile powder.

(a) Specifications. Imidocarb dipropionate powder is reconstituted with sterile water. Each milliliter of solution contains 100 milligrams of imidocarb base.

(b) Sponsor. No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is used in horses and zebras as follows:

(1) Amount. For Babesia caballi infections, use intramuscularly 2 milligrams of imidocarb base per kilogram of body weight, repeating dosage once after 24 hours. For Babesia equi infections, use 4 milligrams of imidocarb base per kilogram of body weight, 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.1

(3) Limitations. Administer intramuscularly in the neck region. Do not inject intravenously. Do not use for other equidae or for animals of other species. Do not use in horses less than 1 year old. Do not use for animals in near-term pregnancies. Imidocarb dipropionate treatment may be continued with an orally administered maintenance dose.

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
§ 522.1156 Imidocarb dipropionate solution.

(a) Specifications. Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Dogs—(i) Amount. 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) Indications for use. Treatment of clinical signs of babesiosis and/or demonstrated Babesia organisms in the blood.

(iii) Limitations. Use subcutaneously or intramuscularly. Do not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments. Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


§ 522.1182 Iron dextran complex injection.

(a)(1) Specifications. Each milliliter of sterile solution contains ferric hydroxide dextran complex equivalent to 100 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2) [Reserved]

(3)(i) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(ii) Conditions of use. It is used in baby pigs as follows:

(a) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(b) For the treatment of anemia due to iron deficiency, administer and intramuscular injection of 200 milligrams of elemental iron.

(4)(i) Sponsor. See Nos. 000061 and 062408 in §510.600(c) of this chapter.

(ii) Conditions of use. It is used in baby pigs as follows:

(a) For prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 milligrams of elemental iron to animals from 1 to 3 days of age.

(b) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 milligrams of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(b)(1) Specifications. Each milliliter of sterile solution contains ferric hydroxide in complex with dextran equivalent to 200 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2)(i) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(ii) Conditions of use. It is used in baby pigs as follows:

(a) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron (1 milliliter) at 1 to 3 days of age.

(b) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron at the first sign of anemia.


§ 522.1183 Iron hydrogenated dextran injection.

(a) Specifications. Each milliliter contains 100 milligrams of elemental iron stabilized with a low molecular weight
hydrogenated dextran and 0.5 percent phenol as a preservative.

(b) NAS/NRC status. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(c)(1) Sponsor. See No. 000966 in §510.600(c) of this chapter.

(2) Conditions of use. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 100 milligrams of elemental iron to each animal when indicated between 5 and 28 days of age.

(d)(1) Sponsor. See No. 000003 in §510.600(c) of this chapter.

(2) Conditions of use. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

(e)(1) Sponsors. See Nos. 000003, 017287, and 050604 in §510.600(c) of this chapter.

(2) Conditions of use. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer intramuscularly 100 milligrams at 2 to 4 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly 100 milligrams. Treatment may be repeated in 10 days.

§522.1192 Ivermectin injection.

(a) Specifications—(1) Horses. Each milliliter of sterile aqueous solution contains 2 milligrams of ivermectin (2 percent).

(2) Cattle, reindeer, swine, and American bison. Each milliliter of sterile aqueous solution contains 10 milligrams of ivermectin (1 percent).

(3) Piglets 70 pounds or less and ranch-raised foxes. Each milliliter of sterile aqueous solution contains 2.7 milligrams of ivermectin (0.27 percent).

(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—(1) Horses—(i) Amount. 20 milligrams per 100 kilograms (220 pounds) of body weight.

(ii) Indications for use. It is used in horses for the treatment and control of large strongyles (adult) (Strongylus vulgaris, Strongylus edentatus, Triodontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cychoclyclus spp., Cyclicostephanus 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. For intramuscular use only. Do not use intravenously. Not for use in horses intended for food. Effects of this drug on pregnant mares have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cattle—(i) Amount. 10 milligrams per 50 kilograms (110 pounds) body weight (200 micrograms per kilogram).

(ii) Indications for use. It is used in cattle 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. pathiger (adults only), Bunostomum phlebotomum), lungworms (adults (and fourth-stage larvae) (Dictyocaulus spp., Onchocerca spp.), and stomach bots (Gastrophilus spp.).
viviparvus); grubs (first, second, and third instars) (Hypoderma bovis, H. lineatum); lice (Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus); mites (Psoroptes ovis (syn. P. communis var. bovis), Sarcopes scabiei var. bovis). It is also used to control infestations of D. viviparus and O. ostertagi for 21 days after treatment, and H. placent, T. axei, C. punctata, C. oncophora, and Oesophagostomum radiatum for 14 days after treatment.

(iii) Limitations. For subcutaneous use only. Not for intramuscular use. 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 breeds in milk has not been established, do not use in female dairy cattle of breeds. Do not treat cattle within 35 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) Reindeer—(i) Amount. 10 milligrams per 50 kilograms (110 pounds) body weight.

(ii) Indications for use. It is used in reindeer for treatment and control of warbles (Oedemagenia tarandi).

(iii) Limitations. For subcutaneous use only. Not for intramuscular use. Do not treat reindeer within 56 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Swine—(i) Amount. 300 micrograms per kilogram (2.2 pounds).

(ii) Indications for use. It is used in swine for 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, Strongyloides ransomi (somatic larvae)); lungworms (Metastrongylus spp. (adults only)); lice (Haematopinus suis); and mites (Sarcopes scabiei var. suis).

(iii) Limitations. For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(5) Ranch-raised foxes—(i) Amount. 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) Indications for use. For treatment and control of ear mites (Otodectes cynotis).

(iii) Limitations. For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) American bison—(i) Amount. 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) Indications for use. It is used in American bison for the treatment and control of grubs (Hypoderma bovis).

(iii) Limitations. For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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§ 522.1193 Ivermectin and clorsulon injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 10 milligrams (1 percent) of ivermectin and 100 milligrams (10 percent) of clorsulon.

(b) Sponsor. See 050604 in § 510.600(c) of this chapter.

(c) Related tolerances. See §§ 556.163 and 556.344 of this chapter.

(d) Conditions of use—(1) Amount. 1 milliliter (10 milligrams of ivermectin and 100 milligrams of clorsulon) per 50 kilograms (110 pounds).

(2) Indications for use. It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. pyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pecamittan, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. spathiger (adults only), Bunostomum phelbotomum; lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparvus); liver flukes (adults only).
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(b) Specifications. The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity and 1:10,000 benzethonium chloride.

§ 522.1222a

(a) [Reserved]
§ 522.1225 Ketoprofen solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains 100 milligrams of ketoprofen.

(b) Sponsor. See 000856 in 21 CFR 510.600(c) of this chapter.

(c) Conditions of use in horses—

(1) Amount. 1.0 milligram 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 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.

[55 FR 40653, Oct. 4, 1990]

§ 522.1228 [Reserved]

§ 522.1244 Levamisole phosphate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) Sponsor. See No. 000061 in 21 CFR 510.600 of this chapter for use of 13.65 percent injection, and see No. 043781 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.

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0.5 percent solution for local anesthesia of large and small animals, as follows:

(i) Cats: Administer approximately 2 milliliters of 2 percent solution with epinephrine by caudal injection.

(ii) Cattle: Administer 5 milliliters of 2 percent solution with epinephrine by epidural injection (standing animal). Administer 10 to 20 milliliters of 2 percent solution with epinephrine by cornual nerve block injection. For teat operations and infiltration, inject 0.5 percent solution with epinephrine to effect.

(iii) Dogs: Administer 2 to 10 milliliters of 2 percent solution with epinephrine by caudal injection. Do not give intravascularly. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(iv) Horses: Administer 5 to 10 milliliters of 2 percent solution with epinephrine by volar nerve block. Administer 10 to 15 milliliters of 2 percent solution with epinephrine by epidural injection. For standing animal, apply slowly and observe individual sensitivity. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(2) Limitations. (i) The drug is contraindicated in the presence of sepsis in the region of proposed injection, shock and heart block, neurologic disease, spinal deformities, septicema, and hypotension.

(ii) Do not give intravascularly.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1260 Lincomycin injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains lincomycin hydrochloride equivalent to 25, 50, 100, or 300 milligrams of lincomycin.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(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 to 10 milligrams per pound of body weight per day.

(ii) Indications for use. Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) Limitations. Administer intramuscularly 10 milligrams per pound of body weight once a day or 5 milligrams per pound of body weight twice daily or intravenously 5 to 10 milligrams per pound of body weight one or two times daily by slow injection. May be diluted with 5 percent glucose in water or normal saline and given as an infusion; as lincomycin hydrochloride monohydrate; for use by or on the order of a licensed veterinarian.

(2) Swine—(i) Amount. 5 milligrams per pound of body weight per day.

(ii) Indications for use. Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) Limitations. Administer intramuscularly as a single daily dose for 3 to 7 days; as lincomycin hydrochloride monohydrate: do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985]

§ 522.1290 Luprostiol sterile solution.

(a) Specifications. Each milliliter of sterile solution contains 7.5 milligrams of luprostiol.

(b) Sponsor. See No. 057926 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 bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(1) Amount. 7.5 milligrams per mare.
§ 522.1335 Medetomidine hydrochloride injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) Sponsor. See 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. Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]

§ 522.1335 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 dihydrochloride 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 No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(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 L5) to mature adult infections of Dirofilaria immitis in dogs.

(3) Limitations. Administer only by deep intramuscular injection in the lumbar muscles (L3-L5). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Syndrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]
§ 522.1372 Mepivacaine hydrochloride injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 20 milligrams of mepivacaine hydrochloride.

(b) Sponsor. See No. 000009 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) It is intended for use in horses 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.

(2) It is administered as follows: for nerve block, 3 to 15 milliliters; for epidural anesthesia, 5 to 20 milliliters; for intra-articular anesthesia, 10 to 15 milliliters; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 milliliters, by infiltration, 20 to 50 milliliters.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.1380 Methocarbamol injection.

(a) Specifications. The product is a sterile, pyrogen-free solution, each milliliter containing 100 milligrams of methocarbamol, 0.5 milliliter of polyethylene glycol 300, and water for injection q.s. Its pH is 3.5 to 6.0.

(b) Sponsor. See 000031 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount—(i) Dogs and cats. 20 milligrams per pound of body weight for moderate conditions, 25 to 100 milligrams per pound of body weight for severe conditions (tetanus and strychnine poisoning), total cumulative dose not to exceed 150 milligrams per pound of body weight.

(ii) Horses. 2 to 10 milligrams per pound of body weight for moderate conditions, 10 to 25 milligrams 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. For intravenous use only. For horses, administer rapidly half the estimated dose, pause until the animal starts to relax, then continue administration to effect. For horses, administer rapidly to effect. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.1410 Sterile methylprednisolone acetate suspension.

(a) Specifications. Each milliliter of aqueous suspension contains 20 or 40 milligrams of methylprednisolone acetate.

(b) Sponsors. See Nos. 000009 and 000010 in § 510.600(c) of this chapter.

(c) Special considerations. (1) Clinical and experimental data have 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.

(2) Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing’s syndrome.

may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

(d) Conditions of use—(1) Amount—(i) Intramuscular. Dosage may be repeated when necessary, as follows: dogs—2 to 40 milligrams (up to 120 milligrams in extremely large breeds or dogs with severe involvement); cats—10 to 20 milligrams; horses—200 milligrams. 1

(ii) Intramuscular. Dosage may be repeated when necessary, as follows: horses—40 to 240 milligrams; dogs—up to 20 milligrams. 1

(2) Indications for use. Treatment of inflammation and related disorders in dogs, cats, and horses; 1 treatment of allergic and dermatologic disorders in dogs and cats; and as supportive therapy to antibacterial treatment of severe infections in dogs and cats.

(3) Limitations. Not for use in horses intended for food. Not for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1462 Naloxone hydrochloride injection.

(a) Specifications. Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) Sponsor. See No. 060951 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1465 Naltrexone hydrochloride injection.

(a) Specifications. Each milliliter of sterile aqueous 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. Available data are inadequate to recommend use in pregnant animals. Avoid using during breeding season. 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.

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§ 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 000856 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.

§ 522.1484 Neomycin sulfate sterile solution.
(a) Specifications. Each milliliter of sterile aqueous solution contains 50 milligrams of neomycin sulfate (equivalent to 35 milligrams of neomycin base). The neomycin sulfate used in manufacturing the drug conforms to the standards of identity, strength, quality, and purity prescribed by §444.42a(a)(1) of this chapter.1
(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Amount. 5 milligrams per pound of body weight daily divided into portions administered every 6 to 8 hours for 3 to 5 days.1
   (2) Indications for use. Administer to dogs and cats for the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.1
   (3) Limitations. For intramuscular or intravenous use only. Neomycin is not for use parenterally in food-producing animals because of prolonged residues in edible tissues. Labeling shall bear an appropriate expiration date. For use by or on the order of a licensed veterinarian.1

§ 522.1503 Neostigmine methylsulfate injection.
(a) Specifications. Neostigmine methylsulfate injection contains two milligrams of neostigmine methylsulfate in each milliliter of sterile aqueous solution.
(b) Sponsor. See No. 00009 in §510.600(c) of this chapter.
(c) Conditions of use—(1) The drug is intended for use for treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions. It is a curare antagonist.
   (2) It is administered to cattle and horses at a dosage level of 1 milligram per 100 pounds of body weight subcutaneously. It is administered to sheep at a dosage level of 1 to 1 1/2 milligrams per 100 pounds body weight subcutaneously. It is administered to swine at a dosage level of 2 to 3 milligrams per 100 pounds body weight intramuscularly. These doses may be repeated as indicated.
   (3) The drug is contraindicated in mechanical, intestinal or urinary obstruction, late pregnancy, and in animals treated with other cholinesterase inhibitors.
   (4) Not for use in animals producing milk, since this use will result in contamination of the milk.
   (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1610 Oleate sodium solution.
(a) Specifications. Each milliliter of sterile aqueous solution contains 50 milligrams of sodium oleate.
(b) Sponsor. See No. 037990 in §510.600(c) of this chapter.
§ 522.1620

Conditions of use—(1) It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(2) The drug is administered by parenteral injection dependent upon the area of response desired. An injection of 1 milliliter will produce a response of approximately 15 square centimeters. Do not inject more than 2 milliliters per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 milliliters.

(3) Not for use in horses intended for food.

(4) 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]

§ 522.1642 Oxymorphone hydrochloride injection.

(a) Specifications. The drug contains 1 or 1.5 milligrams of oxymorphone hydrochloride per milliliter of aqueous solution containing 0.8 percent sodium chloride.

(b) Sponsor. See No. 060951 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is a narcotic analgesic, preanesthetic, anesthetic, and substitute anesthetic adjuvant for intramuscular, subcutaneous or intravenous administration to cats and dogs as follows:

<table>
<thead>
<tr>
<th>Animal</th>
<th>Body weight (pounds)</th>
<th>Dosage (milligram)</th>
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</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>2 to 5</td>
<td>0.75</td>
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<tr>
<td></td>
<td>5 to 15</td>
<td>0.75–1.5</td>
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<td></td>
<td>15 to 30</td>
<td>1.5–2.5</td>
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<td></td>
<td>30 to 60</td>
<td>2.5–4.0</td>
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<tr>
<td></td>
<td>Over 60</td>
<td>4.0</td>
</tr>
<tr>
<td>Cats</td>
<td>Small</td>
<td>0.4–0.75</td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>0.75–1.5</td>
</tr>
</tbody>
</table>

(2) Do not mix with a barbiturate in the same syringe to preclude precipitation.

(3) It tends to depress respiration. Naloxone hydrochloride and other narcotic antagonists are used to counter over-dosing.

(4) 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 63 FR 7701, Feb. 17, 1998]

§ 522.1660 Oxytetracycline injection.

(a) Specifications. Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) Sponsor. See 000010, 000069, 053389, 059130, and 061623 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Beef cattle, nonlactating dairy cattle and calves including preruminating (veal) calves—(i)
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 advanced cases of other indicated diseases; 9 milligrams per pound of body weight as a single dosage where re-treatment for anaplasmosis is impractical; 9 milligrams per pound of body weight as single dosage where re-treatment of calves and yearlings for bacterial pneumonia is impractical; 9 milligrams per pound of body weight as a single dosage for treatment of infectious bovine keratoconjunctivitis.

(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, wound infections and acute metritis caused by Staphylococcus spp. and Streptococcus spp., and infectious bovine keratoconjunctivitis (pink eye) caused by Moraxella bovis. If labeled for use by or on the order of a licensed veterinarian, it may also be used for treatment of anaplasmosis caused by Anaplasma marginale and anthrax caused by Bacillus anthracis.

(iii) Limitations. Administer intramuscularly or intravenously at the 3 to 5 milligrams level, intramuscularly at the 9 milligrams level. Sponsor 000010, may also administer subcutaneously at the 3 to 5 milligrams and 9 milligrams levels. Treatment of all diseases should be instituted early and continued 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, 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 28 days prior to slaughter. Not for use in lactating dairy cattle. For sponsor 000069, use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

(2) Swine—(i) Amount. 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.


(iii) Limitations. Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine. Discontinue treatment at least 42 days prior to slaughter when provided by 000010 and 28 days prior to slaughter when provided by 000069, 053389, 059130, or 061623.
conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (Pasturella spp.; Hemophilus spp.; Klebsiella spp.), bacterial enteritis (scours) (E. coli), foot-rot (Spherophorus necrophorus), diphtheria (Spherophorus necrophorus), wooden tongue (Actinobacillus lignieresii), 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 000010 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., Hemophilus spp., and Klebsiella spp., foot-rot and diphtheria caused by Spherophorus necrophorus, 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.

(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 38 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. 000069 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 Hemophilus 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
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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 sterile solution contains 100 milligrams of oxytetracycline hydrochloride.

(2) Sponsor. See No. 000069 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 Hemophilus spp., foot-rot and diphtheria caused by Fusobacterium necrophorum, 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
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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, 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 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. 000010 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., Hemophilus spp., or Klebsiella spp.

(c) Limitations. Administer intramuscularly, 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 000010 in §510.600(c) of this chapter for use of 50 and 100 milligrams/milliliter solution, and see No. 059130 in §510.600(c) for use of 100 milligrams/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: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly 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 22 days before slaughter. Not for use in lactating dairy cattle.

(k)(1) Specifications. Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) Sponsors. See No. 000864 in §510.600(c) of this chapter.

(3) Conditions of use—(i) Amount. The drug is used in beef cattle and nonlactating dairy cattle as follows: Administer 3 to 5 milligrams per pound of body weight per day.

(ii) Indications for use. Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with Pasteurella spp.; foot rot and diphtheria 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.
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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.

§ 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. 000069 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.

(ii) Obstetrical. Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

<table>
<thead>
<tr>
<th>Species</th>
<th>ml U.S.P. units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cats</td>
<td>0.25 to 0.5</td>
</tr>
<tr>
<td>Dogs</td>
<td>0.25 to 1.5</td>
</tr>
<tr>
<td>Ewes, Sows</td>
<td>1.5 to 2.5</td>
</tr>
<tr>
<td>Cows, Horses</td>
<td>5.0</td>
</tr>
</tbody>
</table>

(ii) Milk letdown. Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

<table>
<thead>
<tr>
<th>Species</th>
<th>ml U.S.P. units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cows</td>
<td>0.5 to 1.0</td>
</tr>
<tr>
<td>Sows</td>
<td>0.25 to 1.0</td>
</tr>
</tbody>
</table>

(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]

§ 522.1680 Oxytocin injection.


(b) Sponsors. See Nos. 000010, 000856, 000857, 000864, 050604, 058639, and 059130 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:

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<thead>
<tr>
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<th>ml U.S.P. units</th>
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</thead>
<tbody>
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<tr>
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<td>5.0</td>
</tr>
</tbody>
</table>

(ii) Milk letdown. Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

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</tr>
<tr>
<td>Sows</td>
<td>0.25 to 1.0</td>
</tr>
</tbody>
</table>

(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. Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished. For

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bio-equivalency and safety information.

EDITORIAL NOTE: For Federal Register citations affecting §522.1662a, see the List of CFR Sections Affected in the Finding Aids section of this volume.
§ 522.1696 Prepartum usage, full relaxation of the cervix should be accomplished either naturally or by administration of estrogen prior to oxytocin therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile 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) See Nos. 000008, 049185, 000856, 000864 and 010515 for use as in paragraph (d)(1) of this section.

(2) See Nos. 049185 and 000864 for use as in paragraph (d)(2) of this section.

(3) See Nos. 000069, 000864, and 010515 for use as in paragraph (d)(3) of this section.

(c) Related tolerances. See §556.510 of this chapter.

(d) Conditions of use—(1) Horses, dogs, and beef cattle. Treatment of bacterial infections susceptible to penicillin G. Repeat dosage in 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) Horses. 2 milliliters per 150 pounds of body weight intramuscularly. Do not use in horses intended for food purposes.

(ii) Dogs. 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously.

(iii) Beef cattle. 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Treatment should be limited to two doses. Not to be used in beef cattle within 30 days of slaughter.

(iv) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter but may require bioequivalency and safety information.

(2) Beef cattle. Treatment of bacterial pneumonia (Streptococcus spp., Corynebacterium pyogenes, Staphylococcus aureus); upper respiratory infections such as rhinitis or pharyngitis (C. pyogenes); blackleg (Clostridium chauvoei); and prophylaxis of bovine shipping fever in 300 to 500 pound beef calves.

(i) Amount. 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours. Limit treatment to two doses. Not for use within 30 days of slaughter.

(ii) NAS/NRC status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter but may require bioequivalency and safety information.

(3) Beef cattle. Treatment of bacterial pneumonia (shipping fever) (Streptococcus spp., C. pyogenes, S. aureus); upper respiratory infections such as rhinitis or pharyngitis (C. pyogenes); and blackleg (C. chauvoei).

(ii) 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours. Limit treatment to two doses. Not for use within 30 days of slaughter.

(2) Bein cattle. Treatment of bacterial pneumonia (shipping fever) (Streptococcus spp., C. pyogenes, S. aureus); upper respiratory infections such as rhinitis or pharyngitis (C. pyogenes); and blackleg (C. chauvoei).

(i) 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours. Limit treatment to two doses. Not for use within 30 days of slaughter.

(ii) [Reserved]

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) Specifications. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) Related tolerances. See §556.510 of this chapter.

(c) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use were NAS/
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§ 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. 053501 in §510.600(c) of this chapter.

(c) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivality and safety information.
§ 522.1698 Pentazocine lactate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains pentazocine lactate equivalent to 30 milligrams of pentazocine base.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Horses—(i) Amount. 0.15 milligram of pentazocine base per pound of body weight per day.

(ii) Indications for use. For symptomatic relief of pain due to colic.

(iii) Limitations. Administer intravenously or intramuscularly. Intravenous injections are given slowly in the jugular vein. In cases of severe pain, a second dose is recommended intramuscularly 10 to 15 minutes after the initial dose at the same level. 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) Dogs—(i) Amount. 0.75 to 1.50 milligrams of pentazocine base per pound of body weight.

(ii) Indications for use. For amelioration of pain accompanying post-operative recovery, fracture, trauma, and spinal disorders.

(iii) Limitations. Administer intramuscularly only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1704 Sodium pentobarbital injection.

(a)(1) Specifications. Sodium pentobarbital injection is sterile and contains in each milliliter 64.8 milligrams of sodium pentobarbital.

(2) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(3) Conditions of use. (i) 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.

(ii) The drug is administered intravenously “to effect”. For general surgical anesthesia, the usual dose is 11 to 13 milligrams per pound of body weight. For sedation, the usual dose is approximately 2 milligrams per pound of body weight. For relieving convulsive seizures in dogs, when caused by strychnine, the injection should be administered intravenously “to effect.” The drug may be given intraperitoneally if desired. However, the results of such injections are less uniform. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration. The dose must be reduced for animals showing under-nourishment, toxemia, shock and similar conditions.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) Specifications. Sodium pentobarbital injection is sterile and contains in each milliliter 65 milligrams of sodium pentobarbital.

(2) Sponsor. See 000402 in §510.600(c) of this chapter.

(3) Conditions of use. (i) The drug is indicated for use as a general anesthetic in dogs and cats.

(ii) The drug is administered intravenously “to effect.” For general anesthesia, the usual dose is 13 milligrams per pound of body weight.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1720 Phenylbutazone injection.

(a) Specifications. The drug contains 100 or 200 milligrams of phenylbutazone in each milliliter of sterile aqueous solution.
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§ 522.1850 Polysulfated glycosaminoglycan.

(a) Specifications. Each 1-milliliter ampule of sterile aqueous solution contains 250 milligrams of polysulfated glycosaminoglycan; each 5-milliliter ampule or vial contains 500 milligrams.

(b) Sponsor. See No. 010797 in §510.600(c) of this chapter.

(c) Conditions of use—horses. (1) Indications for use. Polysulfated glycosaminoglycan is for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) Intramuscular use (carpal and hock): 500 milligrams every 4 days for 28 days. Injection site must be thoroughly cleansed prior to injection.

(2) Limitations. Not for use in horses intended for food. Safe use in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 522.1862 Sterile pralidoxime chloride.

(a) Chemical name. 2-Formyl-1-methylpyridinium chloride oxime.

(b) Specifications. Sterile pralidoxime chloride is packaged in vials. Each vial contains 1 gram of sterile pralidoxime chloride powder and includes directions for mixing this gram with 20 cubic centimeters of sterile water for injection prior to use.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) 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.

(2) It is administered 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 milligram per pound of body weight, followed by administration of an additional 0.15 milligram 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 grams per horse. When administered to dogs and cats, it is 25 milligrams 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.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1870 Praziquantel injectable solution.

(a) Specification. Each milliliter contains 56.8 milligrams of praziquantel.

(b) Sponsor. See 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).

(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. For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) Cats—(i) Amount. For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.

(ii) Indications for use. For removal of feline cestodes Dipylidium caninum and Taenia taeniaeformis.

(iii) Limitations. For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1881 Sterile prednisolone acetate aqueous suspension.

(a) Specifications. Each milliliter of sterile aqueous suspension contains 25 milligrams of prednisolone acetate.
(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.
(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalence and safety information.
(d) Conditions of use. (1) 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 post-operatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.
(2) The drug is administered to horses intra-articularly at a dosage level of 50 to 100 milligrams. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 milligrams. 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 milligrams. The dose may be repeated when necessary after 7 days for two or three doses.
(3) The labeling shall comply with the requirements of § 510.410 of this chapter for corticosteroids.
(4) Not for use in horses intended for food.
(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1883 Prednisolone sodium phosphate injection, sterile.

(b) Sponsor. See No. 000864 in § 510.600(c) of this chapter.
(c) Conditions of use—(i) It is used in treatment of dogs when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.
(ii) It is administered intravenously in a dosage of 2½ to 5 milligrams of prednisolone sodium phosphate 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. If permanent use is required, oral therapy (tablets) may be substituted. If therapy is to be withdrawn after prolonged use, reduce daily dose gradually over a number of days.
(iii) Do not use in viral infections. Except in emergency therapy, do not use with tuberculosis, chronic nephritis, Cushing's disease, or peptic ulcers. With infections, use appropriate antibacterial therapy with, and for at least 3 days after, discontinuance of use and disappearance of all signs of infection.
(iv) Clinical and experimental data have 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.
(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1884 Prednisolone sodium succinate injection.

(a) Chemical name. 11 beta, 17, 21-Trihydroxypregna-1, 4-diene-3, 20-dione 21-succinate sodium salt.
(b) Specifications. Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium

[52 FR 23032, June 17, 1987]
§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) Specifications. Prednisolone tertiary butylacetate (Pregna-1,4-diene-3, 20-dione-11ß, 17α-21-triol 21-(3,3, di methyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.1

(2) (i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, 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.1

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams 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.1

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upward to 30 to 50 milligrams 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.

(iv) In horses, 50 to 100 milligrams as an initial dose given intravenously over a period of 30 to 1 minute. 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. Not for use in horses intended for food. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]
§ 522.1890 Sterile prednisone suspension.

(a) [Reserved]
(b)(1) Specifications. Each milliliter of sterile aqueous suspension contains 10 to 40 milligrams of prednisone.
(2) Sponsor. See 000061 in §510.600(c) of this chapter.
(3) Conditions of use—(i) Amount. Administer intramuscularly as follows:
   (a) Horses. 100 to 400 milligrams, repeating if necessary. If no response is observed after 3 to 4 days of therapy, reevaluate diagnosis.1
   (b) Dogs and cats. 0.25 to 1.0 milligram per pound of body weight for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.1
   (ii) Indications for use. It is used for conditions requiring an anti-inflammatory agent.1
   (iii) Limitations.1 Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushings’s disease. With infections, use appropriate antibacterial therapy with and for at least 3 days after discontinuance of use and disappearance of all signs of infection. Clinical and experimental data have 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. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1920 Prochlorperazine, isopropamide for injection.

(a) Specifications. Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.
(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.
   (2) Dosage is administered by subcutaneous injection twice daily as follows:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Dosage in Milliliters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 4</td>
<td>0.25</td>
</tr>
<tr>
<td>5 to 14</td>
<td>0.5-1</td>
</tr>
<tr>
<td>15 to 30</td>
<td>2-3</td>
</tr>
<tr>
<td>30 to 45</td>
<td>3-4</td>
</tr>
<tr>
<td>45 to 60</td>
<td>4-5</td>
</tr>
<tr>
<td>Over 60</td>
<td>6</td>
</tr>
</tbody>
</table>

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.
(3) For use only by or on the order of a licensed veterinarian.

§ 522.1940 Progesterone and estradiol benzoate in combination.

(a) [Reserved]
(b) Sponsor. See 000856 for use as provided in paragraphs (d)(1) and (d)(2) of this section; see 021641 for use as provided in paragraphs (d)(1) and (d)(2)(i) through (d)(2)(iii)(A) of this section.
(c) Related tolerances. See §§556.240 and 556.540 of this chapter.
(d) Conditions of use. It is used for implantation in animals as follows:
   (1) Suckling beef calves—(i) Amount. 100 milligrams of progesterone and 10 milligrams of estradiol benzoate per dose.
   (ii) Indications for use. Increased rate of weight gain.
   (iii) Limitations. For use in suckling beef calves (at least 45 days of age) up to 400 pounds of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction.
§ 522.1962

(2) Steers—(i) Amount. 200 milligrams of progesterone and 20 milligrams of estradiol benzoate per dose.

(ii) Indications for use. For increased rate of weight gain and improved feed efficiency.

(iii) Limitations. (A) For animals weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal.

(B) For additional improvement in rate of weight gain in steers fed in confinement for slaughter, reimplant at approximately day 70.


§ 522.1962 Promazine hydrochloride injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains 50 milligrams of promazine hydrochloride.

(b) Sponsor. In § 510.600(c) of this chapter, see No. 000008 for conditions of use as in paragraph (c)(1)(i) of this section; see No. 000856 for conditions of use as in paragraph (c)(1)(ii) of this section; see No. 000864 for conditions of use as in paragraph (c)(1)(iii) of this section.

(c) Conditions of use. (1)(i) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats 1 to 3 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer or preanesthetic.

(iii) To horses intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, as a tranquilizer and preanesthetic, as required.

(2) Not for use in conjunction with organophosphates because their toxicity may be potentiated, nor with procaine hydrochloride as its activity may be increased.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18962, Mar. 27, 1981]

§ 522.2002 Propiopromazine hydrochloride injection.

(a) Chemical name. 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) Specifications. Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) Sponsor. See No. 000856 in § 510.600(c) of this chapter.

(d) Conditions of use. (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05 to 0.25 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.


§ 522.2005 Propofol injection.

(a) Specifications. The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.
(c) Conditions of use—(1) Dogs. (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; 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) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements. (iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


(a) Specifications. Each milliliter of sterile solution contains 1 milligram of prostalene.

(b) Sponsor. See No. 000856 in § 510.600(c) of this chapter.

(c) Conditions of use—Horses. (1) It is used in mares for the control of estrus. (2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection. (3) Not for use in horses intended for food. (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.2063 Pyrilamine maleate injection.

(a) Specifications. The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

(b) Sponsor. See No. 000074 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.594 of this chapter.

(d) Conditions of use. 18-day embryonated broiler eggs and day-old broiler chickens: (1) Amount—(i) 18-day embryonated broiler eggs: 0.05 milligram sarafloxacin in 0.1 milliliter dose in single in ovo injection.
§ 522.2100 Selenium, vitamin E injection.

(a)(1) Specifications. The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 250 milligrams polyoxyethylated vegetable oil, 2.0 percent benzyl alcohol, and water for injection.

(2) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(3) Conditions of use. (i) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(ii) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level of 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(iii) Do not use in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) Specifications. The drug contains in each milliliter 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 100 milligrams of polyoxyethylated vegetable oil, 1:10,000 thimerosal, and water for injection.

(2) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(3) Conditions of use. (i) The drug is intended for use as an aid in alleviating and controlling inflammation, pain and lameness associated with certain arthropathies in dogs.

(ii) The drug is administered subcutaneously or intramuscularly in divided doses in 2 or more sites at a dosage level of 1 milliliter per 20 pounds of body weight with a minimum dosage of ¼ milliliter and a maximum dosage of 5 milliliters. The dosage is repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 milliliter per 40 pounds of body weight with a minimum dosage of ¼ milliliter 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.

(iii) 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), 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q.s.

(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, minimum 1 milliliter.

(ii) Indications for use. Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and
Food and Drug Administration, HHS

§ 522.2112 Sterile sometribove zinc suspension.

(a) Specifications. The drug product consists of a single-dose syringe containing 500 milligrams of sometribove zinc in a sterile, prolonged-release suspension.

(b) Sponsor. See No. 059945 in §510.600(c) of this chapter.

(c) Special considerations. Use may result in reduced pregnancy rates and, in first calf heifers, an increase in days open. Use of the product has also been associated with increases in cystic ovaries and disorders of the uterus during the treatment period. Also, the incidence of retained placenta may be higher following subsequent calving. Treated cows are at an increased risk for clinical mastitis and subclinical mastitis. In some herds, use has been associated with increases in somatic cell counts in milk. Care should be taken to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Use may result in an increase in digestive disorders such as indigestion, bloat, and diarrhea. There may be an increase in the number of cows experiencing periods of “off-feed” (reduced feed intake) during treatment. Cows treated with this product may have increased numbers of enlarged hocks and lesions of the knee (carpal region), and second lactation or older cows may have more disorders of the foot region. Use has been associated with reductions in hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

(d) Conditions of use—(1) Amount. 500 milligrams of sometribove zinc every
14 days beginning during the ninth week after calving and continuing until the end of lactation.

(2) Indications for use. For use in healthy lactating dairy cows to increase the production of marketable milk.

(3) Limitations. For use in lactating dairy cows only. Administer subcutaneously. Safety to replacement bulls born to treated dairy cows has not been established. To minimize injection site blemishes on carcass at time of slaughter, avoid injections within 2 weeks of expected slaughter. No milk discard or preslaughter withdrawal period is required.

[58 FR 59947, Nov. 12, 1993]

§ 522.2120 Spectinomycin 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 Nos. 000033 and 050604 for conditions of use as in paragraph (d) of this section, and see No. 000009 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. infants, 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.


§ 522.2150 Stanozolol sterile suspension.

(a) Specifications. Each milliliter of sterile suspension contains 50 milligrams of stanozolol.

(b) Sponsor. No. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Used as an anabolic steroid treatment in dogs, cats, and horses.
(2) Administered to dogs and cats by deep intramuscular injection in the thigh at weekly intervals, for several weeks. For cats and small breeds of dogs, 25 milligrams. For larger dogs, 50 milligrams.
(3) Administered to horses by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks; 25 milligrams per 100 pounds of body weight.
(4) Not for use in horses intended for food.
Food and Drug Administration, HHS

§ 522.2200 Sulfachlorpyridazine.
(a) Chemical name. N\textsubscript{1}-(6-Chloro-3-pyridazinyl) sulfanilamide.
(b) Specifications. Melting point range 190° C to 191° C.
(c) Sponsor. See No. 053501 in § 510.600(c) of this chapter.
(d) Related tolerances. See § 556.630 of this chapter.
(e) Conditions of use. It is used for injection into calves as follows:
   (1) Amount. 30 to 45 milligrams per pound of body weight per day.
   (2) Indications for use. Treatment of diarrhea caused or complicated by E. coli (colibacillosis).
   (3) Limitations. Administer as the sodium salt of sulfachlorpyridazine intravenously in aqueous solution for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment.

§ 522.2220 Sulfadimethoxine injection.
(a)(1) Specifications. Sulfadimethoxine injection containing 400 milligrams per milliliter.
(2) Sponsor. (i) See No. 000069 in § 510.600(c) of this chapter for conditions of use as in paragraphs (a)(3)(i) through (a)(3)(iii) of this section.
   (ii) See No. 057561 for conditions of use as in paragraph (a)(3) of this section.
   (iii) See No. 059130 for use as in paragraph (a)(3)(iii) of this section.
(3) Conditions of use. (i) It is used or intended for use in dogs and cats as follows:
   (a) For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by Streptococcus, Staphylococcus, Escherichia, Salmonella, Klebsiella, Proteus, or Shigella organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.
   (b) It is administered by intravenous or subcutaneous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours.
   (c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
   (ii) It is used or intended for use in horses as follows:
      (a) For the treatment of respiratory disease caused by Streptococcus equi (strangles).
      (b) It is administered by intravenous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.
      (c) Not for use in horses intended for food.
   (d) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
   (iii) It is used or intended for use in cattle as follows:
      (a) For the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot-rot.
      (b) It is administered by intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.
      (c) 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.
      (d) Tissue damage may result from perivascular infiltration.
   (b) [Reserved]
(c)(1) Specifications. Sulfadimethoxine containing 100 milligrams per milliliter.
(2) Sponsor. See No. 000010 in § 510.600(c) of this chapter.
(3) Conditions of use. (i) It is used or intended for use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs.
   (ii) It is administered by subcutaneous, intramuscular, or intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours thereafter.

§ 522.2240 Sulfaethoxypyridazine.

(a) Chemical name. N-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) Specifications. Melting point range of 180°C to 186°C.

(c) Sponsor. See No. 010042 in §510.600(c) of this chapter.

(d) Related tolerances. See §556.650 of this chapter.

(e) Conditions of use. It is used for injection into cattle as follows:

(1) Amount. 20 milliliters for each 50 pounds of body weight (100 milligrams per pound) initially, 20 milliliters per 100 pounds of body weight (50 milligrams per pound) daily thereafter for cattle.

(2) Indications for use. For cattle for treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (Pasteurella spp.), colibacillosis (bacterial scour) (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. For intravenous use only. Not for use in lactating dairy animals. Withdraw medication from cattle 10 days prior to slaughter for food. If symptoms persist for 2 or 3 days, consult a veterinarian. Adequate water intake is important for animals treated with sulfonamides. Treatment should continue 24 to 48 hours beyond the resolution of disease symptoms, but not to exceed a total of 5 consecutive days.

§ 522.2340 Sulfaethoxypyridazine injectable solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains 250 milligrams of sulfamethazine sodium.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.670 of this chapter.

(d) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.2260 Sulfamethazine injectable solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains 250 milligrams of sulfamethazine sodium.

(b) Sponsor. See No. 000069 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:

<table>
<thead>
<tr>
<th>Age of birds in days</th>
<th>Antibiotic activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chickens (units)</td>
<td>Turkeys (units)</td>
</tr>
<tr>
<td>1 to 14</td>
<td>12,500</td>
</tr>
<tr>
<td>15 to 28</td>
<td>25,000</td>
</tr>
<tr>
<td>29 to 63</td>
<td>50,000</td>
</tr>
<tr>
<td>Over 63</td>
<td>50,000</td>
</tr>
</tbody>
</table>

(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.

§ 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. 000856 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Weight of animal in pounds</th>
<th>Dosage in milligrams per pound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>50</td>
<td>14.1</td>
</tr>
<tr>
<td>Do</td>
<td>30-50</td>
<td>18.8</td>
</tr>
<tr>
<td>Do</td>
<td>10-30</td>
<td>23.5</td>
</tr>
<tr>
<td>Do</td>
<td>Under 10</td>
<td>28.2</td>
</tr>
<tr>
<td>Cat</td>
<td>31.3-37.6</td>
<td>6.3-7.8</td>
</tr>
<tr>
<td>Horse</td>
<td></td>
<td>6.7-9.4</td>
</tr>
<tr>
<td>Cattle and swine</td>
<td></td>
<td>9.4-11.8</td>
</tr>
</tbody>
</table>

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2424 Sodium thiamylal for injection.

(a) Specifications. The drug is a sterile dry powder. It is reconstituted aseptically with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) Sponsor. See code Nos. 000010 and 000865 in §510.500(c) of this chapter.

(c) Conditions of use. (1) It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(2) When diluted aseptically to the desired concentration and administered intravenously to effect, the average single dose is:

(i) Dogs and cats: 8 milligrams per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) Swine: 40 milligrams per 5 pounds of body weight.

(iii) Horses: Light anesthesia, 1 gram per 500 pounds to 1,100 pounds of body weight; deep anesthesia, 1 gram per 300 pounds of body weight (40 milligrams per 12 pounds of body weight).

(iv) Cattle: Short duration, 20 milligrams per 7 pounds of body weight; longer duration, 40 milligrams per 7 pounds of body weight.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) NAS/NRC status: The conditions of use specified in this paragraph are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.2444 Sodium thiopental implantation or injectable dosage forms.

§ 522.2444a Sodium thiopental for injection.

(a) Specifications. The drug contains sodium thiopental sterile powder for dilution with sterile water for injection.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) 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.

(2) It is administered as follows:

(i) For brief anesthesia (6 to 10 minutes) a dosage of 6 to 9 milligrams per pound of body weight is suggested.

(ii) To obtain anesthesia of 15 to 25 minutes duration the suggested dosage is 10 to 12 milligrams per pound of body weight.

(iii) Use of a preanesthetic tranquilizer or morphine will decrease the dosage of sodium thiopental required, provide for smoother induction and smoother recovery, and sometimes prolong the recovery period. If morphine is used as a preanesthetic agent the dose of the barbiturate can be reduced as much as 40 to 50 percent. When a tranquilizer is administered the barbiturate dosage can be reduced 10 to 25 percent.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2444b Sodium thiopental, sodium pentobarbital for injection.

(a) Specifications. Each gram of the drug contains 750 milligrams of sodium thiopental and 250 milligrams of sodium pentobarbital sterile powder for dilution with sterile water for injection.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(2) It is administered as follows:

(i) For total anesthesia, it is given at approximately 10 to 12 milligrams per pound of body weight over a period of 3.5 to 5 minutes.

(ii) When preanesthetic medication is used, it is important to 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.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.

(a) Specifications. Tiletamine hydrochloride and zolazepam hydrochloride for injection when reconstituted with sterile distilled water provides tiletamine hydrochloride and zolazepam hydrochloride equivalent to 50 milligrams of tiletamine base and 50 milligrams of zolazepam base per milliliter of solution.

(b) Sponsor. See No. 000031 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. It is used for restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes) requiring mild to moderate analgesia.

(2) Amount. Expressed as milligrams of the drug combination:

(i) In healthy dogs: An initial intramuscular dosage of 3 to 4.5 milligrams per pound of body weight for diagnostic purposes; 4.5 to 6 milligrams per pound 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 milligrams per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.
(ii) In healthy cats: An initial intramuscular dosage of 4.4 to 5.4 milligrams per pound 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 milligrams per pound 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 milligrams per pound 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 milligrams per pound of body weight.

(3) Limitations. Discard unused reconstituted solution after 48 hours. Not for use in dogs and cats with pancreatic disease, or with severe cardiac or pulmonary dysfunction. Not for use in pregnant animals. Not for use in cats suffering with renal insufficiency. The dosage should be reduced in geriatric dogs and cats. Federal law restricts this drug to use or on the order of a licensed veterinarian.

§ 522.2474 Tolazoline hydrochloride injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) Sponsor. See No. 061690 in §510.600(c) of this chapter.

(c) Conditions of use. It is used as follows:

(i) Horses—(i) Amount. Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or 1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) Indications for use. For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) Limitations. The safety of Tolazine™ has not been established in pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-
§ 522.2476

producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

§ 522.2476 Trenbolone acetate.

(a) Specifications. Each pellet for implanting contains 20 milligrams of trenbolone acetate.

(b) Sponsor. See 012579 and 021641 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.739 of this chapter.

(d) Conditions of use—(1) Heifers. 200 milligrams trenbolone acetate (10 pellets of 20 milligrams each) for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers, use last 63 days prior to slaughter.

(2) Steers. 140 milligrams trenbolone acetate (7 pellets of 20 milligrams each) for improved feed efficiency in growing-finishing feedlot steers, use 126 days prior to slaughter, should be reimplanted once after 63 days.

(3) Pasture cattle (slaughter, stocker, feeder steers, and heifers)—(i) Amount. 40 milligrams of trenbolone acetate and 8 milligrams of estradiol (2 pellets, each pellet containing 20 milligrams of trenbolone acetate and 4 milligrams of estradiol) per animal.

(ii) Indications for use. For improved rate of weight gain.

(iii) Limitations. Implant subcutaneously in ear only. Not for use in animals intended for subsequent breeding or in dairy animals.


§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) Sponsor. See 000856 in §510.600(c) of this chapter.

(b) Related tolerances. See §§556.240 and 556.739 of this chapter.

(c) Conditions of use—(1) Steers—(i) Amount. 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.

(ii) Indications for use. For improved feed efficiency in steers fed in confinement for slaughter.

(iii) Limitations. Implant subcutaneously in ear only.
§ 522.2483 Sterile triamcinolone acetonide suspension.

(a) Specifications. Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.

(b) Sponsor. See 000010 and 053501 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount—(i) Dogs and cats—(a) Intramuscular or subcutaneous. Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.1

(b) Intralesional. 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the 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. Single injection of 1 to 3 mg. dose, dependent on size of 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) Horses—(a) Intramuscular or subcutaneous. Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.

(b) Intra-articular and intrasynovial. Single injection of 6 to 18 mg. dose, dependent on size of 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.

(2) Indications for use. Treatment of inflammation and related disorders in dogs, cats, and horses;1 and manage-

1These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 534.111 of this chapter, but may require bioequivalency and safety information.
§ 522.2610

Trimethoprim and sulfadiazine sterile suspension.

(a)(1) Specifications. Each milliliter of sterile aqueous suspension contains 240 milligrams (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine).  
(2) Sponsor. See 000061 and 000856 in §510.600(c) of this chapter.  
(3) Conditions of use—(i) Dosage. One milliliter (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine) per 20 pounds (9 kilograms) of body weight per day.  
(ii) Indications. For dogs for treatment of acute urinary tract infections, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to Streptococcus zooepidemicus.  
(iii) Limitations. For subcutaneous use in dogs only; administer once every 24 hours, or for severe infections, after an initial dose, administer half the normal daily dose every 12 hours; continue therapy 2 to 3 days after clinical signs of infection have subsided; if no improvement is seen in 3 to 5 days, reevaluate diagnosis; injection may be used alone or in conjunction with oral dosing; not recommended for use for more than 14 days; a complete blood count should be done for prolonged use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.  

§ 522.2615

Tripelemnamine hydrochloride injection.

(a) Specifications. Each milliliter of aqueous solution contains 20 milligrams of tripelemnamine hydrochloride.  
(b) Sponsor. See Nos. 053501 and 059130 in §510.600(c) of this chapter.  
(c) Related tolerances. See §556.741 of this chapter.  
(d) Conditions of use—(1) Amount—(i) Dogs, cats, and horses. For intramuscular use only at a dose of 0.5 milligram per pound of body weight.  
1These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(ii) Cattle. Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) Indications for use. For use in treating conditions in which antimicrobial therapy may be expected to lead to alleviation of some signs of disease.

(3) Limitations. Do not use in horses intended for food purposes. 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.


§ 522.2640 Tylosin injectable dosage forms.

§ 522.2640a Tylosin injection.

(a) Specifications. Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled “Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,” which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 22420 Parklaw Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) Sponsors. (1) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) Related tolerances. See § 556.740 of this chapter.

(e) Conditions of use—(1) Beef cattle and nonlactating dairy cattle—(i) Amount. 8 milligrams per pound of body weight once daily.

(ii) Indications for use. Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with Pasteurella multocida and Corynebacterium pyogenes; foot rot (necrotic pododermatitis) and calf diphtheria caused by Fusobacterium necrophorum and metritis caused by Corynebacterium pyogenes.

(iii) Limitations. Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter.

(2) Swine—(i) Amount. 4 milligrams per pound of body weight twice daily.

(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. Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as 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.
§ 522.2640b Tylosin tartrate for injection.

(a) Specifications. The drug is a sterile powder containing a mixture of tylosin tartrate and sodium citrate which is reconstituted to provide 25 milligrams of tylosin activity per milliliter. Tylosin as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled “Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,” which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.740 of this chapter.

(d) Conditions of use—(1) Chickens—(i) Amount. 25 milligrams per 2 pounds of body weight.

(ii) Indications for use. As an aid in the control and treatment of chronic respiratory disease caused by Mycoplasma gallisepticum sensitive to tylosin.

(iii) Limitations. Not for use in laying chickens producing eggs for human consumption; inject under the loose skin of the neck behind the head; if no improvement is noted within 5 days, diagnosis should be reevaluated; do not treat within 3 days of slaughter.

(2) Turkeys—(i) Amount. 6.25 to 12.5 milligrams per sinus.

(ii) Indications for use. As an aid in the control and treatment of infectious sinusitis caused by Mycoplasma gallisepticum sensitive to tylosin.

(iii) Limitations. Do not use in laying turkeys producing eggs for human consumption; inject 6.25 milligrams to 12.5 milligrams per sinus depending on severity of condition; treatment may be repeated in 10 days if the swelling persists; do not treat within 5 days of slaughter; may be used in conjunction with tylosin in drinking water as indicated in §520.2640(e)(2) of this chapter.

(c) Conditions of use. (1) The drug is used in horses, wild deer, elk, dogs, and cats to produce sedation, as an analgesic, and a preanesthetic to local anesthesia. It may also be used in horses, dogs, and cats as a preanesthetic to general anesthesia.

(2) It is administered as follows:
   (i) To horses from a solution containing 100 milligrams of xylazine per milliliter, intravenously at 0.5 milligram per pound of body weight, or intramuscularly at 1.0 milligram per pound of body weight.
   (ii) To dogs and cats from a solution containing 20 milligrams of xylazine per milliliter; intravenously at 0.5 milligram per pound of body weight or intramuscularly or subcutaneously at 1.0 milligram per pound of body weight. In dogs over 50 pounds, a dosage of 0.5 mg. per pound administered intramuscularly may provide sufficient sedation and/or analgesia for most procedures.
   (iii) To wild deer and elk from a solution containing 100 milligrams of xylazine (as xylazine hydrochloride) per milliliter, intramuscularly, by hand syringe or syringe dart, in the heavy muscles of the croup or shoulder as follows:
      (a) Fallow deer, 2 to 4 milligrams per pound.
      (b) Mule deer, sika deer, and white-tailed deer, 1 to 2 milligrams per pound.
      (c) Elk, 0.25 to 0.5 milligram per pound.
   (3) Not to be administered to food-producing animals.
   (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2670 Yohimbine injectable.

(a) Specifications. Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) Sponsor. See 061690 in §510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.
   (1) Amount. 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.
   (2) Indications for use. To reverse the effects of xylazine in dogs.
   (3) Limitations. For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) Sponsor. See 053923 in §510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.
   (1) Amount. 0.2 to 0.3 milligram per kilogram of body weight.
   (2) Indications for use. As an antagonist to xylazine sedation in free-ranging or confined members of the family Cervidae (deer and elk).
   (3) Limitations. For intravenous use only. 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.

§ 522.2680 Zeranol.

(a) Specifications. Each pellet contains 12 milligrams of 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. For use as a subcutaneous ear implant as follows:
   (1) Beef cattle—(i) Amount. 36 milligrams (three 12-milligram pellets) per animal.
   (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.
(2) Feedlot lambs—(i) Amount. 12 milligrams (1 pellet) per animal.
(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.

(3) Steers—(i) Amount. 72 milligrams (six 12-milligram pellets) per animal.
(ii) Indications for use. For increased rate of weight gain in steers fed in confinement for slaughter.
(iii) Limitations. Implant subcutaneously in ear only.

§ 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.
§ 524.1580 Nitrofurazone ophthalmic and topical dosage forms.
§ 524.1580a [Reserved]
§ 524.1580b Nitrofurazone ointment.
§ 524.1580c Nitrofurazone soluble powder.
§ 524.1580d [Reserved]
§ 524.1580e Nitrofurazone ointment with butacaine sulfate.
§ 524.1600 Nystatin ophthalmic and topical dosage forms.
§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.
§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ophthalmic ointment.
§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.
§ 524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.
§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.
§ 524.1742 N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid.
§ 524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.
§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.
§ 524.1881a [Reserved]
§ 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.
§ 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.
§ 524.1882 Proparacaine hydrochloride ophthalmic solution.
§ 524.2101 Selenium disulfide suspension.
§ 524.2140 Squalane, pyrethrins and piperonyl butoxide.
§ 524.2150 Tolnaftate cream.
§ 524.2481 Triamcinolone acetonide cream.
§ 524.2500 Liquid crystalline trypsin, Peru balsam, castor oil.
§ 524.2501 Tylosin, neomycin eye powder.


Source: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

§ 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) Sponsor. To firms identified in §510.600(c) of this chapter as follows:
(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.
(2) To 000061 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) Conditions of use. 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. Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

(a) Sponsor. To firms identified in §510.600(c) of this chapter as follows:
(1) To 000061; each gram contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.
(2) To 025463; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5
milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

(b) Conditions of use. 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. All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.

(a) Specifications. Each gram of the drug contains 10 milligrams cephalonium, 5,000 units polymyxin B sulfate, 0.25 milligram flumethasone, 30 milligrams iodochlorhydroxyquin, and 40 milligrams piperocaine hydrochloride in a suitable and harmless ointment base.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is recommended for dermal and otic use on dogs and cats for the treatment of the following conditions when complicated by bacteria, yeast, or fungus: Pyodermatitis, allergic dermatitis, dermatophytosis, nonspecific pruritus, and external otitis. For mild inflammations a periodic treatment of applying from once daily to twice weekly may be indicated. In severe conditions apply once or twice daily when continuous treatment may be indicated. Dosage per treatment should not exceed 300 milligrams of the ointment. For otic use treatment should not exceed a total of 12 days. For use only by or on the order of a licensed veterinarian.

§ 524.390 Chloramphenicol ophthalmic and topical dosage forms.

§ 524.390a Chloramphenicol ophthalmic ointment.

(a) Specifications. Each gram contains 10 milligrams chloramphenicol in a petrolatum base.

(b) Sponsor. See Nos. 000856 and 025463 in §510.600(c) of this chapter for use as in paragraph (c)(1)(i) of this section.

See No. 017030 for use as in paragraph (c)(1)(ii) of this section.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply as follows:

(i) Every 3 hours around the clock for 48 hours after which night instillations may be omitted.

(ii) Four to six times daily to affected eye for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac.

(2) Indications for use. Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) Limitations. Continue treatment for 48 hours (2 days) after eye appears normal. Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection may be cause of disease, especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. 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.

§ 524.390b Chloramphenicol ophthalmic solution.

(a) Specifications. Each milliliter contains 5 milligrams of chloramphenicol.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply one or two drops, 4 to 6
times a day for the first 72 hours, depending upon the severity of the condition. Intervals between applications may be increased after the first 2 days. (2) Indications for use. Treatment of bacterial conjunctivitis caused by organisms susceptible to chloramphenicol. Therapy should be continued for 48 hours after the eye appears normal.

(3) Limitations. Therapy for cats should not exceed 7 days. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use, and institute appropriate therapy. Prolonged use in cats may produce blood dyscrasias. Chloramphenicol products 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 37333, Aug. 18, 1992]

§ 524.390c Chloramphenicol-prednisolone-tetracaine-squalane topical suspension.

(a) Specification. Each milliliter contains 4.2 milligrams of chloramphenicol, 1.7 milligrams of prednisolone, 4.2 milligrams of tetracaine, and 0.21 milliliter of squalane.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply 2 to 3 times daily as needed for not more than 7 days. Severe infections should be supplemented by systemic therapy.

(2) Indications for use. Treatment of acute otitis externa and pyoderma (acute moist dermatitis, vulvar fold dermatitis, lip fold dermatitis, interdigital dermatitis, and juvenile dermatitis) in dogs and cats.

(3) Limitations. The drug must not be used in the eyes. Prolonged use in cats may produce blood dyscrasias. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Chloramphenicol products 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 37334, Aug. 18, 1992]

§ 524.390d Chloramphenicol-prednisolone ophthalmic ointment.

(a) Specifications. Each gram contains 10 milligrams of chloramphenicol and 2.5 milligrams of prednisolone acetate.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply 4 to 6 times daily to the affected eye for the first 72 hours depending upon the severity of the condition. Continue treatment for 48 hours after the eye appears normal.

(2) Indications for use. Treatment of bacterial conjunctivitis and ocular inflammation caused by organisms susceptible to chloramphenicol.

(3) Limitations. Therapy for cats should not exceed 7 days, prolonged use in cats may produce blood dyscrasias. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs or if clinical improvement is not noted within a reasonable period, discontinue use and institute appropriate therapy. All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Chloramphenicol products 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 37334, Aug. 18, 1992]

§ 524.402 Chlorhexidine diacetate ointment.

(a) Specifications. The product contains 1 percent of chlorhexidine diacetate in an ointment base.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used as a topical antiseptic ointment
§ 524.450  
for surface wounds on dogs, cats, and horses.  

(2) The wound area is carefully cleansed and the drug is applied daily.  

(3) The drug is not to be used in horses intended for use as food.  

§ 524.450 Clotrimazole cream.  
(a) Specifications. Each gram of cream contains 10 milligrams of clotrimazole.  
(b) Sponsor. See § 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. Wash hands thoroughly after use to avoid spread of infection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.  

[40 FR 48128, July 18, 1980]  

§ 524.463 Copper naphthenate solution.  
(a) Specifications. The drug contains 37.5 percent copper naphthenate in a suitable solvent.  
(b) Sponsor. See Nos. 000856 and 017135 in § 510.600(c) of this chapter.  
(c) Conditions of use—(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. Remove debris and necrotic material before applying. Avoid contact around eyes. Do not use on animals that are raised for food production. Do not contaminate feed. Do not allow runoff of excess drug into hair because contact with the drug may cause some hair loss.  

[47 FR 4250, Jan. 29, 1982]  

Chapter 1 (4-1-98 Edition)  

§ 524.520 Cuprimyxin cream.  
(a) Specifications. The drug contains 0.5 percent cuprimyxin (6-methoxy-1-phenazinol 5, 10-dioxide, cupric complex) in an aqueous cream base.  
(b) Sponsor. See No. 000004 in § 510.600(c) of this chapter.  
(c) Conditions of use—(1) Cuprimyxin is a broad spectrum antibacterial and antifungal cream for the topical treatment of superficial infections in horses, dogs, and cats caused by bacteria, dermatophytes (Trichophyton spp., Microsporum spp.) and yeast (Candida albicans) affecting skin, hair, and external mucosae.  
(2) The cream is applied twice daily to affected areas by rubbing into lesions. Treatment should be continued for a few days after clinical recovery to avoid possible relapses.  
(3) After application to cutaneous areas, a change in color from dark green to pink is due to the liberation of free myxin from its copper complex.  
(4) If no response is seen within seven days, diagnosis and therapy should be reevaluated. If any adverse local reaction is observed after topical application, discontinue treatment.  
(5) 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 45 FR 56799, Aug. 26, 1980]  

§ 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 to 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. Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this use to use by or on the order of a licensed veterinarian.  

[40 FR 48250, July 18, 1980]
§ 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

§ 524.660a Dimethyl sulfoxide solution.

(a) Specifications. Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.

§ 524.660b Dimethyl sulfoxide gel.

(a) Specifications. Dimethyl sulfoxide gel, veterinary contains 90 percent of dimethyl sulfoxide in an aqueous gel.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. For use on horses and dogs as a topical application to reduce acute swelling due to trauma.

(2) Amount—(i) Horses. Administer 2 or 3 times daily in an amount not to exceed 100 grams per day. Total duration of therapy should not exceed 30 days.

(ii) Dogs. Administer 3 or 4 times daily in an amount not to exceed 20 grams per day. Total duration of therapy should not exceed 14 days.

(3) Limitations. Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food. Restricted to topical use on horses and dogs only. Due to rapid penetrating ability of dimethyl sulfoxide, rubber gloves should be worn when applying the drug. No other medications should be present on the skin prior to application of the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.770 Doramectin.

(a) Specifications. Each milliliter of solution contains 5 milligrams of doramectin.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.225 of this chapter.

(d) Conditions of use—Cattle—(1) Amount. 5 milligrams per 10 kilograms (5 milligrams per 22 pounds).

(2) Indications for use. For treatment and control of infections of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with Cooperia oncophora and Dictyocaulus viviparus for 21 days, and Ostertagia ostertagia, C. punctata, and Oesophagostomum radiatum for 28 days after treatment.

(3) Limitations. Administer as a single dose. Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 524.814 Eprinomectin.

(a) Specifications. Each milliliter contains 5 milligrams of eprinomectin.

(b) Sponsor. See No. 000006 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.227 of this chapter.

(d) Conditions of use—(1) Amount. One milliliter (5 milligrams) per 10 kilograms of body weight (500 micrograms per kilogram).
§ 524.900  Famphur.

(a) Chemical name. O,O-Dimethyl O-[4-(methylthio)m-tolyl] phosphorothioate.

(b) Specifications. The drug is in liquid form containing 13.2 percent famphur.

(c) Sponsor. See Nos. 000061 and 060594 in §510.600(c) of this chapter.

(d) 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.

(e) Related tolerances. See §556.273 of this chapter.

(f) Conditions of use. (1) The drug is used as a pour-on formulation for the control of cattle grubs and to reduce cattle lice infestations.

(2) It is used at the rate of 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, applied from the shoulder to the tail head as a single treatment. It is applied as soon as possible after heel fly activity ceases. 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, over-excitement 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.

(3) Do not slaughter within 35 days after treatment. Swine should be eliminated from area where run-off occurs.


§ 524.920  Fenthion.

(a) Chemical name. O,O-Dimethyl O-[4-(methylthio)-m-tolyl] phosphorothioate.

(b) Specifications. (1) The drug is in a liquid form containing 3 percent of fenthion.

(2) Sponsor. See No. 000659 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 40 CFR 180.214.

(5) Conditions of use. (i) The drug is used as a pour-on formulation for the control of grubs and lice in beef and nonlactating cattle.

(ii) It is used at the rate of one-half fluid ounce per 100 pounds of body weight placed 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. 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; 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.

(c) Specifications. (1) The drug is in a liquid form containing 20 percent fenthion.

(2) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(3) 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.


(5) Conditions of use. (i) The drug is used for control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(ii) It is applied as a single application placed on the backline of animals as follows:

<table>
<thead>
<tr>
<th>Weight of animal</th>
<th>Dosage (milliliters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 to 200 lb</td>
<td>4</td>
</tr>
<tr>
<td>201 to 300 lb</td>
<td>8</td>
</tr>
<tr>
<td>301 to 400 lb</td>
<td>12</td>
</tr>
<tr>
<td>401 to 600 lb</td>
<td>16</td>
</tr>
<tr>
<td>601 to 900 lb</td>
<td>20</td>
</tr>
<tr>
<td>901 to 1,200 lb</td>
<td>20</td>
</tr>
<tr>
<td>Over 1,200 lb</td>
<td>20</td>
</tr>
</tbody>
</table>

For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. 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. 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. 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.

(iii) Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock.

(iv) Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases.

(v) Do not slaughter within 45 days of treatment.

(d) Specifications. (1) 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.

(2) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(3) Special considerations. Fenthion is a cholinesterase inhibitor. Do not use this product on dogs simultaneously with or within 14 days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use with flea or tick collars.

(4) Conditions of use—(i) Amount. Four to 8 milligrams per kilogram of body weight.

(ii) Indications for use. For flea control on dogs only.

(iii) Limitations. Apply the contents of the proper size, single-dose tube directly to one spot on the dog's skin. Frequency of repeat treatments depends upon rate of flea reinfestations. Do not use more often than once every 2 weeks. Treatment at 2-week intervals is not to exceed 6 months. Do not use on puppies under 10 weeks of age. Do not use on sick, stressed, or convalescing dogs. Safe use in breeding males has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

(a) Specifications. Each milliliter of ophthalmic preparation contains 0.10
§ 524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

§ 524.981a Fluocinolone acetonide 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. (1) The drug is indicated for the relief of pruritus and inflammation associated with certain superficial acute and chronic dermatoses in dogs. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical and physical abrasions and burns.

(2) A small amount is applied to the affected area two or three times daily.

(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]

§ 524.981b Fluocinolone acetonide solution.

(a) Specifications. The drug contains 0.01 percent fluocinolone acetonide in propylene glycol with citric acid.

(b) Sponsor. See No. 099207 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the relief of pruritus and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses in the dog. It is also indicated for the relief of pruritus and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses in the cat.

(2) A small amount of solution is applied to the affected area 2 or 3 times daily.

(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]

§ 524.981c Fluocinolone acetonide, neomycin sulfate cream.

(a) Specifications. The drug contains 0.025 percent fluocinolone acetonide and 0.5 percent neomycin sulfate (0.35 percent neomycin base).
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§ 524.1005 Furazolidone aerosol powder.

(a) Specifications. The product contains either 4 or 10 percent furazolidone in inert dispersing agent and propel-

ant.

(b) Sponsors. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs. For treatment or prevention of bacterial infection of superficial wounds, abra-
sions, lacerations, and pyogenic dermatitis.

(ii) Horses. For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and fol-

lowing firing (heat or electrocautery).
§ 524.1044 Gentamicin sulfate ophthalmic and topical dosage forms.

§ 524.1044a Gentamicin ophthalmic solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs and cats for the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(ii) Cattle. For treatment of bacterial infections of the bovine eye and for treatment and to reduce the incidence of additional cases of infectious bovine keratoconjunctivitis (pink eye) caused by Moraxella bovis.

(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. For treatment of bacterial infections of the bovine eye and infectious bovine keratoconjunctivitis (pink eye) caused by Moraxella bovis: Treat affected eyes once daily on each of 3 to 5 consecutive days; to reduce incidence of additional cases of infectious keratoconjunctivitis also medicate unaffected eyes. Evidence of clinical improvement of bovine eye infections should be noticeable after 5 treatments; if not, reconsult veterinarian. 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 reconsult veterinarian. Not for use in horses intended for food.


§ 524.1044b Gentamicin sulfate, betamethasone valerate otic solution.

(a) Specifications. Each cubic centimeter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone alcohol.

(b) Sponsor. See Nos. 000061 and 051259 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used or indicated for use in dogs in the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin; the drug is also used or indicated for use in dogs and cats in the treatment of superficial infected lesions caused by bacteria sensitive to gentamicin.

(ii) For the treatment of acute and chronic canine otitis externa caused by bacteria sensitive to gentamicin, the drug is administered by instillation of 3 to 8 drops of solution into the ear canal twice daily for 7 to 14 days. Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced but care should be taken not to discontinue therapy prematurely. The external ear and ear canal should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(ii) For the treatment of canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.
(3) If hypersensitivity to any of the components occurs, treatment with this product should be discontinued and appropriate therapy instituted. Concomitant use with other drugs known to induce ototoxicity is not recommended. This preparation should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with this drug. The antibiotic sensitivity of the pathogenic organism should be determined prior to use of this preparation.

(4) For use by or on the order of a licensed veterinarian.

§ 524.1044c Gentamicin ophthalmic ointment.

(a) Specifications. Each gram of sterile ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used on dogs and cats for topical treatment of conjunctivitis caused by susceptible bacteria.

(2) Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.1044d Gentamicin sulfate, betamethasone valerate ointment.

(a) Specifications. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin 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. (1) The drug is used or indicated for use in dogs in the treatment of acute and chronic canine otitis externa and canine infected superficial lesions caused by bacteria sensitive to gentamicin.

(ii) For the treatment of canine infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Observe patients for signs of adrenocorticoid overdosage. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

(4) For 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]

§ 524.1044e Gentamicin sulfate 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. (1) The drug is indicated for the treatment of pink eye in cattle (infectious bovine keratoconjunctivitis) caused by Moraxella bovis.

(2) One actuation of the sprayer delivers 0.7 milliliter containing 0.75 milligram gentamicin. The sprayer should be held upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pumped once. It is advisable to treat once a day for up to 3 days.
§ 524.1044 Gentamicin sulfate, betamethasone valerate topical spray.

(a) Specifications. Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram of gentamicin base and betamethasone valerate equivalent to 0.284 milligram of betamethasone.

(b) Sponsor. See Nos. 000061 and 051259 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs in the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

(2) For the treatment of infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. One actuation of the sprayer delivers 0.7 milliliter of the spray. The drug should be administered with two spray actuations 2 to 4 times daily for 7 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1044g Gentamicin sulfate, betamethasone valerate, 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) Sponsor. See 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the treatment of canine otitis externa associated with yeast (Malassezia pachydermatis, formerly Pityrosporum canis) and/or bacteria susceptible to gentamicin.

(2) For 7.5 or 15 g tube, instill 4 drops of ointment twice daily into the ear canal of dogs weighing less than 30 pounds, instill 8 drops twice daily for dogs weighing 30 pounds or more. For 215 g bottle, instill 2 drops of ointment twice daily into the ear canal of dogs weighing less than 30 pounds, instill 4 drops twice daily for dogs weighing 30 pounds or more. Therapy should continue for 7 consecutive days.

(3) The external ear should be cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable solutions. Excessive hair should be clipped from the treatment area. If hypersensitivity occurs, treatment should be discontinued and alternate therapy instituted.

(4) Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally 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.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) Related tolerances. See §556.344 of this chapter.

(d) Conditions of use—(1) Amount. One milliliter per 22 pounds of body weight.

(2) 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 stage), Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia spp., Oesophagostomum radiatum, O. venulosum (adults), Strongyloides papillosus (adults), Trichuris spp. (adults), lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); cattle grubs (parasitic stages) (Hypoderma bovis, H. lineatum); lice (Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenopotes capillatus); mites (Chorioptes bovis, Sarcoptes scabiei var. bovis); horn flies (Haematobia irritans). It is also used to control infections of gastrointestinal roundworms O. ostertagi, O. radiatum, H. placei, T. axei, Cooperia punctata, and C. oncophora for 14 days after treatment.

(3) Limitations. For use on skin surface only. 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. Drug has been associated with severe adverse reactions in sensitive dogs; therefore drug is not recommended for use in animals other than cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§524.1200b Kanamycin ophthalmic aqueous solution.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30 of this chapter.

(2) The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10.0 milligrams of kanamycin activity (as the sulfate) per cubic centimeter of solution.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. 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. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§524.1200b Kanamycin ophthalmic aqueous solution.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30 of this chapter.

(2) The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. 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. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]
§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30(a)(1) of this chapter. (2) Calcium amphomycin is the calcium salt of amphomycin. It conforms to the following specifications: (i) Its potency is not less than 863 micrograms of amphomycin per milligram; (ii) Its moisture content is not more than 10 percent; and (iii) Its pH in a 2-percent aqueous suspension is 6.0 to 7.5. (3) The drug is in a water-miscible ointment or cream base and each gram of ointment or cream contains: 5.0 milligrams of kanamycin activity as the sulfate, 5.0 milligrams of amphomycin activity as the calcium salt, and 10.0 milligrams of hydrocortisone acetate.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated for use in dogs in the following conditions associated with bacterial infections caused by organisms susceptible to one or both antibiotics: Acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcer, superficial wounds, and superficial abscesses. (2) The ointment should be applied 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. Before application, hair in the affected area should be closely clipped and the area should be thoroughly cleansed of crusts, scales, dirt, or other detritus. When treating infections of the anal gland, the drug should be introduced into the orifice of the gland and not through any fistulous tract. If no response is evident in 7 days, diagnosis and therapy should be reevaluated. (3) For use only by or on the order of a licensed veterinarian.

§ 524.1240 Levamisole.

(a) Specifications. The drug contains 200 milligrams of levamisole per milliliter of diethylene glycol monobutyl ether (DGME) solution. (b) Sponsor. See 000061 and 010042 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.

§ 524.1376 2-Mercaptobenzothiazole solution.

(a) Specifications. The drug contains 1.3 percent 2-mercaptobenzothiazole in a suitable solvent. (b) Sponsor. See 011509 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 treating moist dermatitis and hotspots 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.
§ 524.1443 Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.

(a) Specifications. (1) The cream contains 23 milligrams of miconazole nitrate (equivalent to 20 milligrams of miconazole base) per gram.

(2) The lotion contains 1.15 percent of miconazole nitrate (equivalent to 1 percent miconazole base).

(3) The spray product consists of a dispensing container, sprayer pump assembly, and lotion which contains 1.15 percent of miconazole nitrate (equivalent to 1 percent miconazole base).

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter for use of cream, lotion, and spray; see No. 051295 in § 510.600(c) of this chapter for use of lotion and spray.

(c) Conditions of use. (1) Miconazole nitrate is an antifungal agent for topical treatment of infections in dogs and cats caused by Microsporum canis, Microsporum gypseum, and Trichophyton mentagrophytes.

(2) 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.

(3) Accurate diagnosis of infecting organism is essential. Identify by microscopic examination of a mounting of infected tissue in potassium hydroxide for 10 minutes, reevaluate diagnosis, and treat appropriate medium.

(4) If no improvement is observed in 2 weeks, reevaluate diagnosis and therapy.

(5) Avoid contact with eyes since irritation may result.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.1451 Moxidectin.

(a) Specifications. Each milliliter contains 5 milligrams of moxidectin (0.5 percent solution).

(b) Sponsor. See No. 000856 in § 510.600(c) of this chapter.

(c) Conditions of use. See § 556.426 of this chapter.

(d) Conditions of use—(1) Amount. 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.

(2) Indications for use. Beef and nonlactating dairy cattle for treatment and control of internal and external parasites; gastrointestinal roundworms (Ostertagia ostertagi (adult and L4, including inhibited larvae), Haemonchus placei (adult), Trichostrongylus axei (adult and L4), T. colubriformis (adult), Cooperia oncopora (adult), C. punctata (adult), Bunostomum phlebotomum (adult), Oesophagostomum radiatum (adult), Nematodirus helvetianus (adult)); 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, Damalinia bovis); and horn flies (Haematobia irritans). To control infections and to protect from reinfection with O. ostertagi for 28 days after treatment and with D. viviparus for 42 days after treatment.

(3) Limitations. Apply topically along the top of the back from the withers to the tailhead. Because a withdrawal time for milk has not been established, do not use on 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[63 FR 14036, Mar. 24, 1998]

§ 524.1465 Mupirocin ointment.

(a) Specifications. Each gram contains 20 milligrams of mupirocin.

(b) Sponsor. See No. 000069 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs:

(i) Indications for use. Topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of Staphylococcus aureus and Staphylococcus intermedius.

(ii) Limitations. Apply twice daily. Treatment should not exceed 30 days. Because of potential hazard of nephrotoxicity due to polyethylene glycol content, care should be exercised in treating deep lesions. Safety of
use in pregnant or breeding animals has not been determined. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) Specifications. Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

(6) 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]

§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used in treating such conditions as 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.

(2) In treatment of otitis externa and other inflammatory conditions of the...
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§ 524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.

(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.

(1) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the product. If such signs are noted, therapy with the product should be stopped. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984]

§ 524.1484e Neomycin sulfate and polymyxin B sulfate 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. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is recommended for the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivities, and blepharitis in the dog.

(2) The recommended dosage is 1 to 2 drops per eye every 6 hours.

(3) In treating ophthalmological conditions associated with bacterial infections the drug is contraindicated in those cases in which microorganisms are nonsusceptible to the antibiotics incorporated in the drug.

(4) 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]

§ 524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated for treating acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. In treatment of ear canker 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.1

(2) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the product. If such signs are noted, therapy with the product should be stopped. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984]
§ 524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.

(a) Specifications. Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is recommended for use as an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(2) In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (two to four drops per square inch) twice daily. In treating otitis externa, five to 15 drops of the drug should be instilled in the ear twice daily. The drug is limited to 7 days maximum duration of administration.

(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 63271, Nov. 28, 1997]

§ 524.1484h Neomycin, penicillin, polymyxin, 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 000009 in §510.600(c) of this chapter.

(c) Special considerations. The labeling shall state: This medication contains penicillin. Allergic reactions in humans are known to occur from topical exposure to penicillin.

(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]

§ 524.1484i Neomycin sulfate, hydrocortisone acetate, sterile 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. No. 000009 in §510.600(c) of this chapter.
(c) Conditions of use. (1) Amount. Apply three or four times daily into the conjunctival sac. With improvement, frequency may be reduced to two or three times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal one to three times daily.1
(2) Indications for use. For treating infections, allergic, and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats.1
(3) Limitations. All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia. Federal law restricts this drug to use by or on the order of a licensed veterinarian.1
[43 FR 40456, Sept. 12, 1978]
§ 524.1580c Nitrofurazone soluble powder

(a) Specifications. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) Sponsor. See Nos. 000010, 000069, and 050749 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 a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

§ 524.1580d [Reserved]

§ 524.1580e Nitrofurazone ointment with butacaine sulfate.

(a) Specifications. The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) Sponsor. See No. 051259 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).

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

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(3) Limitations. For mild inflammations, use once daily to once a week. For severe conditions, apply initially two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not for ophthalmic use. 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]

§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

(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. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is indicated for relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions. The indications include 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 in dogs and cats.

(2) 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.

(3) Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of
§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate 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. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae, E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pink eye, 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.

(2) It is administered topically to the eye two to four times daily.

(3) 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.

§ 524.1742 N-(Mercaptomethyl) phthalimide S-(O,0-dimethyl phosphorodithioate) emulsifiable liquid.

(a) Specifications. The emulsifiable liquid contains 11.6 percent N-(mercaptomethyl) phthalimide S-(O,0-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:

<table>
<thead>
<tr>
<th>To control/method of use</th>
<th>Dilution rate (gal. drug: gal. of water)</th>
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</thead>
<tbody>
<tr>
<td>Grubs:</td>
<td></td>
</tr>
<tr>
<td>Dip</td>
<td>1:6</td>
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<tr>
<td>Pour-on</td>
<td>1:2</td>
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<tr>
<td>Lice:</td>
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<tr>
<td>Dip</td>
<td>1:60</td>
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<tr>
<td>Pour-on</td>
<td>1:2 or 1:5</td>
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<tr>
<td>Hornflies:</td>
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<tr>
<td>Dip</td>
<td>1:60</td>
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<tr>
<td>Spray</td>
<td>1:49 or 1:100</td>
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<tr>
<td>Southern cattle ticks:</td>
<td></td>
</tr>
<tr>
<td>Dip</td>
<td>1:60</td>
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<tr>
<td>Spray</td>
<td>1:49</td>
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<tr>
<td>Scabies mites:</td>
<td></td>
</tr>
<tr>
<td>Dip</td>
<td>1:60</td>
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<tr>
<td>Lone Star Ticks:</td>
<td></td>
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<tr>
<td>Dip</td>
<td>1:60</td>
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<tr>
<td>Spray</td>
<td>1:49 or 1:100</td>
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</table>

(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 ⅔ to ¾ 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 evaporation, 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 "run-off," 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 190.261.


§524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.

(a) Specifications. Prednisolone-neomycin sulfate ophthalmic ointment contains 2 milligrams prednisolone and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants. A small quantity of the ointment should be expressed into the conjunctival sac four times a day for 7 days. After 7 days, if clinical improvement is not noted, re-evaluation of the diagnosis should be considered. All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under
§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

§ 524.1881a [Reserved]

§ 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.

(a) Specifications. Prednisolone acetate-neomycin sulfate sterile suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base) in each milliliter of sterile suspension.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is indicated for treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa in dogs and cats. For beginning treatment of acute ocular inflammations 1 or 2 drops may be placed in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, the dosage may be reduced to 1 drop 2 to 4 times daily. In otitis externa, 2 to 6 drops may be placed in the external ear canal 2 or 3 times daily.

(2) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1882 Proparacaine hydrochloride 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. 053501 in §510.600(c) of this chapter.

(c) 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

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
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.

§ 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) NAS/NRC status. These conditions are NAS/NRC reviewed and found effective. NADA’s for similar products for these conditions of use need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(c) Sponsors. See 015563, 017135, 023851, and 050604 in §510.600(c) of this chapter.

(1) Indications for use. For use on dogs as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and non-specific 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.


§ 524.2140 Squalane, pyrethrins and piperonyl butoxide.

(a) Specifications. The drug contains 25 percent squalane (hexamethyldiotracane), 0.05 percent pyrethrins and 0.50 percent technical piperonyl butoxide.
(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is used for the treatment of ear mites in dogs and cats.
   (2) It is administered as follows: Cats and dogs 5-15 pounds body weight, 4 to 5 drops in each ear daily. Dogs 16-30 pounds body weight, 5 to 10 drops in each ear daily. Dogs 30 pounds body weight and over 10 to 15 drops in each ear daily. The recommended treatment is for 7 to 10 days with repeated treatment in 2 weeks if necessary.

§ 524.2350 Tolnaftate cream.

(a) Specifications. The drug contains 1 percent tolnaftate (2-naphthyl-N-methyl-N-(3-tolyl) thionocarbamate) in an anhydrous cream base.
(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is indicated for treatment of ringworm lesions due to Microsporum canis and Microsporum gypseum in dogs and cats.
   (2) A small amount of the cream is applied to the affected areas once or twice a day for 2 to 4 weeks. The areas to be treated are first cleared of exudate and the hair clipped if the areas are not already denuded. The cream is massaged into each lesion and immediate surrounding area until the cream is no longer visible.
§ 524.2481

(3) If no response is seen after 2 weeks of treatment with the drug the diagnosis should be reviewed.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.2481 Triamcinolone acetonide cream.

(a) Specifications. Triamcinolone acetonide cream contains 0.1 percent triamcinolone acetonide in an aqueous vanishing cream base.

(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is recommended for use on dogs as an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

(2) The drug is applied by rubbing into affected areas two to four times daily for 4 to 10 days.

(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]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a)(1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Sponsor. See No. 000514 in §510.600(c) of this chapter.

(b)(1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) Sponsor. See No. 017135 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.


§ 524.2640 Tylosin, neomycin eye powder.

(a) Specifications. Tylosin is the antibiotic substance produced by growth of Streptomyces fradiae or the same antibiotic substance produced by any other means. Tylosin, present as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used in cattle for the treatment of pinkeye (infectious keratoconjunctivitis).

(2) It is administered by holding the eyelids open and dusting powder into both eyes. The treatment is repeated daily for up to 7 days depending on the severity of the infection. Affected animals should be protected from direct sunlight, dust, and flies. In an affected herd, all animals with or without signs of the disease should receive at least one treatment.

(3) If there is severe eye damage or if the condition persists or increases, discontinue administering the drug and consult a veterinarian.

PART 526—INTRAMAMMARY DOSAGE FORMS

§ 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. 000069 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]

§ 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. 000856 in §510.600(c) of this chapter.
(c) Related tolerances. See §556.115 of this chapter.
(d) Conditions of use—(1) Amount. Infuse contents of one syringe into each infected quarter.
(2) Indications for use. Use in dry cows for treatment of mastitis caused by susceptible strains of Streptococcus agalactiae and Straphylococcus aureus.
(3) Limitations. Infuse each infected quarter following last milking or early in the dry period, 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.


§ 526.365 Cephapirin sodium for intramammary infusion.
(a) Specifications. Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanut-oil gel.
(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.
(c) Related tolerances. See §556.115 of this chapter.
(d) Conditions of use. (1) The drug is used for the treatment of lactating cows having bovine mastitis caused by susceptible strains of Streptococcus agalactiae and Straphylococcus aureus.
(2) Administer one dose into each infected quarter immediately after the quarter has been completely milked.
§ 526.464 Cloxacillin intramammary dosage forms.

§ 526.464a Cloxacillin benzathine for intramammary infusion.

(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. 000856 in §510.600(c) of this chapter.

(1) Amount. Administer aseptically into each infected quarter immediately after last milking or early in dry period.

(2) Indications for use. 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. Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for food. Animals infused with this product must not be slaughtered for food use 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. 000069 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 non-lactating 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.

§ 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 Streptococcus 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. 000069 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 non-lactating 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.
§ 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. 000069 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.

§ 526.464d Cloxacillin sodium for intramammary infusion.

(a) Specifications. 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.

(b) Sponsor. See No. 050604 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.

§ 526.1130 Hetacillin potassium for intramammary infusion.

(a) Specifications. Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.

(b) Sponsor. See No. 000856 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. If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated. 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]

§ 526.1590 Novobiocin oil suspension.

(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. 000009 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]

§ 526.1696 Penicillin intramammary dosage forms.

§ 526.1696a Penicillin G procaine in oil.

(a) Specifications. Each milliliter contains penicillin G procaine equivalent to 100,000 units of penicillin G in peanut, sesame, or soybean oils.
(b) Related tolerances. See §556.510 of this chapter.
(c) Sponsor. See No. 010515 in §510.600(c) of this chapter.
(1) National Academy of Sciences/National Research Council (NAS/NRC) status. The conditions specified in paragraph (c)(2)(i)(B) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(2) Conditions of use. Treating bovine mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and S. uberis in lactating cows as follows:
(i) Three-dose regimen. Administer by intramammary infusion in each infected quarter as follows:

(A) 6-milliliter dose (peanut oil). Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 84 hours (7 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after the latest treatment.

(B) 10-milliliter dose (sesame oil). Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 60 hours (5 milkings) 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.

(ii) Two-dose regimen. 10-milliliter dose (peanut oil). Administer by intramammary infusion in each infected quarter. Treatment may be repeated at intervals of 12 hours. Milk taken from animals during treatment and for 60 hours (5 milkings) 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.

(d) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(1) 10-milliliter dose (peanut oil). Administer by intramammary infusion in 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. Treating bovine mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and S. uberis in lactating cows as follows:

(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) Sponsor. See No. 010515 (sesame oil) and No. 050604 (peanut oil) in §510.600(c) of this chapter.

(1) NAS/NRC status. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(2) Single-dose regimen. One 10-milliliter dose (sesame oil or peanut oil) in each infected quarter at time of drying-off.

(3) Indications for use. Treating bovine mastitis caused by Streptococcus agalactiae in dry cows.

(4) 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.

§526.1696c 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. 000010 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.

§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.
§ 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Lactating cows—(i) Amount. 10 milliliters in each 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 36 hours (three milkings) following the last 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]

§ 526.1810 Pirlimycin hydrochloride aqueous gel.

(a) Specifications. Each 10-milliliter syringe contains 50 milligrams of pirlimycin (as pirlimycin hydrochloride).

(b) Sponsor. See 000009 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.515 of this chapter.

(d) Conditions of use. (1) Dose. 50 milligrams in each infected quarter, repeated once after 24 hours.

(2) Indications for use. For lactating dairy cattle for the treatment of clinical and subclinical mastitis caused by 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 (three milkings) following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 28 days following the last treatment. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993]
Food and Drug Administration, HHS

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec. 529.50 Amikacin sulfate intrauterine solution.
529.360 Cephalothin discs.
529.400 Chlorhexidine tablets and suspension.
529.1003 Flurogestone acetate-impregnated vaginal sponge.
529.1030 Formalin solution.
529.1044 Gentamicin sulfate in certain other dosage forms.
529.1044a Gentamicin sulfate intrauterine solution.
529.1044b Gentamicin sulfate solution.
529.1115 Halothane.
529.1126 Isoflurane.
529.1526 Nifurpirinol capsules.
529.2090 Salicylic acid.
529.2464 Ticarcillin powder.
529.2503 Tricaine methanesulfonate.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.50 Amikacin sulfate intrauterine solution.
(a) Specifications. Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).
(b) Sponsor. See No. 000856 and 059130 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Amount. Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.
(2) Indications for use. For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.
(3) Limitations. Prior to administration, remove any unattached placent 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.\(^1\)

\(^{1}\)These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.
(a) Specifications. Each vaginal sponge contains 20 milligrams of flurogestone acetate.
(b) Sponsor. See No. 000014 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Indications for use. For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.
(2) Limitations. Using applicator provided, insert sponge into ewe's vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not
§ 529.1030

had lambs. Use plastic or rubber gloves when handling large numbers of sponges to minimize exposure to drug. Do not leave sponges in the vagina for more than 21 days. Ewes must not be slaughtered for food within 30 days of sponge removal.

[49 FR 45420, Nov. 16, 1984]

§ 529.1030 Formalin solution.

(a) Specifications. Formalin solution is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

(b) Sponsor. Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) No. 050378 for use as in paragraph (c) of this section.

(2) Nos. 049968 and 051212 for use as in paragraphs (c)(1)(i), (c)(1)(ii), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(c) Conditions of use—

(1) Indications for use. The drug is added to the environmental water as follows:


(ii) For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

(iii) For control of external protozoan parasites Bodo spp., Epistylis spp., and Zoothamnium spp. on penaeid shrimp.

(2) Amount. The drug concentrations required are as follows:

(i) For control of external parasites on fish:

<table>
<thead>
<tr>
<th>Fish</th>
<th>Concentration of formalin (microliters per liter)</th>
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<tr>
<td>Salmon and trout:</td>
<td>Tanks and raceways (for up to 1 hour) Earthen ponds (indefinitely)</td>
</tr>
<tr>
<td>Above 50 °F</td>
<td>Up to 170</td>
</tr>
<tr>
<td>Below 50 °F</td>
<td>Up to 250</td>
</tr>
<tr>
<td>Catfish, largemouth bass, and bluegill</td>
<td>Up to 250</td>
</tr>
</tbody>
</table>

1 Use the lower concentrations when pond is heavily loaded with fish or phytoplankton.

(ii) For control of fungi of the Saprolegniaceae on salmon, trout, and esocid eggs: Apply in constant flow water supply of incubating facilities for 15 minutes. Concentration of formalin used is 1,000 to 2,000 microliters per liter.

(iii) For control of external protozoan parasites on shrimp:

<table>
<thead>
<tr>
<th>Shrimp</th>
<th>Concentration of formalin (microliters per liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penaeid Shrimp ...</td>
<td>50 to 100 [1] ... 25 [2]</td>
</tr>
</tbody>
</table>

1 Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when the tanks and raceways are heavily loaded.

2 Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(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 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 apply formalin which has been subjected to temperatures below 40 °F, or allowed to freeze. Do not treat ponds containing striped bass. Treatments in tanks should never exceed 1 hour even if fish show no signs of stress. 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.


§ 529.1044 Gentamicin sulfate in certain other dosage forms.

§ 529.1044a Gentamicin sulfate intrauterine solution.

(a) Specifications. Each milliliter of the drug contains 50 or 100 milligrams of gentamicin (as the sulfate) in sterile aqueous solution.

(b) Sponsor. See Nos. 000010, 000061, 000856, 000864, 057561, and 059130 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is indicated for use for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving...
conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(2) It is administered at a dosage level of 2 to 2.5 grams per day for 3 to 5 days during estrus, each dose being diluted with 200 to 500 milliliters of sterile physiological saline before aseptic infusion into the uterus.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Not for use in horses intended for food.

Food and Drug Administration, HHS § 529.1044b Gentamicin sulfate solution.

(a) Specifications. Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) Sponsor. See Nos. 000061 and 051259 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount—(i) Horses: For induction of surgical anesthesia: 3 to 5 percent isoflurane (with

§ 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 000856 and 012164 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.1

(2) Indications for use. For nonfood animals for the induction and maintenance of anesthesia.1

(3) Limitations. Administered by inhalation. May be administered with either oxygen or a mixture of oxygen and nitrous oxide. Place drug vaporizer between the gas supply and breathing bag to prevent overdosage. Not recommended for obstetrical anesthesia except when uterine relaxation is required. Do not use in pregnant animals; information on possible adverse effects on fetal development is not available. Operating rooms should have adequate ventilation to prevent accumulation of anesthetic gases. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.1


§ 529.1186 Isoflurane.

(a) Specifications. The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers. It is nonflammable and nonexplosive.

(b) Sponsors. See Nos. 000074, 010019, 012164, and 059258 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount—(i) Horses: For induction of surgical anesthesia: 3 to 5 percent isoflurane (with

1These conditions have been reviewed by FDA and found effective. NADA's for similar products for these conditions of use need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
§ 529.1526 Nifurpirinol capsules.

(a) Specifications. Each capsule contains 3.8 or 7.6 milligrams of nifurpirinol.

(b) Sponsor. See No. 000074 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in treating aquarium fish for the control of columnaris disease caused by Chondrococcus columnaris susceptible to nifurpirinol.

(2) Use one 3.8 milligram nifurpirinol capsule for each 10 gallons of aquarium water. Empty the contents of the capsule directly into the water and stir briefly. Treat for at least 1 hour. If activated charcoal or carbon filtration is being used, disconnect during treatment, but maintain adequate aeration. Resume water filtration after 1 hour treatment. Usually a single treatment is sufficient. For aquariums with charcoal filters, nifurpirinol can be used once each 24 hours up to 3 consecutive days without additional treatment if aquarium does not have charcoal filter, but do not retreat within 5 days. Do not use in salt water aquaria.

(4) Do not use while egg bearers or live bearers are reproducing.

§ 529.2090 Salicylic acid.

(a) Specifications. (1) Each dose contains 0.55 grain of salicylic acid in a gum arabic and dextrin vehicle.

(2) Each dose is incorporated upon a device (teat dilator) suitable for insertion into and subsequent removal from the teat canal.

(b) Sponsor. See No. 045087 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the removal of scar tissue in the teat canal of milk-producing cows.

(2) The labeling bears directions to the user to:

(i) Treat lactating cows initially by inserting the device into and subsequent removal from the teat canal.

(ii) Insert second dose and permit device to remain in canal until the next milking;

(iii) Insert one dose following each milking for up to 2 days.

(3) Milk that has been drawn from animals within 48 hours of such treatment may not be used for food.

§ 529.2464 Ticarcillin powder.

(a) Specifications. Each vial contains ticarcillin disodium equivalent to 6 grams of ticarcillin to be reconstituted with 25 milliliters of sterile water for injection or sterile physiological saline.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) Amount. 6 grams per day, intrauterine, for 3 consecutive days during estrus.

(2) Indications for use. Horses.

(a) Intrauterine treatment of endometritis caused by beta-hemolytic streptococci.

(3) Limitations. For intrauterine use in horses only. Infuse aseptically. Not for use in horses raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Food and Drug Administration, HHS

use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

§ 529.2503 Tricaine methanesulfonate.

(a) Chemical name. Ethyl-m-amino-benzoate methanesulfonate.

(b) Sponsor. See Nos. 050378 and 051212 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used for the temporary immobilization of fish, amphibians, and other aquatic cold-blooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(2) It is used as follows:

(i) For 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) For amphibians and other aquatic cold-blooded 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.

(iii) 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 should exceed 10°C (50°F.). In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use.


PART 530—EXTRALABEL DRUG USE IN ANIMALS

Subpart A—General Provisions

Sec. 530.1 Scope.  
530.2 Purpose.  
530.3 Definitions.
§ 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 an 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 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 only 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 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
§ 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 (except for approved topical use);
(8) Nitrofurazone (except for approved topical use);
(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfathoxypyridazine);
(10) Fluoroquinolones; and
(11) Glycopeptides.
(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals:
[Reserved]

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

§ 556.20 2-Acetylamino-5-nitrothiazole.
A tolerance of 0.1 part per million is established for negligible residues of 2-acetylamino-5-nitrothiazole in the edible tissues of turkeys.

§ 556.30 Aklomide.
Tolerances are established for combined residues of aklomide (2-chloro-4-nitrobenzamide) and its metabolite (4-amino-2-chlorobenzamide) in uncooked edible tissues of chickens as follows:
(a) 4.5 parts per million in liver and muscle.
(b) 3 parts per million in skin with fat.

§ 556.34 Albendazole.
Tolerances are established for residues of albendazole in uncooked edible tissues as follows:
(a) Cattle. The tolerance for the 2-aminosulfone metabolite (marker residue) in cattle liver (target tissue) is 0.2 part per million. The tolerance refers to the concentration of marker residue in the target tissue used to monitor for total drug residues in the target animals.
(b) Sheep. The tolerance for the 2-aminosulfone metabolite (marker residue) in sheep liver (target tissue) is 0.25 part per million.

§ 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.

§ 556.40 Ampicillin.
A tolerance of 0.01 ppm 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.

§ 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.

§ 556.60 Arsenic.
Tolerances for total residues of combined arsenic (calculated as As) in food are established as follows:
(a) In edible tissues and in eggs of chickens and turkeys:
   (1) 0.5 part per million in uncooked muscle tissue.
   (2) 2 parts per million in uncooked edible by-products.
   (3) 0.5 part per million in eggs.
   (b) In edible tissues of swine:
      (1) 2 parts per million in uncooked liver and kidney.
      (2) 0.5 part per million in uncooked muscle tissue and by-products other than liver and kidney.

§ 556.70 Bacitracin.
Tolerances for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate are established at 0.5 part per million (0.02 unit per gram), negligible residue, in uncooked
edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and
in milk and eggs.
[42 FR 18614, Apr. 8, 1977]

§ 556.90 Buquinolate.
Tolerances are established for residues of buquinolate as follows:
(a) In edible tissues of chickens:
(1) 0.4 part per million in uncooked liver, kidney, and skin with fat.
(2) 0.1 part per million in uncooked muscle.
(b) In eggs:
(1) 0.5 part per million in uncooked yolk.
(2) 0.2 part per million in uncooked whole eggs.

§ 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.
Cattle, swine, poultry, and sheep: A tolerance for residues of ceftiofur in edible tissue is not required.

§ 556.115 Cepahpin.
A tolerance of 0.02 parts per million (ppm) is established for residues of cepahpin in the milk and 0.1 ppm in the uncooked edible tissues of dairy cattle.
[40 FR 57454, Dec. 10, 1975]

§ 556.120 Chlorhexidine.
A tolerance of zero is established for residues of chlorhexidine in the uncooked edible tissues of calves.

§ 556.140 Chlorobutanol.
A tolerance of zero is established for residues of chlorobutanol in milk from dairy animals.

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§ 556.150 Chlortetracycline.
Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, as follows:
(a) 2 parts per million (ppm) in muscle.
(b) 6 ppm in liver.
(c) 12 ppm in fat and kidney.
[61 FR 67453, Dec. 23, 1996]

§ 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.
Tolerances are established for residues of clorsulon in cattle as follows:
(a) The tolerance for clorsulon (marker residue) in kidney (target tissue) is 1.0 part per million. A marker residue of 1.0 part per million corresponds to a total residue of 3.0 parts per million in kidney.
(b) The safe concentrations for total clorsulon residues in uncooked edible cattle tissues are: muscle, 1.0 part per million; liver, 2.0 parts per million; kidney, 3.0 parts per million; and fat, 4.0 parts per million.
[50 FR 10221, Mar. 14, 1985]

§ 556.165 Cloxacillin.
A tolerance of 0.01 part per million is established for negligible residues of
§ 556.167  Colistimethate.

A tolerance for residues of colistimethate in the edible tissues of chickens is not required. [63 FR 13123, Mar. 18, 1998]

§ 556.170  Decoquinate.

Tolerances for residues of decoquinate in food are established as follows in uncooked edible tissues of chickens, cattle, and goats at 2 parts per million in tissues other than skeletal muscle and 1 part per million in skeletal muscle. [52 FR 43061, Nov. 9, 1987]

§ 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. § 556.200  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]

§ 556.220  3,5-Dinitrobenzamide.

No residues of 3,5-dinitrobenzamide may be found in the uncooked edible tissues of chickens as determined by the following method of analysis:

I. Method of analysis—3,5-dinitrobenzamide. A method for 3,5-dinitrobenzamide (3,5-DNBA) in chicken tissues is described with a cleanup step that removes most of the interfering materials, thus allowing uncompensated measurements to be read. The 3,5-DNBA is extracted from the sample with acetone and chloroform and prepared for chromatography by removing the aqueous phase in a separatory funnel and the solvents in a flash evaporator. The extract residue is chromatographed on alumina to remove several lipid components and residues of other drugs. The benzamide eluate is passed through a column of Dowex-50 resin, or equivalent, to remove arylamines; for example, 3-amino-5-nitrobenzamide. The 3,5-DNBA fraction is reduced, after removal of alcohol, with TiCl₃ in basic solution to an arylamine, presumably 3,5-diaminobenzamide. The reduced fraction is placed on another Dowex-50 column, most of the interfering substances are removed with washings of alcohol and water, and the arylamine residue is eluted with 4N HCl. Colorimetric measurement is made in a 100-millimeter cell at 530 millimicrons after reacting the residue with Bratton-Marshall reagents.

II. Reagents. A. Acetone.

B. Acetyl-(p-nitrophenyl)-sulfanilamide (APNPS) standard—melting point range 264° C.±267° C. Weigh and transfer 10 milligrams of APNPS to a 100-milliliter flask, dissolve and dilute to volume with acetone.

C. Alumina—activated F-20, 80-200 mesh, Aluminum Co. of America, or equivalent substance.

D. Ammonium sulfamate.

E. Ammonium sulfamate solution 1.25 grams of ammonium sulfamate per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.

F. Cation-exchange resin—Dowex 50W-X8, 200-400 mesh, Baker Analyzed Reagent, or equivalent, prepared as follows:

1. Place 500 grams of resin into a 3-liter beaker.

2. Add 2,000 milligrams of 6N HCl.

3. Heat and stir while on a bath at 80° C. for 6 hours. Discontinue heating and continue stirring overnight.

4. Filter the resin on a Buchner funnel (24 cm.) fitted with Whatman No. 1 paper.

5. Wash the resin bed with four 500-milliliter portions of 6N HCl.

6. Wash the resin bed with 500-milliliter portions of deionized water until the effluent has a pH of 5 or higher.

7. Wash the resin bed with three 400-milliliter portions of specially denatured alcohol 3A. Drain thoroughly.

8. Make a slurry of resin in 1,250 milliliters of specially denatured alcohol 3A.


H. Coupling reagent—0.25 gram of N-1-naphthyl-ethylenediamine dihydrochloride per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.

I. 3,5-Dinitrobenzamide (3,5-DNBA standard). Add to boiling specially denatured alcohol 3A until a saturated solution is obtained and treat with activated carbon, filtered and crystallized by cooling to room temperature. The 3,5-DNBA therefrom is treated a second time with activated carbon and then recrystallized three more times from specially denatured alcohol 3A. The third crystallization is washed with diethyl ether and dried in a vacuum desiccator, melting point range 185° C.±186° C.

J. Ethyl alcohol—absolute, A.C.S.

K. Eluting reagent A. The formula and volume required in procedure step V-D is dependent on the adsorptive strength of the Al₂

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O₃. For each lot Al₂O₃, make the following test:

1. Prepare a column (see procedure step V-D for determining formula and volume to eluting reagent A).
2. Transfer 1 milliliter of APNPS standard (100 micrograms per milliliter) in 75 milliliters of chloroform to the column.
3. Wash the column with 100 milliliters of chloroform and discard the eluate.
4. Pass through 100 milliliters of solution consisting of specially denatured alcohol 3A and ethyl alcohol 1:1 (volume to volume). Collect one 50-milliliter and five 10-milliliter portions; these make up the first, second, third, fourth, fifth, and sixth portions of eluate.
5. Place in beakers under a stream of air on a water bath (90°C) until the solvents are evaporated.
6. Add 10 milliliters of 4N HCl to each, cover with watch glasses and heat (90°C) for 30 minutes; cool to room temperature.
7. Add the Bratton-Marshall reagents.
8. All fractions show a slight color. Note the portion containing the first significant increase in pink color.
   a. If the color increases in the second, third, or fourth portions of eluate, the formula in procedure step V-D is suitable and, depending on the portion, 45, 55, or 65 milliliters, respectively, should be used in procedure step V-D4. Thereby, the APNPS is retained on the column and the benzamides are eluted.
   b. If the color increases in the first portion, the eluting strength of the reagent is too strong. Return the test, substituting 1:4 (volume to volume) in procedure step V-D4. If 1:4 (volume to volume) is too strong, rerun the test, substituting in procedure step V-D4, respectively, 41 (volume to volume), specially denatured alcohol 3A; methyl alcohol, 41 (volume to volume), until a suitable formula is found. If none of these are suitable, another lot of Al₂O₃ should be used.
   c. If the color increases in the fifth or sixth portion, the eluting strength of the reagent is too weak. Rerun the test, substituting in procedure step V-D4, respectively, 41 (volume to volume), specially denatured alcohol 3A; methyl alcohol, 41 (volume to volume), until a suitable formula is found. If none of these are suitable, another lot of Al₂O₃ should be used.

L. Hydrochloric acid, 4N. Add two volumes of water to one volume of HCl.
M. Diatomaceous earth—Hyflo Super Cel, Johns-Manville Co., or equivalent substance.
N. N-1-Naphthylethylenediamine dihydrochloride.
O. Sodium hydroxide solution, 10N. Dissolve 100 grams of sodium hydroxide in water and dilute to 25 milliliters.
P. Sodium nitrite solution—0.25 grams of sodium nitrite per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.
Q. Specially denatured alcohol, formula 3A–100 parts of 190-proof ethyl alcohol plus 5 parts of commercial methyl alcohol.
R. Titanium(ous) chloride—20 percent solution.

III. Special apparatus. A. Absorption cells—Beckman No. 75195 matched set of two cylindrical silica cells with 100 millimeter optical length, or equivalent cells.
B. Autotransformer—type 500B, or equivalent. To regulate speed of mixer.
C. Centrifuge.
D. Centrifuge tubes—50-milliliter size with glass stopper.
E. Chromatography tubes—Corning No. 30460, 20 millimeters A 400 millimeters and having a tapered 29/42 joint with coarse, fritted disc, or equivalent tubes.
F. Evaporator—vacuum, rotary, thin film.
H. Glycerol manostat. For regulating pressure on columns: To Al₂O₃ columns, 15-inch head pressure; to ion-exchange columns, 35-inch head pressure.
I. Motor speed control. For regulating speed on 1-quart blender.
J. Volumetric flasks—50 milliliter size, actinic ware.
L. One-quart blender.
M. Water bath (45°C–50°C).
N. Water bath (90°C).
IV. Standard curve. A. 1. Weigh 100 milligrams of 3,5-DNBA and transfer to a 1-liter volumetric flask with acetone.
   2. Dissolve and dilute with acetone to volume.
   3. Dilute 1 milliliter to 100 milliliters.
   4. Add 5.0 milliliters of water to each of six centrifuge tubes.
   5. Add standard to each of the tubes to contain one of the following amounts: 0.0, 1.0, 2.0, 3.0, 5.0, and 10.0 micrograms of 3,5-DNBA.
B. Prepare each tube for colorimetric measurement as follows:
   1. Place the tube in a hot water bath (90°C) until 5.0 milliliters remain. Cool to room temperature.
   2. While mixing on Vortex mixer, or equivalent, regulated with an autotransformer, add 2 drops of TiCl₃ and 4 drops of 10N NaOH. Continue mixing until chalky-white in appearance.
   3. Add 2 milliliters of HCl, mix, and allow to stand for 5 minutes.
   4. Transfer to 50-milliliter volumetric flask and dilute with 4N HCl to 40-45 milliliters.
   5. Cool to 0°C–5°C by placing in a freezer or ice bath.
   6. Perform the Bratton-Marshall reaction in subdued light as follows:
a. Add 1 milliliter of sodium nitrite reagent, mix, and allow to stand for 1 minute.
b. Add 1 milliliter of ammonium sulfamate reagent, mix, and allow to stand for 1 minute.
c. Add 1 milliliter of coupling reagent, mix, and allow to stand for 10 minutes.
d. Dilute to volume with 4N HCl.

C. Perform colorimetric measurement at 530 millimicrons as follows:
1. Fill two matched 100-millimeter cells with 4N HCl and place into spectrophotometer.
2. Adjust dark current.
3. Adjust to zero absorbance.
4. Replace acid in cell of sample side of compartment with standard to be measured.
5. The standard curve should be run five different times. Plot equivalent concentration in tissue versus mean absorbance at each concentration. If computer is available, a better procedure is to calculate the equation of the standard curve by means of least squares.

V. Procedure. A. Extraction. 1. Mince 350 grams of tissue in a 1-quart blending jar for 3 minutes. Use samples obtained from either freshly killed or quickly frozen birds. The latter should be analyzed as soon as thawed. For fibrous meats (for example, muscle, skin) put through a meat grinder before mincing.
2. Weight 100±0.5 grams of each replicate sample in a 150-milliliter beaker. Analyze each sample in triplicate and average the results. Reproducibility of ±10 percent between such analyses has been obtained.
3. Transfer the sample to a 1-quart blender jar. For kidney and liver tissues, make a slurry with acetone in the weighing beaker. Transfer with several rinses of acetone.
4. Blend the sample for 5 minutes with 250 milliliters of acetone and a 100-milliliter beakerful of diatomaceous earth.
5. Filter through a Buchner funnel containing a wetted Whatman No. 5 filter paper (12.5 cm.) into a 1-liter suction flask.
6. Rinse the blender jar into the funnel with three 25-milliliter portions of acetone.
7. Transfer the pulp and paper from the funnel to the aforementioned blender jar.
8. Add 250 milliliters of chloroform.
9. Blend for 3 minutes.
10. Filter through the aforementioned apparatus of procedure step V-A3. For rapid filtration of skin and blood samples, prepare funnel by adding diatomaceous earth and tamping evenly over paper to a thickness of 3 to 5 millimeters.
11. Rinse the blender jar into the funnel with three 25-milliliter portions of chloroform.
12. Phasic separation. 1. Pour the combined filtrates into a 1-liter separatory funnel.
2. Rinse the suction flask twice with 25 milliliters of chloroform.
3. Mix the funnel contents by gently rocking and swirling for 30 seconds.
4. Let stand 10 minutes to allow phases to separate.
5. Withdraw the lower phase into a 1-liter round-bottom flask, and discard upper phase. Withdraw nearly all of the lower phase, let stand for 2 to 3 minutes, then withdraw the remainder.
C. Evaporation. Attach the flask on a thin-film rotary evaporator connected to a vacuum supply, and place in a water bath maintained at 45° C.±50° C., until an oily residue remains. Do not overheat the sample or allow to go to dryness.
D. Adsorption chromatography. 1. Prepare a chromatography column using a column with calibrated etchings to indicate appropriate adsorbent and solvent levels as follows:
  a. Fill tube to a depth of 60 millimeters with Al2O3.
  b. Tap walls gently with hands.
  c. Add anhydrous sodium sulfate to an additional depth of 25 millimeters.
  d. Wet and wash column with 50 milliliters of chloroform.
  i. During chromatography, make each addition to the tube when the liquid level has reached the top of the sodium sulfate layer.
  ii. Increase the percolation rates by applying a slight air pressure to the top of the column.
  2. Transfer the residue from procedure step V-C to the column with four 15-milliliter rinses of chloroform. Then rinse the walls of the tube and sodium sulfate layer with three 5-milliliter portions of chloroform. Percolation rate: 15 to 25 milliliters per minute. No color from sample should be seen in sodium sulfate layer after final rinse.
  3. Wash column with 100 milliliters of chloroform. Discard eluate.
  4. Add 75 milliliters of eluting reagent A and collect eluate A in a 250-milliliter beaker for cation-exchange chromatography.
  a. Refer to “Eluting reagent A” under “Reagents” (II-K) for determining formula and volume.
  b. Percolation rate: 8 to 12 milliliters per minute.
E. Cation-exchange chromatography—No. 1. 1. Prepare an ion-exchange column as follows:
  a. Add a uniform slurry of resin to the column to obtain a 4 to 5 centimeter bed depth after settling.
  b. Obtain a uniform slurry using a magnetic stirrer. To add the required amount of resin, calibrate the slurry and transfer it with a 10-milliliter pipette to deliver a reproducible volume.

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i. Increase the flow rate to 2 to 4 milliliters per minute by applying air pressure to the column. A glycerol manostat adjusted to 30 inches and attached between an air supply and column provides adequate pressure.

b. Wash the resin with 10 milliliters of eluting reagent A. Discard eluate.

2. Pass eluate A from procedure step V-D4 through the column. Collect in a 250-milliliter beaker.

3. Pass 50 milliliters of specially denatured alcohol 3A through the column. Combine with the eluate of procedure step V-E2.

F. Reduction. 1. Place the eluate A fraction from procedure step V-E3 on a hot water bath (90°C) and evaporate with a stream of air until 5 to 10 milliliters remain. Do not overheat the sample or allow the sample to go to dryness.

2. Transfer to centrifuge tube and rinse beaker three times with 3 milliliters of specially denatured alcohol 3A.

3. Evaporate on a hot water bath (90°C) under a stream of air until alcohol has evaporated. Do not overheat the sample or allow the sample to go to dryness.

4. Remove the tube from the water bath and immediately add 5.0 milliliters of water.

5. While mixing, add 2 drops of titanium chloride and 4 drops of 10N sodium hydroxide. Continue mixing until greyish color disappears.

a. Mix on Vortex Jr. mixer, or equivalent, regulated with autotransformer.

b. Precipitate of insoluble tissue substances and white titanium salts is present after reduction is complete.

6. Dilute to 50 milliliters with specially denatured alcohol 3A.

7. Centrifuge for 5 minutes at 2,000 r.p.m.

G. Cation-exchange chromatography—No. 2. 1. Prepare resin column by procedure step V-E.

2. Pass the centrifugate of procedure step V-F7 through column. Use three rinses of specially denatured alcohol 3A, each 5 milliliters, to aid in transferring of sample.

3. Pass 50 milliliters of specially denatured alcohol 3A through the column.

4. Pass 50 milliliters of deionized water through the column.

5. Elute arylamine residue from the resin with 40 to 43 milliliters of 4N HCl into a 50-milliliter volumetric flask (actinic ware) for 3,5-DNBA analysis. Avoid direct sunlight. The arylamine has been found to be photosensitive.

H. Color development and measurement. 1. Cool to 0°C ± 5°C by placing in a freezer or ice bath.

2. Perform the Bratton-Marshall reaction in subdued light as follows:

   a. Add 1 milliliter of sodium nitrite reagent, mix, and allow to stand for 1 minute.

   b. Add 1 milliliter of ammonium sulfamate reagent, mix, and allow to stand for 1 minute.

   c. Add 1 milliliter of coupling reagent, mix, and allow to stand for 10 minutes.

   d. Dilute to volume with 4N HCl.

   3. Perform colorimetric measurement at 530 millimicrons as follows:

      a. Fill two matched 100-millimeter cells with 4N HCl and place into instrument.

      b. Adjust dark current.

      c. Adjust to zero absorbance.

      d. Replace acid in cell of sample side of compartment with sample to be measured.

      e. Record absorbance observed.

   i. Calculations. Determine parts per billion (observed) from the standard curve.

§ 556.225 Doramectin

A tolerance of 0.1 part per million (ppm) is established for parent doramectin (marker residue) in liver (target tissue) of cattle and 0.16 ppm in liver of swine.


§ 556.227 Eprinomectin

Tolerances are established for residues of eprinomectin B1a (marker residue) in milk of 12 parts per billion and in liver (target tissue) of 4.8 parts per million.


§ 556.228 Enrofloxacin

A tolerance of 0.3 part per million is established for residues of enrofloxacin (marker residue) in muscle (target tissue) of chickens and turkeys.

[61 FR 56893, Nov. 5, 1996]

§ 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) In uncooked edible tissues of lambs:
(1) 120 parts per trillion for muscle.
(2) 600 parts per trillion for fat, kidney, and liver.

§ 556.260 Ethopabate.
Tolerance for residues of ethopabate converted to metaphenetidine are established in the edible tissues of chicks as follows:
(a) 1.5 parts per million in uncooked liver and kidney.
(b) 0.5 part per million in uncooked muscle.

§ 556.270 Ethylenediamine.
A tolerance of zero is established for residues of ethylenediamine in milk.

§ 556.273 Famphur.
Tolerances are established for residues of famphur including its oxygen analog in or on meat, fat, or meat by-products of cattle at 0.1 part per million.

§ 556.275 Fenbendazole.
(a) Cattle and goats. A tolerance \(^1\) of 0.8 part per million is established for parent fenbendazole (the marker residue) in the liver of cattle and goats.
(b) Swine. A tolerance \(^1\) for marker residues of fenbendazole in swine is not needed.
(c) Cattle milk. A safe concentration of 1.67 parts per million is established for total fenbendazole residues. A tolerance of 0.6 part per million is established based on the fenbendazole sulf oxide metabolite (marker residue).

\(^1\) 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.

§ 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 confirmatory 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,
§ 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.

§ 556.310 Haloxon.

A tolerance of 0.1 part per million is established for negligible residues of haloxon (3-chloro-1-hydroxy-4-methylcoumarin bis(2-chloroethyl) phosphate) in the edible tissues of cattle.

§ 556.320 Hydrocortisone.

A tolerance is established for negligible residues of hydrocortisone (as hydrocortisone sodium succinate or hydrocortisone acetate) in milk at 10 parts per billion.

§ 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.

The marker residue used to monitor the total residues of ivermectin and its metabolites in American bison is 22,23-dihydroavermectin B\(_1\). The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B\(_1\) in liver as follows:

(a) Cattle: 100 parts per billion.
(b) Swine: 20 parts per billion.
(c) Sheep: 30 parts per billion.
(d) Reindeer: 15 parts per billion.
(e) American bison: 15 parts per billion.

§ 556.347 Lasalocid.

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.

(a) Chickens. The marker residue selected to monitor for total residues of lasalocid in chickens is parent lasalocid. The target tissue is skin with adhering fat. A tolerance for the marker is established in chickens of 0.3 part per million for parent lasalocid in skin with adhering fat. A marker residue concentration of 0.3 part per million in skin with adhering fat corresponds to a concentration for total residues of lasalocid of 7.2 parts per million in liver. The safe concentrations for total residues of lasalocid in the uncooked edible tissues of chickens are 1.2 parts per million in muscle, 2.4 parts per million in skin with adhering fat, and 7.2 parts per million in liver.

(b) Cattle. The marker residue selected to monitor for total residues of lasalocid sodium in cattle is parent lasalocid and the target tissue selected is liver. A tolerance is established in cattle of 0.7 part per million for parent lasalocid in liver. A marker residue concentration of 0.7 part per million in liver corresponds to a concentration for total residues of lasalocid of 4.8 parts per million in liver. The safe concentrations for total residues of lasalocid in the uncooked edible tissues of swine and poultry.
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§ 556.426 Moxidectin.

An acceptable daily intake (ADI) of 4 micrograms per kilogram per day in

§ 556.390 Methylparaben.

A tolerance of zero is established for residues of methylparaben in milk from dairy animals.

§ 556.400 Methylprednisolone.

A tolerance is established for negligible residues of methylprednisolone in milk at 10 parts per billion.

§ 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) Cattle and goats. A tolerance of 0.05 part per million is established for negligible residues of monensin in the edible tissues of cattle and goats.

(b) Chickens, turkeys, and quail. A tolerance for marker residues of monensin in chickens, turkeys, and quail is not needed. The safe concentrations for total residues of monensin in chickens, turkeys, and quail are 1.5 parts per million in muscle, 3.0 parts per million in skin with adhering fat, and 4.5 parts per million in liver. Tolerance in this paragraph refers to the concentration of a marker residue in the target tissue selected to monitor for total residues of the drug in the target animals. Safe concentrations refers to the concentration of total residues considered safe in edible tissues.

§ 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.

§ 556.426 Moxidectin.

An acceptable daily intake (ADI) of 4 micrograms per kilogram per day in

§ 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) Swine. A tolerance of 0.1 part per million is established for negligible residues in the edible tissues.

(b) Chickens. A tolerance for residues of lincomycin in chickens is not required.

§ 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.

§ 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.

§ 556.390 Methylparaben.

A tolerance of zero is established for residues of methylparaben in milk from dairy animals.

§ 556.400 Methylprednisolone.

A tolerance is established for negligible residues of methylprednisolone in milk at 10 parts per billion.

§ 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) Cattle and goats. A tolerance of 0.05 part per million is established for negligible residues of monensin in the edible tissues of cattle and goats.

(b) Chickens, turkeys, and quail. A tolerance for marker residues of monensin in chickens, turkeys, and quail is not needed. The safe concentrations for total residues of monensin in chickens, turkeys, and quail are 1.5 parts per million in muscle, 3.0 parts per million in skin with adhering fat, and 4.5 parts per million in liver. Tolerance in this paragraph refers to the concentration of a marker residue in the target tissue selected to monitor for total residues of the drug in the target animals. Safe concentrations refers to the concentration of total residues considered safe in edible tissues.

§ 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.

§ 556.426 Moxidectin.

An acceptable daily intake (ADI) of 4 micrograms per kilogram per day in
§ 556.428 Narasin.
A tolerance for narasin residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 part per million in muscle; 1.8 parts per million in liver; 1.2 parts per million in skin with adhering fat and fat. A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals. A safe concentration refers to the total residue concentration considered safe in edible tissues.

§ 556.430 Neomycin.
A tolerance of 7.2 parts per million (ppm) is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue), 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk.

§ 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.

§ 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.

§ 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.

§ 556.480 Oleandomycin.
Tolerances are established for negligible residues of oleandomycin in uncooked edible tissues of chickens, turkeys, and swine at 0.15 part per million.

§ 556.490 Ormetoprim.
A tolerance of 0.1 part per million is established for negligible residues of ormetoprim in the edible tissues of chickens, turkeys, ducks, salmonids, and catfish.

§ 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.

§ 556.500 Oxytetracycline.
Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:
(a) 2 parts per million (ppm) in muscle.
(b) 6 ppm in liver.
(c) 12 ppm in fat and kidney.
§ 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]

§ 556.515 Pirlimycin.
A tolerance is established for residues of parent pirlimycin (marker substance) in cattle liver (target tissue) of 0.5 part per million and in milk of 0.4 part per million.
[58 FR 58486, Nov. 2, 1993]

§ 556.520 Prednisolone.
A tolerance of zero is established for residues of prednisolone in milk from dairy animals.

§ 556.530 Prednisone.
A tolerance of zero is established for residues of prednisone in milk from dairy animals.

§ 556.540 Progesterone.
No residues of progesterone are permitted in excess of the following increments above the concentrations of progesterone naturally present in untreated animals:
(a) In uncooked edible tissues of steers and calves:
   (1) 3 parts per billion for muscle.
   (2) 12 parts per billion for fat.
   (3) 9 parts per billion for kidney.
   (4) 6 parts per billion for liver.
(b) In uncooked edible tissues of lambs:
   (1) 3 parts per billion for muscle.
   (2) 15 parts per billion for fat, kidney, and liver.
[49 FR 13873, Apr. 9, 1984]

§ 556.550 Propylparaben.
A tolerance of zero is established for residues of propylparaben in milk from dairy animals.

§ 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.

§ 556.580 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.

§ 556.590 Salicylic acid.
A tolerance of zero is established for residues of salicylic acid in milk from dairy animals.

§ 556.594 Sarafloxacin.
A tolerance for residues of sarafloxacin in edible turkey and broiler chickens tissues is not required.
[60 FR 50098, Sept. 28, 1995]

§ 556.600 Spectinomycin.
A tolerance of 0.1 part per million is established for negligible residues of spectinomycin in the uncooked edible tissues of chickens and turkeys.
[61 FR 31028, June 19, 1996]

§ 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).
§ 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 Sulfachlorpyrazine.

A tolerance of 0.1 part per million is established for negligible residues of sulfachlorpyrazine in the uncooked edible tissues of calves and swine.

§ 556.640 Sulfadimethoxine.

Tolerances are established for residues of sulfadimethoxine in edible products of animals as follows:

(a) In the uncooked edible tissues of chickens, turkeys, cattle, ducks, salmonids, and catfish at 0.1 part per million (negligible residue).

(b) In milk at 0.01 part per million (negligible residue).


§ 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-[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.

§ 556.680 Sulfaquinoxaline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of calves, swine, sheep, chickens, and turkeys, as follows:

(a) 2 parts per million (ppm) in muscle.

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

§ 556.700 Sulfathiazole.

A tolerance of 0.1 part per million is established for negligible residues of sulfathiazole in the uncooked edible tissues of swine.

[61 FR 24443, May 15, 1996]

§ 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.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of calves, swine, sheep, chickens, and turkeys, as follows:

(a) 2 parts per million (ppm) in muscle.

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

[61 FR 67453, Dec. 23, 1996]
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§ 556.735 Tilmicosin.
A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) of cattle at 1.2 parts per million (ppm) and of swine at 7.5 ppm.

§ 556.738 Tiamulin.
A tolerance of 0.6 part per million is established for 8-alpha-hydroxymutilin (marker compound) in liver (target tissue) of swine.

§ 556.739 Trenbolone.
A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed. The safe concentration for total trenbolone residues in uncooked edible tissues of cattle is 50 parts per billion (ppb) in muscle, 100 ppb in liver, 150 ppb in kidney, and 200 ppb in fat. A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals. A safe concentration refers to the total residue concentration considered safe in edible tissues.

§ 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.

§ 556.750 Virginiamycin.
Tolerances are established for negligible residues of virginiamycin in edible tissues of swine as follows:

(a) Swine—
(1) 0.4 ppm in kidney, skin, and fat.
(2) 0.3 ppm in liver.
(3) 0.1 ppm in muscle.

(b) Broiler chickens—
(1) 0.5 ppm in kidney.
(2) 0.3 ppm in liver.
(3) 0.2 ppm in skin and fat.
(4) 0.1 ppm in muscle.

(c) Cattle. A tolerance for residues of virginiamycin in cattle is not required.

§ 556.760 Zeranol.

(a) Cattle. A tolerance for total zeranol residues in uncooked edible tissues of cattle is not needed. The safe concentration for total zeranol residues in uncooked edible tissues of cattle is 150 parts per billion (ppb) in muscle, 300 ppb in liver, 450 ppb in kidney, and 600 ppb in fat. A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animal. A safe concentration refers to the total residue concentration considered safe in edible tissues.

(b) Sheep. No residues of zeranol may be found in the uncooked edible tissues of sheep as determined by the following method of analysis:

I. Method of Analysis—Zeranol

A gas chromatographic method for the determination of the drug in frozen beef tissues is described. Tissue is frozen and stored in a deep freezer until ready for examination. A weighed portion of wet tissue (with exception of fat) is homogenized and lyophilized to dry solid. The drug is recovered from dry tissue by an extraction with methanol in a Soxhlet extractor. The methanol extract is
digested in the presence of hydrochloric acid to hydrolyze conjugates should any be present. Elimination of impurities is brought about by liquid partition transfer successively to chloroform to 1N sodium hydroxide, to carbon tetrachloride, to 1N sodium hydroxide, to ethyl ether, and, finally, to a dry residue. The residue is reacted with a silane mixture to create a volatile derivative which is quantitated by peak area measurements from a flame ionization detector. The drug can be detected at a level of 20 parts per billion with negligible interference from tissues or reagents.

II. REAGENTS
B. Chloroform, N.F., Fisher Scientific C-296, or equivalent.
C. Chromatograph gases, flow rates adjusted to maximize sensitivity for specific chromatograph.
   1. Carrier gas, conventional tank helium.
   2. Flame makeup gas.
      a. Oxygen, conventional tank oxygen.
      b. Hydrogen, Linde high purity, or equivalent.
   D. Column packing, 3 percent GE SE-52 (Applied Science Laboratories) on P.E. Celite 60-80 mesh (product No. 154-0048), or equivalent.
   E. Ether, anhydrous, Fisher Scientific E-138, or equivalent.
   F. Hexamethyldisilazane, Dow-Corning, or equivalent.
   G. Hydrochloric acid, analytical reagent grade.
   H. Methanol, certified A.C.S., Fisher Scientific A-408, or equivalent.
   I. Phosphoric acid, analytical reagent grade.
   J. Pyridine, anhydrous, A.C.S. reagent grade.
   K. Silating reagent mixture: Pipet 8 milliliters each of pyridine and hexamethyldisilazane and 4 milliliters of trimethylchlorosilane into a clean glass vial with a polyethylene cap and mix thoroughly. Let stand overnight and decant supernatant liquid into a vial. Cap and store at room temperature for daily use. If kept dry, the reagent is stable for more than a month. If kept dry, the reagent is stable for more than a month.
   L. Sodium chloride, analytical reagent grade.
   M. Sodium hydroxide, analytical reagent grade.
   N. Trimethylchlorosilane, Dow-Corning, Peninsular, or equivalent.
   O. Water, distilled in glass.
   P. Zeranol, primary standard.

Q. Solutions.
   1. 2N Hydrochloric acid in water.
   2. 3N Phosphoric acid in water.
   3. 2 percent w/v sodium chloride in water.
   4. 1N Sodium hydroxide in water.

III. APPARATUS
A. Extraction assemblies, Soxhlet, improved, standard taper grindings, Pyrex brand glass, 1,000 milliliters capacity, Sargent Catalog S-31265D, or equivalent.
B. Flasks, freeze drying, widemouth, 1,000 milliliters capacity, 29/40 standard taper grindings, Pyrex brand glass, Sargent Catalog S-28875-20-F, or equivalent.
C. Flasks, homogenizing, 250 milliliters, Sargent Catalog S-6716, or equivalent.
D. Funnels, separatory, Squibb stopper, with Teflon stopcock plug, Pyrex brand glass, 250- and 500-milliliter capacities, Sargent Catalog S-36815-20-F or G, or equivalent.
E. Gas chromatograph, F and M Model 5750 with flame ionization detector, or equivalent.
F. Gas chromatography column: Stainless steel tubing, 6 feet by 9/16 inch packed with 3 percent by weight GE SE-52 (Applied Science Laboratories) deposited on P.E. Celite 60-80 mesh (product No. 154-0048), or equivalent. Condition the column by baking for 40-80 hours at 325 °C with a helium flow, but detached from the detector input. Injections of 1-2 micrograms of a 50/50 mixture of hexamethyldisilazane and trimethylchlorosilane will help remove active sites in the column.
   1. Prepare a TMS derivative of a 1,000-microgram zeranol standard as described in the procedure section. Inject 1-microgram standards to determine whether the column is responding to the conditioning. After the column shows a response at the 1,000-microgram level, proceed to smaller quantities to determine whether the column is responding to the conditioning. After the column shows a response at the 1,000-microgram level, proceed to smaller quantities to optimize conditions.
   2. The column and chromatograph must be conditioned to achieve a minimum sensitivity response so that a peak 5 millimeters in height results from an injection of 5 microliter of standard preparation containing 1 microgram of zeranol in the derivative preparation. This criterion must be met before tissue assay is attempted.
   3. The column is brought to 250 °C after conditioning and held at that temperature for at least 12 hours before making a run.
G. Heating mantle, electric, Glas-Col, Sargent Catalog S-40866H, or equivalent.
H. Hot plate, with gradient rheostat heat control.
I. Meat grinder, manually operated or equivalent.
J. Steam bath.
K. Syringe, Hamilton Micro Syringe Model 701, 10-microliter capacity, or equivalent.
L. Torsion balance, 0.1 gram sensitivity, 500 grams capacity.
V. PROCEDURE

A. Preparation of glassware: Glassware should be washed in detergent or chrome acid solution to remove contaminants and rinsed in water to remove traces of cleaning agent. Rinse with methanol before using.

B. Preparation of sample.
1. Collect muscle, liver, kidney, and tripe from a freshly sacrificed animal under the cleanest conditions possible.
2. Grind the fresh tissue in a meat grinder, divide into 100-gram portions, and wrap in aluminum foil. Store wrapped tissue in a deep freeze. Fat should be wrapped in foil and stored in a deep freeze.
3. Weigh 100 grams of partially thawed tissue into a 250-milliliter homogenizing flask, and add 60 milliliters of water, and attach to a Virtis ‘45’ Tissue Mill, or equivalent.
4. Place the flask on its side in a nearly horizontal position in a slurry of dry ice and acetone. Rotate the flask on its side as the homogenate cools to set down a uniform frozen solid layer on the wall of the flask.
5. Mount the flask on a Virtis freeze drier, or equivalent, and lyophilize to dry solids. This operation usually requires 20-24 hours. Stopping place.
6. Transfer the solid cake to a clean sheet of paper and dry by hand to a size convenient for transfer to an extraction thimble.
7. Transfer the solids to a single thickness 60 x 180 millimeter Soxhlet extraction thimble and compact the solids sufficiently to guarantee complete immersion during solid extraction.
8. Transfer 600 milliliters of methanol to a 1-liter pot of a Soxhlet extraction assembly and place the thimble in the extractor. Mount a large glass funnel in the neck of the extractor with the stem extending into the thimble. Rinse the 1-liter freeze drying flask with three 50-milliliter portions of fresh methanol and transfer the rinses through the funnel into the thimble. Mount the condenser in the extractor and extract the solids for 15 hours. The extractor should be heated with the electric heating mantle so that a fill-empty cycle requires 18-24 minutes.
9. Drain the methanol from the thimble. Composite the methanol from the extractor and pot in an 800-milliliter beaker.
10. Rinse the pot with 10 milliliters of methanol and add to the methanol composite. Transfer 50 milliliters of solution A to a 1-dram glass vial, evaporate to a dry residue in a vacuum desiccator at reduced pressure. The residue contains 2 micrograms of zeranol to be used as a calibration standard in operation of the gas chromatograph.

E. Solvent partition.
1. Transfer the methanol concentrate to a 500-milliliter separatory funnel, identified by number as 1, with 70 milliliters of chloroform rinse and mix.
2. Add 300 milliliters of water and without shaking allow liquid phases to separate.
3. Withdraw the chloroform layer into a separatory funnel, identified by number as 2,
§ 556.760
containing 100 milliliters of 2 percent aqueous sodium chloride.
4. Gently mix the contents of funnel 2 horizontally and end to end 30 times and allow phases to separate. Usually about 20 minutes are required to obtain maximum chloroform separation.
5. Withdraw the chloroform layer into a beaker.
6. Extract with shaking the contents of funnels 1 and 2 successively with three more 50-milliliter portions of chloroform.
7. Composite the chloroform extracts and concentrate to 125 milliliters by evaporation on a steam bath and cool to room temperature.
8. Transfer the chloroform composite to a 250-milliliter separatory funnel, fitted with a Teflon stopcock, using 10 milliliters of chloroform as a rinse.
9. Extract the chloroform with three separate 20-milliliter portions of 1N sodium hydroxide solution retaining the emulsion in the sodium hydroxide phase. Agitation of sodium hydroxide with the chloroform extract for the first time is accompanied by the appearance of emulsion.
10. Perform an extraction by gently inverting the closed funnel and returning the funnel to an upright position.
11. Repeat phase mixing 30 times per extraction.
12. Allow phases to separate for 10 minutes. The time delay allows for gradual dissipation of the emulsion to improve phase separation. The zeranol transfers from the chloroform to the upper sodium hydroxide phase in this operation.
13. Composite the sodium hydroxide extracts.
14. Wash the sodium hydroxide extract with three separate 50-milliliter portions of chloroform using the technique as in step 9 and the same 10-minute interval for phase separation. Washing the chloroform removes the emulsion and unwanted impurities from the sodium hydroxide phase.
15. Discard the chloroform washes. Transfer the sodium hydroxide extracts to a 250-milliliter beaker. Rinse each separatory funnel with two 5-milliliter portions of water and add to the sodium hydroxide extract. Wash each funnel twice with tap water and twice with distilled water before next use.
16. Neutralize the washed sodium hydroxide extract to pH 8.0 by dropwise addition of 3N phosphoric acid using a pH meter for pH detection.
17. Transfer the pH 8.0 water extract to a 250-milliliter separatory funnel using 10 to 20 milliliters of water for a rinse.
18. Extract the solution with three separate 50-milliliter portions of carbon tetrachloride. The zeranol transfers to the lower carbon tetrachloride phase. Use the same 30-count phase-mixing technique as in step 9 and allow the mixture to stand 5 minutes for phase separation.
19. Composite the carbon tetrachloride extracts.
20. Extract the carbon tetrachloride composite with two 20-milliliter portions of 1N sodium hydroxide. Zeranol transfers from carbon tetrachloride to the upper sodium hydroxide phase. After phase mixing, allow the mixture to stand 5 minutes for phase separation.
21. Composite the sodium hydroxide extracts.
22. Wash the extract with two 50-milliliter portions of carbon tetrachloride. Allow the mixture to stand 5 minutes for phase separation. Discard the carbon tetrachloride washes.
23. Transfer the sodium hydroxide extract into a 250-milliliter beaker. Rinse the separatory funnel with two 5-milliliter portions of water and add to the sodium hydroxide extract. Wash each funnel twice with tap water and twice with distilled water before next use. Adjust the sodium hydroxide extract to a pH of 9.5 by dropwise addition of 3N phosphoric acid and transfer to a 250-milliliter separatory funnel using 10-20 milliliters of water for a rinse.
24. Extract the pH 9.5 water solution with three separate 30-milliliter portions of anhydrous ethyl ether. Allow the mixture to stand 5 minutes for phase separation. The zeranol transfers to the upper ether phase.
25. Composite the ether extracts into a 125-milliliter Erlenmeyer flask.
26. Reduce the volume of ether to about 1-2 milliliters by evaporation on a hot plate with low heat while removing vapor from top of flask by vacuum aspiration.
27. Transfer ether residue to a 1-dram glass vial. Rinse down flask side wall with 1-2 milliliters of fresh ether and transfer to the glass vial.
28. Continue evaporation of ether to 0.1 milliliter.
29. Place vial in a vacuum desiccator and evaporate residue at line vacuum and room temperature overnight to dryness.
F. Gas liquid chromatography.
1. Start the gas chromatography and maintain the following operational conditions: Carrier gas pressure: 50 p.s.i. at tank. Carrier gas flow rate: Sufficient to give zeranol derivative peak a retention time of 4-8 minutes. Electrometer range: 102 or 101. Carrier temperature: 325 °C. Detector temperature: 325 °C. Column temperature: 250-280 °C. Operate isothermally. Recorder sensitivity: 1 millivolt. Recorder chart speed: 1 inch per minute.
Sample size: 1 microliter to 5 microliters as necessary to give desired peak area for quantitative measurement.

Septums: Replace each evening and allow to condition overnight at operational temperature.

Flame assembly: Remove silica ash from the flame assembly each week. The flame assembly is removed; the anode, flame jet, and chimney are cleaned with a nylon bristle brush. Water and acetone are drawn through the jet capillary to remove any foreign material.

2. Add 0.2 milliliter of silating reagent to the sample or to the zeranol standard.

3. Stopper the vial and shake vigorously.

4. Warm the vial at 40±50°C for a few minutes, then roll the vial on a horizontal plane to insure that all of the interior surfaces of the vial have been in contact with the reagent.

5. Let vial stand for 4 hours or overnight in a warm area (40°C) to allow reaction to reach completion.

6. Place vial in a small padded centrifuge tube and centrifuge to settle the precipitate and insure that all the liquid is at the bottom of the vial.

7. Inject 1.0±5.0 microliters of clear solution into the chromatograph. At the beginning of the day’s run, make 3±5 injections of a standard to condition the column for that day before taking quantitative data.

8. Run known mixtures at the beginning, middle, and end of the day’s run over the concentration range of samples to be analyzed to compensate for day-to-day sensitivity fluctuations and drift. If four or less samples are to be run, calibrating at the beginning and end of the run is sufficient.

VII. RECOVERY STUDY

A. Fortification of reagent blank.

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with zeranol should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of the standard zeranol. Level of recovery should be in the same range as the samples.

2. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate.

3. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate. Spike the concentrate with 1.0 milliliter of stock solution D.

4. Assay both samples as described in the procedure beginning extraction step V-E1.

B. Fortification of samples.

1. Transfer 100-gram portions of partially thawed tissues into 250-milliliter homogenizing flasks and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution D to serve as fortified samples to which 20 parts per billion zearalanol have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with V-C1.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989]
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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 species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved or are regulated on a “no-residue” basis or with a “zero” tolerance because of a carcinogenic concern regardless whether a withdrawal period is required.

(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(a) 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 I, Type A medicated article is exempt from the requirement of an approved medicated feed application. The manufacture of a Type B medicated feed from a Type C medicated feed from a Category II, Type A medicated article requires an application approved under §514.105(b) 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 an application approved under §514.105(b) 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(a) of this chapter.


§ 558.4 Medicated feed applications.

(a) The manufacture of a Type B or Type C medicated feed from a Category I, Type A medicated article is exempt from the requirement of an approved medicated feed application.

(b) The manufacture of a Type B or Type C medicated feed from a Category II, Type A medicated article requires an approved medicated feed application.

(c) The use of Type B and Type C medicated feeds shall conform to the conditions of use provided for in subpart B of this part and in §§510.515 and 558.15.

(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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Assay limits percent (^1) type A</th>
<th>Type B maximum (200x)</th>
<th>Assay limits percent (^1) type B/C (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aklomide</td>
<td>90–110</td>
<td>22.76 g/lb (5.0%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Amprolium with Ethopabate</td>
<td>94–114</td>
<td>22.76 g/lb (5.0%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Bacitracin methylene disalicylate</td>
<td>85–115</td>
<td>25.0 g/lb (5.5%)</td>
<td>80–120/130.</td>
</tr>
<tr>
<td>Bacitracin zinc</td>
<td>90–110</td>
<td>5.0 g/lb (1.1%)</td>
<td>70–130.</td>
</tr>
<tr>
<td>Bambergamins</td>
<td>90–110</td>
<td>800 g/ton (0.09%)</td>
<td>80–120/70/130.</td>
</tr>
<tr>
<td>Busamolute</td>
<td>90–110</td>
<td>9.8 g/lb (2.2%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Chlorotetracycline</td>
<td>90–115</td>
<td>40.0 g/lb (8.8%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Coumaphos</td>
<td>95–115</td>
<td>6.0 g/lb (1.3%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Decoquinate</td>
<td>90–105</td>
<td>2.72 g/lb (0.6%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Dichlorvos</td>
<td>90–115</td>
<td>3.33 g/lb (0.7%)</td>
<td>90–120/80/130.</td>
</tr>
<tr>
<td>Eflornitromycin</td>
<td>94–113</td>
<td>1.45 g/lb (0.32%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Erythromycin (thiocyanate salt)</td>
<td>85–115</td>
<td>9.25 g/lb (0.24%)</td>
<td>&lt;20 g/ton 70–115/150</td>
</tr>
</tbody>
</table>

\(^1\) Type A or B/C, \(^2\) Type C.
### CATEGORY I—Continued

<table>
<thead>
<tr>
<th>Drug</th>
<th>Assay limits percent (^1) Type A</th>
<th>Type B maximum (20x)</th>
<th>Assay limits percent (^1) Type B/C (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodinated casein</td>
<td>85-115</td>
<td>20.0 g/lb (4.4%)</td>
<td>75-125.</td>
</tr>
<tr>
<td>Lasalocid</td>
<td>90-110</td>
<td>40.0 g/lb (8.8%)</td>
<td>Type B (cattle and sheep): 80-120; Type C (all): 75-125.</td>
</tr>
<tr>
<td>Lincomycin</td>
<td>90-115</td>
<td>20.0 g/lb (4.4%)</td>
<td>80-130.</td>
</tr>
<tr>
<td>Melengestrol acetate</td>
<td>90-110</td>
<td>10.0 g/ton (0.0011%)</td>
<td>70-120.</td>
</tr>
<tr>
<td>Monensin</td>
<td>90-110</td>
<td>40.0 g/lb (8.8%)</td>
<td>Chickens, turkeys, and quail: 75-125; Cattle: 5-10 g/ton 80-120; Goats: 20 g/ton 85-115; Liq. feed: 80-120.</td>
</tr>
<tr>
<td>Nitromide</td>
<td>90-110</td>
<td>11.35 g/lb (2.5%)</td>
<td>85±115/80±120.</td>
</tr>
<tr>
<td>Nicarbazin (powder)</td>
<td>98±106</td>
<td>5.675 g/lb (1.25%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Neomycin</td>
<td>90-110</td>
<td>7.0 g/lb (1.54%)</td>
<td>70-120.</td>
</tr>
<tr>
<td>Maduramicin ammonium</td>
<td>90-110</td>
<td>545 g/ton (.06%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Levamisole</td>
<td>85-120</td>
<td>11.4 g/lb (2.5%)</td>
<td>90±115.</td>
</tr>
<tr>
<td>Poloxalene</td>
<td>90-110</td>
<td>11.35 g/lb (2.5%)</td>
<td>85±115/80±120.</td>
</tr>
<tr>
<td>Nequinate</td>
<td>90-110</td>
<td>7.2 g/lb (1.6%)</td>
<td>85±115/75-125.</td>
</tr>
<tr>
<td>Neocarbazole</td>
<td>90-110</td>
<td>5.675 g/lb (1.25%)</td>
<td>85±115/80±120.</td>
</tr>
<tr>
<td>Narasin</td>
<td>90-110</td>
<td>7.2 g/lb (1.6%)</td>
<td>85±115/75-125.</td>
</tr>
<tr>
<td>Narasin (powder)</td>
<td>98±106</td>
<td>5.675 g/lb (1.25%)</td>
<td>85±115/80±120.</td>
</tr>
<tr>
<td>Narasin (granular)</td>
<td>90-110</td>
<td>5.675 g/lb (1.25%)</td>
<td>85±115/80±120.</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>90-110</td>
<td>11.25 g/lb (2.5%)</td>
<td>85±115/70-130; 11.25 g/ton 75-125.</td>
</tr>
<tr>
<td>Salinomycin</td>
<td>90-110</td>
<td>6.0 g/lb (1.3%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Semduramicin</td>
<td>90-110</td>
<td>2.25 g/lb (0.50%)</td>
<td>80±110.</td>
</tr>
<tr>
<td>Tiamulin</td>
<td>113.4 g/lb, 120±125</td>
<td>3.5 g/lb (0.8%)</td>
<td>90±115.</td>
</tr>
<tr>
<td>5 and 10 g/ lb.</td>
<td>100-108</td>
<td>5 and 10 g/ lb.</td>
<td>70-130.</td>
</tr>
<tr>
<td>Tylosin</td>
<td>85-115</td>
<td>10.0 g/lb (2.2%)</td>
<td>75-125.</td>
</tr>
<tr>
<td>Virginiamycin</td>
<td>85-115</td>
<td>10.0 g/lb (2.2%)</td>
<td>70-130.</td>
</tr>
<tr>
<td>Zolecine</td>
<td>90-104</td>
<td>10.35 g/lb (2.5%)</td>
<td>85±115.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90-110</td>
<td>2.276 g/lb (0.5%)</td>
<td>85±120.</td>
</tr>
</tbody>
</table>

\(^1\) 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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Assay limits percent (^1) Type A</th>
<th>Type B maximum (100x)</th>
<th>Assay limits percent (^1) Type B/C (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amprolium</td>
<td>94-114</td>
<td>11.35 g/lb (2.5%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Apramycin</td>
<td>88-112</td>
<td>7.5 g/lb (1.65%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Arsanilate sodium</td>
<td>90-100</td>
<td>4.5 g/lb (1.0%)</td>
<td>85±115/75±125.</td>
</tr>
<tr>
<td>Arsanic acid</td>
<td>90-100</td>
<td>4.5 g/lb (1.0%)</td>
<td>85±115/75±125.</td>
</tr>
<tr>
<td>Carbarsone</td>
<td>90-100</td>
<td>2.5 g/lb (0.55%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Clopidol</td>
<td>93-102</td>
<td>17.0 g/lb (3.74%)</td>
<td>85±115.</td>
</tr>
<tr>
<td>Fenbendazole</td>
<td>93-113</td>
<td>8.87 g/lb (1.96%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Halotrunooydrobromide</td>
<td>90-115</td>
<td>272.0 g/ton (0.3%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Hygromycin B</td>
<td>90-110</td>
<td>1.200 g/ton (0.13%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>95-105</td>
<td>1.180 g/ton (0.13%)</td>
<td>80±110.</td>
</tr>
<tr>
<td>Levamisole</td>
<td>85-120</td>
<td>113.0 g/lb (25%)</td>
<td>85±125.</td>
</tr>
<tr>
<td>Maduramicin ammonium</td>
<td>90-110</td>
<td>545 g/ton (.06%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Morantel tartrate</td>
<td>90-110</td>
<td>66.0 g/lb (14.52%)</td>
<td>85±115.</td>
</tr>
<tr>
<td>Neomycin</td>
<td>80-120</td>
<td>7.0 g/lb (1.54%)</td>
<td>70±125.</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>80-120</td>
<td>10.0 g/lb (2.2%)</td>
<td>65±135.</td>
</tr>
<tr>
<td>Nicarbazol (granular)</td>
<td>90-110</td>
<td>5.675 g/lb (1.25%)</td>
<td>85±115/75-125.</td>
</tr>
<tr>
<td>Narasin</td>
<td>90-110</td>
<td>5.675 g/lb (1.25%)</td>
<td>85±115/75-125.</td>
</tr>
<tr>
<td>Nitrazosine</td>
<td>90-110</td>
<td>8.5 g/lb (1.87%)</td>
<td>85±120.</td>
</tr>
<tr>
<td>Nitroicide</td>
<td>90-115</td>
<td>11.35 g/lb (2.5%)</td>
<td>80±120.</td>
</tr>
<tr>
<td>Sulfintrin</td>
<td>85-115</td>
<td>13.6 g/lb (3.0%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Nitroside</td>
<td>90-110</td>
<td>11.35 g/lb (2.5%)</td>
<td>85±115.</td>
</tr>
<tr>
<td>Sulfintrin</td>
<td>85-115</td>
<td>5.65 g/lb (1.24%)</td>
<td>75±125.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90-110</td>
<td>2.276 g/lb (0.5%)</td>
<td>85±120.</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS

CATEGORY II—Continued

<table>
<thead>
<tr>
<th>Drug</th>
<th>Assay limits percent (^1) Type A</th>
<th>Type B maximum (100x)</th>
<th>Assay limits percent (^1) Type B/C (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novobiocin</td>
<td>85–115</td>
<td>17.5 g/lb (3.85%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Pyrantel tartrate</td>
<td>90–110</td>
<td>36 g/lb (7.9%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Robenidine</td>
<td>95–115</td>
<td>1.5 g/lb (0.33%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Ronnel</td>
<td>85–115</td>
<td>27.2 g/lb (6.0%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.275 g/lb (0.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.275 g/lb (0.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Akloamide</td>
<td>90–110</td>
<td>11.35 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.275 g/lb (0.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Clopidol</td>
<td>94–106</td>
<td>11.35 g/lb (2.5%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Basitracin methylene disalicylato</td>
<td>85–115</td>
<td>5.0 g/lb (1.1%)</td>
<td>70–130.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.275 g/lb (0.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Monensin</td>
<td>90–110</td>
<td>5.5 g/lb (1.2%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Sulfadimethoxine</td>
<td>95–115</td>
<td>5.675 g/lb (1.25%)</td>
<td>85–115/75–125.</td>
</tr>
<tr>
<td>Ormetoprim (5/3)</td>
<td>95–115</td>
<td>3.405 g/lb (0.75%)</td>
<td>85–115.</td>
</tr>
<tr>
<td>Sulfadimethoxine</td>
<td>95–115</td>
<td>85.1 g/lb (18.75%)</td>
<td>85–115/75–125.</td>
</tr>
<tr>
<td>Ormetoprim (5/1)</td>
<td>95–115</td>
<td>17.0 g/lb (3.75%)</td>
<td>85–115.</td>
</tr>
<tr>
<td>Sulfanitran</td>
<td>85–115</td>
<td>18.6 g/lb (4.0%)</td>
<td>85–115.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>80–120.</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Chlorotetrazycline</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Penicillin</td>
<td>85–115</td>
<td>5.0 g/lb (1.1%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–125/70–130.</td>
</tr>
<tr>
<td>Tylosin</td>
<td>80–120</td>
<td>10.0 g/lb (2.2%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Sulfanitran</td>
<td>85–115</td>
<td>13.6 g/lb (3.0%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Akloamide</td>
<td>90–110</td>
<td>11.2 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Akloamide</td>
<td>90–110</td>
<td>11.2 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.716 g/lb (6.0%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Sulfanitran</td>
<td>85–115</td>
<td>13.6 g/lb (3.0%)</td>
<td>75–125.</td>
</tr>
<tr>
<td>Akloamide</td>
<td>90–110</td>
<td>11.2 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Roxarsone</td>
<td>90–110</td>
<td>2.275 g/lb (0.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>85–115</td>
<td>11.2 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Sulfamerazine</td>
<td>90–110</td>
<td>11.2 g/lb (2.5%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>85–115</td>
<td>10.0 g/lb (2.2%)</td>
<td>85–120.</td>
</tr>
<tr>
<td>Chlorotetrazycline</td>
<td>85–125</td>
<td>10.0 g/lb (2.2%)</td>
<td>70–130.</td>
</tr>
<tr>
<td>Penicillin</td>
<td>80–120</td>
<td>5.0 g/lb (1.1%)</td>
<td>70–130.</td>
</tr>
<tr>
<td>Thiamphenicol</td>
<td>94–106</td>
<td>45.4 g/lb (10.0%)</td>
<td>7–8% 85–115; &lt;7% 90–110.</td>
</tr>
<tr>
<td>Timicosin</td>
<td>90–110</td>
<td>18.2 g/lb (4.0%)</td>
<td>85–115.</td>
</tr>
</tbody>
</table>

\(^1\) 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 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 in the Finding Aids section of this volume.

§558.5 New animal drug requirements for liquid Type B feeds.

(a) Information available to the Commissioner of Food and Drugs shows that certain drugs are unstable when added to some liquid Type B medicated feeds. The demonstrated instability of these drugs gives rise to the question of the stability of other drugs when added to liquid Type B medicated feeds, except where specific approval has been granted for such use. Therefore, the labeling of a drug to provide for its use in a liquid Type B medicated feed causes the drug to be a new animal drug for such use for which an approved new animal drug application is required pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act.

(b) The addition of a drug to a liquid Type B medicated feed causes such Type B feed to become an animal feed bearing or containing a new animal
§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 18, 1975, or by December 4, 1975, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofuran, and sulfonamide drugs pursuant to section 512(1) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 18, 1975, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1975; and for the nitrofuran drugs by March 4, 1976. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1975, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella
reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofuran, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofuran, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements of this section: Provided, That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

<table>
<thead>
<tr>
<th>Drug sponsor</th>
<th>Type A article</th>
<th>Species</th>
<th>Use levels</th>
<th>Indications for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitman-Moore, Inc.</td>
<td>Bacitracin zinc</td>
<td>Chickens, turkeys, swine, pheasants, quail, and cattle.</td>
<td>Sec. 558.78</td>
<td>Sec. 558.78</td>
</tr>
<tr>
<td>A.L. Laboratories, Inc</td>
<td>do</td>
<td>Chickens, turkeys, pheasants, and quail.</td>
<td>do</td>
<td>Do</td>
</tr>
<tr>
<td>Elanco Products Co</td>
<td>Hygromycin B</td>
<td>Chickens and swine.</td>
<td>Sec. 558.274</td>
<td>Sec. 558.274</td>
</tr>
<tr>
<td>Do</td>
<td>Tylosin</td>
<td>Chickens, swine, and beef cattle.</td>
<td>Sec. 558.625</td>
<td>Sec. 558.625</td>
</tr>
</tbody>
</table>
(2) The following is a list of drug combinations permitted when prepared from antibacterial Type A articles listed in paragraph (g)(1) of this section. Drug combinations listed in subpart B of this part name their sponsors and are incorporated herein by reference since they are safe and effective by contemporary standards, or such sponsors have been notified of any additional safety or efficacy data required on an individual basis:

<table>
<thead>
<tr>
<th>Drug sponsor</th>
<th>Type A article</th>
<th>Species</th>
<th>Use levels</th>
<th>Indications for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fermenta Animal Health Co.</td>
<td>Chlortetracycline and arsanilic acid.</td>
<td>Swine</td>
<td>10 to 50 g/ton and 0.005 to 0.01 percent.</td>
<td>Enhancement of growth and feed efficiency.</td>
</tr>
<tr>
<td>American Cyanamid Co.</td>
<td>Chlortetracycline and sulfamethazine.</td>
<td>Cattle</td>
<td>Sec. 558.128</td>
<td>Sec. 558.128.</td>
</tr>
<tr>
<td>Pfizer, Inc., PennField Oil Co., and VPO, Inc.</td>
<td>Oxytetracycline and neomycin.</td>
<td>Swine</td>
<td>As provided in paragraph (g)(2) of this section.</td>
<td>As provided in paragraph (g)(2) of this section.</td>
</tr>
<tr>
<td>Do</td>
<td>Chlortetracycline, sulfathiazole, and penicillin.</td>
<td></td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Chlortetracycline, sulfathiazole, and penicillin.</td>
<td></td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td></td>
<td></td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Drug sponsor</td>
<td>Type A article</td>
<td>Species</td>
<td>Use levels</td>
<td>Indications for use</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
<td>---------------</td>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Do</td>
<td>......do</td>
<td>chickens</td>
<td>......do</td>
<td>To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at time of stress. As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of bluecomb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>......do</td>
<td>Turkeys</td>
<td>50 g/ton and 35 to 140 g/ton.</td>
<td>Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>......do</td>
<td>Turkeys</td>
<td>50 g/ton and 35 to 140 g/ton.</td>
<td>As an aid in the prevention of disease from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>......do</td>
<td>Turkeys</td>
<td>50 to 100 g/ton and 35 to 140 g/ton.</td>
<td>To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality prevention of hexamitiasis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Drug sponsor</td>
<td>Type A article</td>
<td>Species</td>
<td>Use levels</td>
<td>Indications for use</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------</td>
<td>---------</td>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>Turkeys (first 4 weeks)</td>
<td>.....do .......</td>
<td>As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>100 to 150 g/ton and 35 to 100 g/ton.</td>
<td>As an aid in reducing mortality in birds which have suffered an attack of airsacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>Turkeys</td>
<td>.....do .......</td>
<td>As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>100 to 200 g/ton and 35 to 140 g/ton.</td>
<td>Control of bluecomb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>200 g/ton and 70 to 140 g/ton.</td>
<td>Control of infectious synovitis. For the treatment of bacterial enteritis and bluecomb (mud fever or nonspecific enteritis).</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>Swine</td>
<td>50 g/ton and 35 to 140 g/ton.</td>
<td>As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery, and salmonellosis (necrotic enteritis).</td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>50 to 150 g/ton and 70 to 140 g/ton.</td>
<td>As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>Calves</td>
<td>50 g/ton and 35 to 140 g/ton.</td>
<td>As an aid in the prevention of bacterial enteritis (scours).</td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>100 g/ton and 70 to 140 g/ton.</td>
<td>As an aid in the treatment of bacterial enteritis (scours).</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>8 to 100 mg/gal and 100 to 200 mg/gal reconstituted milk replacer.</td>
<td>As an aid in the prevention of bacterial diarrhea (scours).</td>
<td></td>
</tr>
<tr>
<td>Do</td>
<td>.....do .......</td>
<td>40 to 200 mg/gal and 200 to 400 mg/gal reconstituted milk replacer.</td>
<td>As an aid in the treatment of bacterial diarrhea (scours).</td>
<td></td>
</tr>
</tbody>
</table>

The Upjohn Co. Lincomycin, amprolium, and ethopabate. | Chickens | Secs. 558.58 and 558.325.
Do Lincomycin and zoalene... | Secs. 558.325 and 558.680.
Do Lincomycin, amprolium, ethopabate, and roxarsone. | Secs. 558.58, 558.325, and 558.530. | Secs. 558.58 and 558.325.
<table>
<thead>
<tr>
<th>Drug sponsor</th>
<th>Type A article</th>
<th>Species</th>
<th>Use levels</th>
<th>Indications for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>Lincomycin, monensin, and roxarsone.</td>
<td>Chickens</td>
<td>0.01 to 0.02 percent and 2.4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Nicarbazin and procaine penicillin.</td>
<td>Chickens</td>
<td>0.01 to 0.02 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Nicarbazin and bacitracin methylene disalicylate.</td>
<td>Chickens</td>
<td>0.01 to 0.02 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Nicarbazin, procaine penicillin, and roxarsone.</td>
<td></td>
<td>0.01 to 0.02 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Nicarbazin and bacitracin methylene disalicylate.</td>
<td>Chickens and turkeys.</td>
<td>0.0125 to 0.025 percent and 4 to 50 g/ton.</td>
<td>Secs. 558.55 and 558.76.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium and bacitracin methylene disalicylate.</td>
<td>Chickens and turkeys.</td>
<td>0.0125 to 0.025 percent, 0.0004 percent, and 4 to 50 g/ton.</td>
<td>Secs. 558.58 and 558.76.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, ethopabate, and bacitracin methylene disalicylate.</td>
<td>Chickens</td>
<td>0.0125 to 0.025 percent, 0.0004 percent, and 4 to 50 g/ton.</td>
<td>Secs. 558.58, 558.76, and 558.530.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone.</td>
<td>Chickens and turkeys.</td>
<td>0.004 to 0.025 percent and 2.4 to 50 g/ton.</td>
<td>Secs. 558.55 and 558.460.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, procaine penicillin, and roxarsone.</td>
<td>Chickens</td>
<td>0.004 to 0.025 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.</td>
<td>Secs. 558.55, 558.460, and 558.530.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, ethopabate, procaine penicillin, and erythromycin.</td>
<td></td>
<td>0.0125 to 0.025 percent, 2.4 to 50 g/ton, and 4.6 to 18.5 g/ton.</td>
<td>Secs. 558.58 and 558.460.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium and erythromycin.</td>
<td></td>
<td>0.0125 to 0.025 percent and 4.6 to 18.5 g/ton.</td>
<td>Secs. 558.55.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium and ethopabate.</td>
<td></td>
<td>0.0125 to 0.025 percent and 0.0004 percent.</td>
<td>Secs. 558.58.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, arsanic acid, and erythromycin.</td>
<td></td>
<td>0.0125 to 0.025 percent, 0.01 percent, and 4.6 to 18.5 g/ton.</td>
<td>Secs. 558.55.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, arsanic acid, and ethopabate.</td>
<td></td>
<td>0.0125 to 0.025 percent, 0.01 percent, and 0.0004 percent.</td>
<td>Secs. 558.58.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, ethopabate, and bacitracin methylene disalicylate.</td>
<td></td>
<td>0.0125 percent, 0.004 percent, and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone.</td>
<td></td>
<td>0.0125 percent, 0.004 percent, 5 to 35 g/ton, and 0.00375 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Drug sponsor</td>
<td>Type A article</td>
<td>Species</td>
<td>Use levels</td>
<td>Indications for use</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pitman-Moore, Inc.</td>
<td>Bacitracin zinc, amprolium, and ethopabate.</td>
<td>Chicken</td>
<td>4 to 50 g/ton, 0.0125 to 0.025 percent, and 0.0004 percent.</td>
<td>Prevention of coccidiosis.</td>
</tr>
<tr>
<td>Do</td>
<td>Bacitracin zinc, amprolium, ethopabate, and roxarsone.</td>
<td>Chicken</td>
<td>4 to 50 g/ton, 0.0125 to 0.025 percent, 0.0004 percent, and 0.0025 to 0.005 percent.</td>
<td>Prevention of coccidiosis. Growth promotion and feed efficiency.</td>
</tr>
<tr>
<td>Do</td>
<td>Bacitracin zinc and arsanic acid.</td>
<td>Swine</td>
<td>10 to 50 g/ton and 0.005 to 0.01 percent.</td>
<td>Increased rate of weight gain and improved feed efficiency.</td>
</tr>
<tr>
<td>Merck Sharp &amp; Dohme Research Labs</td>
<td>Amprolium, ethopabate, procaine penicillin, and roxarsone.</td>
<td>Chickens</td>
<td>0.125 to 0.025 percent, 0.0004 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.</td>
<td>Secs. 558.58, 558.460 and 558.530.</td>
</tr>
<tr>
<td>A. L. Laboratories, Inc.</td>
<td>Zoalene and bacitracin methylene disalicylate.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Sec. 558.680.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, roxarsone, and bacitracin methylene disalicylate.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene and bacitracin zinc.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, roxarsone, and bacitracin zinc.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene and penicillin.</td>
<td>Chicken</td>
<td>0.0025 to 0.005 percent, and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, roxarsone, and penicillin.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, arsanic acid, and bacitracin methylene disalicylate or bacitracin zinc.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, arsanic acid, and penicillin.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, and bacitracin methylene disalicylate.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Do</td>
<td>Zoalene, and bacitracin methylene disalicylate.</td>
<td>Chicken</td>
<td>0.0125 percent and 4 to 50 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>Whitmoyer Labs, Inc</td>
<td>Carbarsone and bacitracin.</td>
<td>Turkey</td>
<td>Sec. 558.120</td>
<td>Sec. 558.120.</td>
</tr>
<tr>
<td>Elianco Products Co.</td>
<td>Hygromycin B and tylosin.</td>
<td>Chicken</td>
<td>8 to 12 g/ton and 4 to 50 g/ton.</td>
<td>Sec. 558.274.</td>
</tr>
<tr>
<td>Do</td>
<td>Swine</td>
<td>Swine</td>
<td>12 g/ton and 10 to 100 g/ton.</td>
<td>Do.</td>
</tr>
<tr>
<td>A. L. Laboratories, Inc.</td>
<td>Nitarosone and bacitracin zinc.</td>
<td>Turkey</td>
<td>0.01975 percent, and 4 to 50 g/ton.</td>
<td>As an aid in the prevention of blackhead. To increase rate of weight gain and improve feed efficiency.</td>
</tr>
</tbody>
</table>
Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.35 Akloamide.

(a) Approvals. Type A medicated articles: to 053501 in § 510.600(c) of this chapter, as follows:
(1) 50 percent aklomide.
(2) 20 percent sulfanitran and 25 percent aklomide.
(3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.
(4) 50 percent aklomide and 10 percent roxarsone.

(b) Related tolerances. See § 556.30 of this chapter.

(c) Conditions of use. It is used in feed for chickens as follows:

(i) Indications for use. As an aid in the prevention of coccidiosis caused by E. tenella and E. necatrix.

(ii) Limitations. Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(2) Amount per ton. Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent).

(i) Indications for use. As an aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, and E. acervulina.

(ii) Limitations. Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium.

(3) Amount per ton. Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent) + roxarsone, 22.7-45.4 grams (0.0025-0.005 percent).

(i) Indications for use. As an aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, and E. acervulina; growth promotion and feed efficiency; improving pigmentation.

(ii) Limitations. Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium.

(4) Amount per ton. Aklomide, 227 grams (0.025 percent) combined with roxarsone, 22.7-45.4 grams (0.0025-0.005 percent).

(i) Indications for use. As an aid in the prevention of coccidiosis caused by E. tenella, and E. necatrix; growth promotion and feed efficiency; improving pigmentation.

(ii) Limitations. Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.


§ 558.55 Amprolium.

(a) Approvals. Type A medicated articles: 25 percent to 050604 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) Calves. It is top-dressed on or thoroughly mixed in the daily feed ration as follows:

(i) Amount. 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria bovis and E. zurnii.

(b) Limitations. Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(ii) Amount. 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

(a) Indications for use. As an aid in the treatment of coccidiosis caused by Eimeria bovis and E. zurnii.

(b) Limitations. Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment;
§ 558.55

(2) Chickens and turkeys. It is used as follows:

<table>
<thead>
<tr>
<th>Amprolium in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 36.3 to 113.5 (0.004% to 0.0125%)</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis.</td>
<td>Feed as follows—</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Growing conditions</th>
<th>Up to 5 weeks of age</th>
<th>From 5 to 8 weeks of age</th>
<th>Over 8 weeks of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amprolium grams per ton</td>
<td>Amprolium grams per ton</td>
<td>Amprolium grams per ton</td>
<td></td>
</tr>
<tr>
<td>Severe exposure to coccidiosis.</td>
<td>113.5 (0.0125%)</td>
<td>72.6–113.5 (0.008%–0.0125%)</td>
<td>36.3–113.5 (0.004%–0.0125%)</td>
</tr>
<tr>
<td>Moderate exposure to coccidiosis.</td>
<td>72.6–113.5 (0.008%–0.0125%)</td>
<td>54.5–113.5 (0.006%–0.0125%)</td>
<td>36.3–113.5 (0.004%–0.0125%)</td>
</tr>
<tr>
<td>Slight exposure to coccidiosis.</td>
<td>36.3–113.5 (0.004%–0.0125%)</td>
<td>36.3–113.5 (0.004%–0.0125%)</td>
<td>36.3–113.5 (0.004%–0.0125%)</td>
</tr>
</tbody>
</table>

Arsanilate sodium 90 (0.01%).
Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.
Withdraw 5 d before slaughter; as sole source of arsenic; feed according to subtable in item (i).

Arsanlic acid 90 (0.01%).
Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.
Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).

Arsanlic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.
Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.
Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).

Arsanlic acid 90 (0.01%) plus erythromycin 92.5.
1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.
Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).

Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).

Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).
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<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration</th>
<th>Use</th>
<th>Duration and Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsanilic acid 90</td>
<td>0.01% to 0.004%</td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Bacitracin 100 to 200</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).</td>
<td>As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Chlortetracycline 100 to 200</td>
<td></td>
<td>Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by <em>Mycoplasma synoviae</em> susceptible to chlorotetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400</td>
<td></td>
<td>Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <em>M. gallisepticum</em> and <em>E. coli</em> susceptible to chlorotetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
</tr>
<tr>
<td>Erythromycin 4.6 to 18.5</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.</td>
<td>Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Erythromycin 92.5</td>
<td></td>
<td>Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by <em>Mycoplasma synoviae</em> susceptible to chlorotetracycline.</td>
<td>Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Erythromycin 185</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.</td>
<td>Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Hygromycin B 8 to 12</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Penicillin 2.4 to 50</td>
<td></td>
<td>Replacement chickens; development of active immunity to coccidiosis; control of infestations of large round worms (<em>Ascaris galli</em>), cecal worms (<em>Heterakis gallinae</em>), and capillary worms (<em>Capillaria obignata</em>).</td>
<td>Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Roxarsone 22.7 to 45.4</td>
<td>0.005% to 0.0025%</td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.</td>
<td>As procaine penicillin. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Broiler chickens; prevention of coccidiosis caused by <em>Eimeria tenella</em> only.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).</td>
</tr>
<tr>
<td>Drug</td>
<td>Indications</td>
<td>Adverse Effects</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Arsanilate sodium 90</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanic acid 90</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As bacitracin methylene disalicylate, or zinc bacitracin.</td>
<td></td>
</tr>
<tr>
<td>Bacitracin 100 to 200</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; treatment of chronic respiratory disease (air-sac infection) and blue comb (non-specific infectious enteritis).</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
<td></td>
</tr>
<tr>
<td>Chlortetracycline 100</td>
<td>Chickens; prevention of coccidiosis caused by E. tenella only; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.</td>
<td></td>
</tr>
<tr>
<td>Chlortetracycline 200</td>
<td>Chickens; prevention of coccidiosis caused by E. tenella only; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>Feed according to subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Hygromycin B 8 to 12</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; control of infection of large round worms (Heterakis gallinae), and capillary worms (Capillaria obsignata).</td>
<td>As procaine penicillin.</td>
<td></td>
</tr>
<tr>
<td>Penicillin 2.4 to 50</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; growth promotion and feed efficiency.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Roxarsone 22.7 to 45.4</td>
<td>Broiler chickens; prevention of coccidiosis caused by E. tenella only; growth promotion and feed efficiency; improving pigmentation.</td>
<td>For moderate outbreaks of coccidiosis; administer for 2 weeks.</td>
<td></td>
</tr>
<tr>
<td>Bambermycins 1 to 3</td>
<td>Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.</td>
<td>Feed continuously as the sole source of amprolium and organic arsenic; roxarsone as provided by No. 053501 in §510.600(c) of this chapter, bambermycins by No. 012799; withdraw 5 d before slaughter.</td>
<td></td>
</tr>
<tr>
<td>Bambermycins 1 to 4</td>
<td>Growing turkeys; prevention of coccidiosis; increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously as the sole source of amprolium; bambermycins as provided by No. 012799 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>(iii) 113.5 (0.0125%)</td>
<td>1. Laying chickens; prevention of coccidiosis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Laying chickens; treatment of coccidiosis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bambermycins 1 to 4</td>
<td>Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.</td>
<td>Feed continuously as the sole source of amprolium; bambermycins as provided by No. 012799 in §510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>(iv) 113.5 to 227</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(iv) 113.5 to 227</td>
<td>2. Turkeys; prevention of coccidiosis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arsanilate sodium 90 (0.01%)</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%)</td>
<td>2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>do</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 92.5</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 185</td>
<td>2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.</td>
<td>Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5</td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Bacitracin 4 to 50</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.</td>
<td>do</td>
<td></td>
</tr>
</tbody>
</table>

Bacitracin 4 to 50 ... 1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. As bacitracin methylene dicalcylate or bacitracin zinc.
<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Dosage</th>
<th>Indications</th>
</tr>
</thead>
</table>
| Bacitracin 100 to 200 | 1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (non-specific infectious enteritis).  
2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (non-specific infectious enteritis). | As bacitracin zinc |
| Bacitracin 100 to 500 | Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever). | Feed contains 50% to 75% of bacitracin but not more than 125 g penicillin; as procaine penicillin; as bacitracin zinc. |
| Bacitracin plus penicillin 100 to 500 (of combination) | ...do | Feed continuously 2 weeks before coccidiosis and blackhead are expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; carbarsone by 046573 in § 510.600(c) of this chapter. |
| Carbarsone 227 to 340.5 | Turkeys; aid in prevention of coccidiosis (Eimeria adenoeides, E. meleagrimitis, and E. gallopavonis) and blackhead. | Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. |
| Chlortetracycline 100 to 200 | Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline. | Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d. |
| Chlortetracycline 200 to 400 | Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline. | Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d. |
| Erythromycin 4.6 to 18.5 | Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. | As erythromycin thiocyanate. |
| Erythromycin 92.5 | 1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.  
2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza. | Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.  
Feed for 7 to 14 d; withdraw 24 h before slaughter. |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Use</th>
<th>Conditions of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin 185</td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.</td>
<td>Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.</td>
</tr>
<tr>
<td>Hygromycin B 8 to 12</td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms (Heterakis gallinae) and capillary worms (Capillaria obignata).</td>
<td>Feed according to suitable in item (i).</td>
</tr>
<tr>
<td>Penicillin 2.4 to 50</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. &lt;br&gt;2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.</td>
<td>As procaine penicillin. ........do ........................................</td>
</tr>
<tr>
<td>Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).</td>
<td>1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. &lt;br&gt;2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic. ....do ........................................</td>
</tr>
<tr>
<td>(v) 227 (0.025%)</td>
<td>Laying chickens; treatment of coccidiosis.</td>
<td>For severe outbreaks of coccidiosis; administer for 2 weeks. ....do ........................................</td>
</tr>
</tbody>
</table>

(3) Pheasants. It is used as follows:

(i) Amount. 0.0175 percent (159 grams per ton).

(ii) Indications for use. For the prevention of coccidiosis in growing pheasants caused by Eimeria colchici, E. duodenalis, and E. phasiani.

(iii) Limitations. Feed continuously as sole ration. Use as sole source of amprolium. Fertility, hatchability, and other reproductive data are not available on amprolium in breeding pheasants. Do not use in feeds containing bentonite.

[41 FR 10985, Mar. 15, 1976]

**Editorial Note:** For Federal Register citations affecting §558.55, see the List of CFR Sections Affected in the Finding Aids section of this volume.

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§ 558.58 Amprolium and ethopabate.

(a) Approvals. Type A medicated articles: (1) 25 percent amprolium and 0.8 percent ethopabate; 25 percent amprolium and 8 percent ethopabate; 5 percent amprolium and 0.16 percent ethopabate; 5 percent amprolium and 1.6 percent ethopabate; to 000000. <br>2. 0.15 percent amprolium and 0.004 percent ethopabate and 0.05 gram per pound bacitracin (as bacitracin methylene disalicylate) to 047019 in §510.600(c) of this chapter.

(b) Special considerations. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) Related tolerances. See §§556.50 and 556.260 of this chapter.

(d) Conditions of use. (1) It is used for chickens as follows:
### § 558.58

<table>
<thead>
<tr>
<th>Amprolium and ethopabate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).</td>
<td>Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).</td>
<td>Broiler chickens as an aid in the prevention of coccidiosis.</td>
<td>Not for laying hens; as sole source of amprolium.</td>
<td>Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone by No. 046573, bambermycins by No. 012799; withdraw 5 d before slaughter.</td>
</tr>
<tr>
<td>(ii) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).</td>
<td>Lincomycin 2 to 4 plus roxarsone 45.4 (0.005%).</td>
<td>Broiler chickens; for increased rate of weight gain; improved feed efficiency and pigmentation.</td>
<td>Not for laying hens; as sole source of amprolium and organic arsenic; as provided by No. 050604.</td>
<td>Not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.</td>
</tr>
<tr>
<td></td>
<td>Roxarsone 45.4 (0.005 ppt).</td>
<td>Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <em>Eimeria acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur.</td>
<td>Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.</td>
<td>Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combinations as provided by No. 050604.</td>
</tr>
<tr>
<td>(iii) Amprolium 113.5 (0.0125%) and ethopabate 36.3 (0.004%).</td>
<td>Arsanilic acid 90 (0.01 ppt) plus erythromycin 4.6 to 18.5.</td>
<td>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 <em>Eimeria acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur.</td>
<td>Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thioceyanate.</td>
<td>Not for chickens over 16 weeks of age; do not feed to laying hens; as sole source of organic arsenic; as erythromycin thioceyanate.</td>
</tr>
<tr>
<td></td>
<td>Bacitracin 4 to 50 plus methylene disalicylate</td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.</td>
<td>Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thioceyanate.</td>
<td>Not for chickens over 16 weeks of age; do not feed to laying hens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by No. 050604 in § 510.600(c) of this chapter.</td>
</tr>
</tbody>
</table>
Amprolium and ethopabate in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor
---|---|---|---|---
| | | 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; improved feed efficiency. | 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 Nos. 000004 and 046573 in §510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until market weight; combination as provided by Nos. 000004 and 046573. | 000004 and 046573
| Bacitracin 5 to 35 plus roxarsone 34 (0.00375%). | Broiler chickens; for increased rate of weight gain and as an aid in the prevention of coccidiosis from *Eimeria acervulina*, *E. maxima*, and *E. brunetti* is likely to occur in broiler chickens raised in floor pens. | Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by Nos. 000004 and 046573 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter; combination as provided by No. 050604 in §510.600(c) of this chapter. | 000004 and 046573
| Bacitracin 20 to 35 plus roxarsone 34 (0.00375%). | Broiler chickens; for increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis from *Eimeria acervulina*, *E. maxima*, and *E. brunetti* is likely to occur in broiler chickens raised in floor pens. | Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter; combination as provided by No. 050604 in §510.600(c) of this chapter. | 000004 and 046573

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<table>
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<tr>
<th>Amprolium and ethopabate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
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<tbody>
<tr>
<td>Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%).</td>
<td>Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <em>Eimeria</em> acervulina, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur; improved feed efficiency.</td>
<td>Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin zinc as provided by Nos. 000004 and 046573 roxarsone as provided by No. 046573 combination as provided by Nos. 000004 and 046573.</td>
<td>000004, 046573</td>
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<td>Bacitracin 10 plus roxarsone 30 to 45.4 (0.0033% to 0.005%).</td>
<td>Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <em>Eimeria</em> acervulina, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur; improved feed efficiency and improved pigmentation.</td>
<td>Feed continuously as the sole ration; as sole source of amprolium, amprolium, withdrawal 5 d before slaughter; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter.</td>
<td>00004</td>
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<td>Bambermycins 1 to 3.</td>
<td>Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <em>Eimeria</em> acervulina, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur; for increased rate of weight gain, and improved feed efficiency.</td>
<td>Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter. bambermycins as provided by No. 012799. Withdraw 5 days before slaughter.</td>
<td>000069</td>
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<td>Erythromycin 4.6 to 18.5.</td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.</td>
<td>Not for laying hens; withdraw 24 hours before slaughter; erythromycin thioycanate.</td>
<td>000069</td>
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<td>Virginiamycin, 15 ....</td>
<td>Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <em>Eimeria</em> acervulina, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur, for increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously as sole ration, do not feed to laying hens, not for chickens over 16 weeks of age, as sole source of amprolium, amprolium and ethopabate as provided by 050604 in §510.600(c), virginiamycin as provided by 000069.</td>
<td>000069</td>
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<td>Virginiamycin, 5 to 15.</td>
<td>Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <em>Eimeria</em> acervulina, <em>E. maxima</em>, and <em>E. brunetti</em> is likely to occur, for increased rate of weight gain.</td>
<td>Not for laying hens.</td>
<td>000069</td>
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<td>(iv) Amprolium 113.5 to 227 (0.0125% to 0.025%) and ethopabate 3.6 (0.0004%).</td>
<td>For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.</td>
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<tr>
<td>Amprolium and ethopabate in grams per ton</td>
<td>Combination in grams per ton</td>
<td>Indications for use</td>
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<td>Arsanilic acid 90 (0.01%)</td>
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<td>infectious enteritis).</td>
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</table>
§ 558.59 Apramycin.

(a) Approvals. Type A articles to sponsors identified in §510.600(c) of this chapter as follows:

<table>
<thead>
<tr>
<th>Amprolium and ethopabate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlortetracycline 200 to 400.</td>
<td></td>
<td>For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and airsac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.</td>
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<tr>
<td>Erythromycin 92.5</td>
<td></td>
<td>1. For broiler chickens and for replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.</td>
<td>Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.</td>
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<tr>
<td>Erythromycin 185</td>
<td></td>
<td>2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.</td>
<td>Feed for 7 to 14 d; withdraw 24 h before slaughter; not for laying hens.</td>
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<tr>
<td>Penicillin 2.4 to 50</td>
<td></td>
<td>For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Not for laying hens; as procaine penicillin.</td>
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<tr>
<td>Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).</td>
<td></td>
<td>Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.</td>
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<tr>
<td>(v) Amprolium 136.2 (0.015%) and ethopabate 3.6 (0.0004%).</td>
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<td>Broiler chickens; as an aid in the prevention of coccidiosis; growth promotion and feed efficiency.</td>
<td>Feed as sole ration; use as sole source of amprolium; do not feed to laying hens; as bacitracin methylene disalicylate.</td>
<td>047019</td>
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</tbody>
</table>

(b) Related tolerances. See §556.52 of this chapter.

(c) Conditions of use—(1) Swine—(i) Amount. 150 grams per ton. (ii) Indications for use. For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of Escherichia coli. (iii) Limitations. Use for 14 days. Withdraw 28 days before slaughter. (2) [Reserved]

[51 FR 9190, Mar. 18, 1986]

(2) [Reserved]
§ 558.60 Arsanilate sodium.

(a) Approvals. Type A medicated articles: 20, 50, or 100 percent to 015565 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.60 of this chapter.

(c) Conditions of use. (1) It is used for chickens and turkeys as follows:
   (i) Grams per ton. 90 (0.01 percent).
   (ii) Indications for use. For growth promotion and feed efficiency; improving pigmentation.
   (iii) Limitations. Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Arsanilate sodium may be used in accordance with the provisions of this section in the combinations provided as follows:
   (i) Amprolium in accordance with §558.55.

§ 558.62 Arsanilic acid.

(a) Approvals. Type A medicated articles to sponsors in §510.600(c) of this chapter as follows:

(1) To 015565: 20, 50, and 100 percent for use as in the table in paragraph (c)(1), entry (ii), item 1; entry (ii), item 2; entry (iii); entry (iv); and entry (v) of this section.

(2) To 015565: 20 percent for use as in paragraph (c)(1), entry (i); entry (ii), item 3 of this section.

(b) Related tolerances. See §556.60 of this chapter.

(c) Conditions of use. (1) It is used as follows:

<table>
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<tr>
<th>Arsanilic acid in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
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<tbody>
<tr>
<td>(i) 45 to 90 (0.005% to 0.01%).</td>
<td>Swine; for increased rate of weight gain and improved feed efficiency in growing swine.</td>
<td>Withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>015565</td>
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<td>(ii) 90 (0.01%)</td>
<td>1. Chickens; growth promotion and feed efficiency; improving pigmentation.</td>
<td>do</td>
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<td>2. Turkeys; growth promotion and feed efficiency; improving pigmentation.</td>
<td>do</td>
<td>015565</td>
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<td></td>
<td>3. Swine; and aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery).</td>
<td>do</td>
<td>015565</td>
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<tr>
<td>(iii) Erythromycin 4.6 to 18.5</td>
<td>Chickens; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>15565</td>
<td></td>
</tr>
<tr>
<td>(iv) Erythromycin 92.5</td>
<td>1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As erythromycin thiocyanate; feed for 2 days before stress and 3 to 6 days after stress; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>015565</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Chickens; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As erythromycin thiocyanate; feed for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>015565</td>
<td></td>
</tr>
<tr>
<td>(v) Erythromycin 185</td>
<td>Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.</td>
<td>As erythromycin thiocyanate; feed for 5 to 8 days; do not use in birds producing eggs for food purposes; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>15565</td>
<td></td>
</tr>
</tbody>
</table>

(2) Arsanilic acid may be used in accordance with the provisions of this section in the combinations provided as follows:
   (i) Amprolium in accordance with §558.55.
   (ii) Amprolium and ethopabate in accordance with §558.58.
§ 558.76 Bacitracin methylene disalicylate.

(a) Approvals. Type A medicated articles: 10, 25, 30, 40, 50, 60, or 75 grams per pound to 046573 in § 510.600(c) of this chapter.
(b) Special considerations. The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.
(c) Related tolerances. See § 556.70 of this chapter.
(d) Conditions of use. (1) It is used as follows:

<table>
<thead>
<tr>
<th>Bacitracin methylene disalicylate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 4 to 50 ..................................</td>
<td></td>
<td>Chickens, turkeys, and pheasants; increased rate of weight gain and improved feed efficiency</td>
<td>.................................</td>
<td>046573</td>
</tr>
<tr>
<td>(ii) 5 to 20 ..................................</td>
<td></td>
<td>Quail not over 5 weeks of age; increased rate of weight gain and improved feed efficiency</td>
<td>.................................</td>
<td>046573</td>
</tr>
<tr>
<td>(iii) 10 to 25 ..................................</td>
<td></td>
<td>Chickens; for increased egg production and improved feed efficiency for egg production.</td>
<td>For first 7 months of production</td>
<td>046573</td>
</tr>
<tr>
<td>(iv) 10 to 30 ..................................</td>
<td>Chlorotetraacyline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.</td>
<td>Swine: for increased rate of weight gain and improved feed efficiency.</td>
<td>For growing and finishing swine</td>
<td>000004 and 046573</td>
</tr>
<tr>
<td>(v) [Reserved] ..................................</td>
<td></td>
<td>.................................</td>
<td>.................................</td>
<td>.................................</td>
</tr>
<tr>
<td>(vi) 50 ........................................</td>
<td></td>
<td>Broiler chickens; as an aid in the prevention of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin.</td>
<td>.................................</td>
<td>046573</td>
</tr>
<tr>
<td>(vii) 100 to 200 ................................</td>
<td></td>
<td>Broiler chickens; as an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin.</td>
<td>.................................</td>
<td>046573</td>
</tr>
<tr>
<td>(viii) 200 .....................................</td>
<td></td>
<td>Turkeys; as an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylene disalicylate.</td>
<td>.................................</td>
<td>046573</td>
</tr>
<tr>
<td>(ix) 200 ......................................</td>
<td></td>
<td>Quail: for the prevention of ulcerative enteritis in growing quail due to Clostridium colinum susceptible to bacitracin methylene disalicylate.</td>
<td>From Type A medicated articles containing 25, 40, or 50 grams of bacitracin methylene disalicylate. Feed continuously as the sole ration.</td>
<td>046573</td>
</tr>
</tbody>
</table>

### Food and Drug Administration, HHS

#### § 558.78

<table>
<thead>
<tr>
<th>Bacitracin methylene disalicylate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(x) 250</td>
<td>..........................</td>
<td>1. Growing/Finishing Swine: For control of swine dysentery associated with <em>Treponema hyodysenteriae</em> on premises with a history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition. 2. Pregnant sows: For control of clostridial enteritis caused by <em>C. perfringens</em> in suckling piglets.</td>
<td>As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.</td>
<td>046573</td>
</tr>
</tbody>
</table>

1 These conditions are NAS/NRC reviewed and found effective. Applications for these uses may not require effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(2) It is used as bacitracin methylene disalicylate in feed for animals as follows:

(i) Amount. 70 milligrams per head per day.

(a) Indications for use. Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) Limitations. Administer continuously throughout the feeding period.

(ii) Amount. 250 milligrams per head per day.

(a) Indications for use. Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) Limitations. Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) It is used as bacitracin methylene disalicylate in feed for animals as follows:

(i) Amprolium in accordance with §558.55.

(ii) Amprolium with ethopabate in accordance with §558.58.

(iii) Arsanilic acid with zoalene in accordance with §558.60.

(iv) Carbarsone (not U.S.P.) in accordance with §558.120.

(v) Nicarbazin as in §558.366.

(vi) Hygromycin B in accordance with §558.274.

(vii) Monensin in accordance with §558.355.

(viii) Lasalocid sodium alone or with roxarsone as in §558.311.

(ix) Monensin and roxarsone in accordance with §558.355.

(x) Salinomycin alone or with roxarsone as in §558.363.

(xi) Halofuginone hydrobromide and roxarsone in accordance with §558.265.

(xii) Halofuginone in accordance with §558.265.

(xiii) Narasin alone or in combination with roxarsone as in §558.550.

(xiv) Semduramicin alone or in combination with roxarsone as in §558.555.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTE: For Federal Register citations affecting §558.78, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.78 Bacitracin zinc.

(a) Approvals. To sponsors listed in §510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) To 046573: 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(iv), and (d)(2) of this section.

(2) To 000004: 10, 25, 40, and 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(v), (d)(1)(vi), (d)(2), and (d)(3) of this section.

(3) To 000010: 5 and 50 grams per pound for chickens as in paragraph (d)(1)(i) of this section.

(b) Special considerations. The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(c) Related tolerances. See §556.70 of this chapter.
§ 558.95 Bambermycins.

(a) Approvals. To sponsors identified by drug labeler codes in §510.600(c) of this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

(1) To 012799: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) To 012799: 0.4 gram for use as in paragraph (d)(2) of this section.

(3) To 011490: 0.4 and 2 grams for use as in paragraph (d)(2) of this section.

(4) To 012286, 016968, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.

(5) To 012799: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

(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) Broiler chickens. It is used as follows:

(i) Amount per ton. 1 to 2 grams.

(ii) Indications for use. For increased rate of weight gain and improved feed efficiency.

(iii) Limitations. Feed continuously as the sole ration.

(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 000004.

(3) Bacitracin zinc is used in accordance with the provisions of this section in combination with:

(i) Amprolium as in §558.55.

(ii) Amprolium with ethopabate as in §558.58.

(iii) Arsanilic acid and zoalene as in §558.680.

(iv) [Reserved]

(v) Hygromycin B as in §558.274.

(vi) Monensin as in §558.355.

(vii) Zoalene as in §558.680.

(viii) Lasalocid sodium and roxarsone as in §558.311.

(ix) Monensin and roxarsone as in §558.355.

(x) Sinolinamide alone or with roxarsone as in §558.550.

(xi) Carbarsone as in §558.120.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For Federal Register citations affecting §558.78, see the List of CFR Sections Affected in the Finding Aids section of this volume.
(ii) Amount per ton. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus etopabate, 36.3 grams (.004 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from E. acervulina, E. maxima, and E. brunetti is likely to occur. For increased rate of weight gain and improved feed efficiency.

(b) Limitations. Feed continuously as the sole ration; as sole source of amprolium; amprolium and etopabate as provided by No. 050604 in §510.600(c) of this chapter.

(iii) Amount per ton. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus etopabate, 36.3 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-0.00375 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from E. acervulina, E. maxima, and E. brunetti is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) Limitations. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and etopabate as provided by No. 046573 in §510.600(c) of this chapter; roxarsone as provided by No. 050604 in §510.600(c) of this chapter. Withdraw 5 days before slaughter.

(iv) Amount per ton. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus etopabate, 3.63 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-0.00375 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) Limitations. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and etopabate as provided by No. 050604 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter. Withdraw 5 days before slaughter.

(v) Amount per ton. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-0.00375 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) Limitations. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and etopabate as provided by No. 050604 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter. Withdraw 5 days before slaughter.

(vi) Amount per ton. Bambermycins, 1 to 2 grams plus monensin, 90 to 110 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; as monensin sodium provided by No. 000986 in §510.600(c) of this chapter; as bambermycins provided by No. 012799 in §510.600(c) of this chapter.

(vii) Amount per ton. Bambermycins, 1 gram plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent).

(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; use as sole source of organic arsenic; withdraw 5 days before slaughter; as monensin sodium provided by No. 000986 in §510.600(c) of this chapter; as bambermycins provided by No. 012799 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(viii) Amount per ton. Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent).

(a) Indications for use. As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.
§ 558.95  

(b) Limitations. Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; zoalene as provided by No. 025700 in § 510.600(c) of this chapter.

(ix) Amount per ton. Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(a) Indications for use. As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) Limitations. Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; feed as sole source of organic arsenic; withdraw 5 days before slaughter; zoalene as provided by No. 025700; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(x) Amount per ton. Bambermycins, 1 gram plus lasalocid sodium, 68 to 113 grams (0.0075 to 0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) Indications for use. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima; as an aid in the reduction of lesions due to E. tenella; and for increased rate of weight gain.

(b) Limitations. For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; lasalocid sodium as provided by Nos. 012799 and 000004 in § 510.600(c) of this chapter.

(xi) Amount per ton. Bambermycins 1 to 2 grams, plus roxarsone 22.7 to 45.4 grams (0.0025 to 0.005 percent).

(a) Indications for use. For increased rate of weight gain; as an aid in prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.

(b) Limitations. See paragraph (b)(1)(vii)(b) of this section.

(2) Growing-finishing swine. It is used as follows:

(i) Amount per ton. 2 grams.

(a) Indications for use. For increased rate of weight gain and improved feed efficiency.

(b) Limitations. Feed continuously as sole ration.

(ii) Amount per ton. 2 to 4 grams.

(a) Indications for use. For increased rate of weight gain.

(b) Limitations. Feed continuously as sole ration.

(3) Growing turkeys. It is used as follows:

(i) Amount per ton. 1 to 2 grams.

(a) Indications for use. For improved feed efficiency.

(b) Limitations. Feed continuously as sole ration.

(ii) Amount per ton. 2 grams.

(a) Indications for use. For increased rate of weight gain and improved feed efficiency.

(b) Limitations. Feed continuously as sole ration.

(iii) Amount per ton. Bambermycins, 1 to 4 grams plus amprolium, 113.5 grams (0.0125 percent).
(a) Indications for use. For prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) Limitations. Feed continuously as the sole source of amprolium; amprolium as provided by No. 050604 in §510.600(c) of this chapter.

(iv) Amount per ton. Amprolium, 1 or 4 grams plus carbarsone, 227 grams (0.025 percent).

(a) Indications for use. For improved feed efficiency (1 gram per ton) or increased rate of weight gain (4 grams per ton); as an aid in the prevention of blackhead.

(b) Limitations. Feed continuously 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of organic arsenic; carbarsone by 046573 in §510.600(c) of this chapter.

(4) Cattle—(i) Amount per ton. 1 to 4 grams.

(a) Indications for use. For increased rate of weight gain and improved feed efficiency.

(b) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C medicated feed at a rate of 10 to 20 milligrams of bambermycins per head per day. Not for use in animals intended for breeding. Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.

(ii) Amount per ton. 4 to 20 grams.

(a) Indications for use. For increased rate of weight gain.

(b) Limitations. Feed continuously to pasture cattle (slaughter, stocker, and feeder) at a rate of 10 to 20 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed. Not for use in animals intended for breeding.

(iii) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder) as follows:

(a) Specifications.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>International Feed No.</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)</td>
<td>6-01-080</td>
<td>42.50</td>
</tr>
<tr>
<td>Sodium chloride (salt)</td>
<td>6-04-152</td>
<td>20.10</td>
</tr>
<tr>
<td>Calcium carbonate (38% calcium)</td>
<td>6-01-069</td>
<td>15.24</td>
</tr>
<tr>
<td>Corn distillers dried grains w/solubles</td>
<td>5-28-236</td>
<td>9.57</td>
</tr>
<tr>
<td>Magnesium oxide</td>
<td>6-02-756</td>
<td>5.15</td>
</tr>
<tr>
<td>Vitamin and trace mineral premix *</td>
<td>7-05-533</td>
<td>0.75</td>
</tr>
<tr>
<td>Mineral oil</td>
<td></td>
<td>0.60</td>
</tr>
<tr>
<td>Yeast (primary dehydrated yeast)</td>
<td>6-02-431</td>
<td>0.50</td>
</tr>
<tr>
<td>Bambermycins Type A article (10 g/lb)</td>
<td>6-02-758</td>
<td>0.32</td>
</tr>
<tr>
<td>Iron oxide</td>
<td></td>
<td>0.21</td>
</tr>
<tr>
<td>Magnesium sulfate (67%)</td>
<td>6-06-098</td>
<td>0.18</td>
</tr>
<tr>
<td>Selenium premix (270 mg/lb) *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copper sulfate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*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).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 5.33 ounces per head per day. Feed continuously to provide 10-20 milligrams bambermycins per head per day. Not for use in animals intended for breeding. Each use of this free-choice Type C medicated feed must be the subject of an approved Form FDA 1900 as required by 21 CFR 510.455.

(5) Bambermycins may be used as in this section in combination with:

(i) Halofuginone as in §558.265.

(ii) Narasin as in §558.363.

(iii) Narasin and roxarsone as in §558.363.

[40 FR 13959, Mar. 27, 1975]
§ 558.105

Sections Affected in the Finding Aids section of this volume.

§ 558.105  [Reserved]

§ 558.115 Carbadox.

(a) Approvals. Type A medicated articles: 2.2 percent (10 grams per pound) to 0.00069 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. Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in complete feeds containing less than 15 percent crude protein.

(2) Amount per ton. 50 grams (0.0055 percent).

(i) Indications for use. For control of swine dysentery (vibriotic dysentery, bloody scour, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by Salmonella cholerasuis); increased rate of weight gain and improved feed efficiency.

(ii) Limitations. Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in complete feeds containing less than 15 percent crude protein.

(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 (vibriotic dysentery, bloody scour, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by Salmonella cholerasuis); 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.


§ 558.120 Carbarsone (not U.S.P.).

(a) Approvals. Type A medicated articles: (1) 37.5 percent to 0.046573 in §510.600(c) of this chapter.

(2) 25 percent carbarsone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 0.046573 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.60 of this chapter.

(c) [Reserved]

(d) Conditions of use. (1) It is used for turkeys as follows:

(i) Grams per ton. 227 to 340.5 (0.025 to 0.0375 percent).

(a) Indications for use. As an aid in the prevention of blackhead.

(b) Limitations. Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) Grams per ton. 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(a) Indications for use. As an aid in the prevention of blackhead; for increased rate of weight gain.

(b) Limitations. Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) Grams per ton. 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 4 to 45 grams per ton bacitracin from bacitracin zinc.

(a) Indications for use. As an aid in the prevention of blackhead, increased rate of weight gain, and improved feed efficiency.

(b) Limitations. Feed continuously as sole ration. Withdraw 5 days before slaughter. As sole source of organic arsenic; as bacitracin zinc provided by

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Food and Drug Administration, HHS § 558.128

Nos. 000004 and 046573 in § 510.600(c) of this chapter.

(2) Carbarsone (not U.S.P.) may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Zoalene in accordance with § 558.680.

(ii) Amprolium as in § 558.55.

(iii) Bambermycins as in § 558.95.

§ 558.128 Chlortetracycline.

(a) Approvals. Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

1. 50 to 100 grams per pound to 000004 in § 510.600(c) of this chapter.

2. 50 to 100 grams per pound to 000069.

3. 50 to 100 grams per pound to 046573.

4. 50 grams per pound to 017519.

5. 50 to 100 grams per pound to 053389.

(b) Related tolerances. See § 556.150 of this chapter.

(c) [Reserved]

(d)(1) It is used in feeds as follows:

<table>
<thead>
<tr>
<th>Chlortetracycline amount</th>
<th>Combination</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 10 to 50 g/ton</td>
<td></td>
<td>1. Chickens; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to chickens producing eggs for human consumption.</td>
<td>000004, 000069, 017519, 046573, 053389</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Growing turkeys; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to turkeys producing eggs for human consumption.</td>
<td>Do</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Growing swine; increased rate of weight gain and improved feed efficiency.</td>
<td></td>
<td>Do</td>
</tr>
<tr>
<td>(ii) 20 to 50 g/ton</td>
<td>Growing sheep; increased rate of weight gain and improved feed efficiency.</td>
<td></td>
<td></td>
<td>000004, 000069, 046573, 053389</td>
</tr>
<tr>
<td>(iii) 50 to 100 g/ton</td>
<td>Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E. Streptococci susceptible to chlortetracycline.</td>
<td></td>
<td></td>
<td>000004, 000069, 017519, 046573, 053389</td>
</tr>
<tr>
<td>(iv) 100 to 200 g/ton</td>
<td>Chickens; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.</td>
<td>Do</td>
<td></td>
</tr>
<tr>
<td>(v) 200 g/ton</td>
<td>Turkeys; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td>Do</td>
<td></td>
</tr>
<tr>
<td>(vi) 200 to 400 g/ton</td>
<td>1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.</td>
<td>Do</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Ducks; control and treatment of fowl cholera caused by Pasturella multocida susceptible to chlortetracycline.</td>
<td>Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Chlortetracycline amount</td>
<td>Combination</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>---------------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>(vi) 400 g/ton</td>
<td></td>
<td>1. Turkeys; control of hexamitiasis caused by <em>Hexamita meleagrides</em> susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td>000004, 000069, 017519, 046573, 053389 Do.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by <em>Salmonella typhimurium</em> susceptible to chlortetracycline.</td>
<td>Feed continuously for not more than 14 d.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospires) caused by <em>Leptospira pomona</em> susceptible to chlortetracycline.</td>
<td>Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.</td>
<td>Do.</td>
</tr>
<tr>
<td>(vii) 500 g/ton</td>
<td></td>
<td>Chickens; reduction of mortality due to <em>E. coli</em> infections susceptible to chlortetracycline.</td>
<td>Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.</td>
<td>00004</td>
</tr>
<tr>
<td>(ix) 10 mg/g of finished feed daily</td>
<td></td>
<td>Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by <em>Chlamydia psittaci</em> sensitive to chlortetracycline.</td>
<td>Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. 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.”</td>
<td></td>
</tr>
<tr>
<td>(x) 0.1 mg/lb of body weight daily</td>
<td></td>
<td>Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.</td>
<td>In milk replacers or starter feed; include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td>000004, 000069, 017519, 046573, 053389</td>
</tr>
<tr>
<td>(xi) 0.5 mg/lb of body weight daily</td>
<td></td>
<td>Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by <em>Anaplasma marginale</em> susceptible to chlortetracycline.</td>
<td>Withdraw 48 h prior to slaughter. For sponsor 000004 zero withdrawal time.</td>
<td>Do.</td>
</tr>
<tr>
<td>(xii) 10 mg/lb of body weight</td>
<td></td>
<td>Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <em>E. coli</em> and bacterial pneumonia caused by <em>P. multocida</em> organisms susceptible to chlortetracycline.</td>
<td>Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter except for 24 h for sponsor 046573; zero withdrawal for sponsor 000004; include on labeling the warning: “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.”</td>
<td>Do.</td>
</tr>
<tr>
<td>Chlortetracycline amount</td>
<td>Combination</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
<tr>
<td>-------------------------</td>
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<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td>2. Calves (up to 250 lb); treatment of bacterial enteritis caused by E. coli susceptible to chlortetracycline.</td>
<td>In milk replacers or starter feed; include on labeling the warning: &quot;A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.&quot;</td>
<td></td>
<td>000004, 000069, 017519, 046573, 053389</td>
</tr>
<tr>
<td></td>
<td>3. Swine; treatment of bacterial enteritis caused by E. coli and S. choleraesuis and bacterial pneumonia caused by P. multocida susceptible to chlortetracycline.</td>
<td>Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(xii) 25 mg/lb of body weight</td>
<td>Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.</td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>(xiv) 25 to 70 mg/head/day</td>
<td>Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.</td>
<td>Include on labeling the warning: &quot;A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.&quot;</td>
<td></td>
<td>000004, 000069, 017519, 046573, 053389</td>
</tr>
<tr>
<td>(xv) 70 mg/head/day</td>
<td>Growing cattle (over 400 lb); increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.</td>
<td>Do.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(xvi) 80 mg/head/day</td>
<td>Breeding sheep; reducing the incidence of (vibronic) abortion caused by Campylobacter fetus infection susceptible to chlortetracycline.</td>
<td>Withdraw 48 h prior to slaughter. For sponsor 000004; zero withdrawal time.</td>
<td></td>
<td>000004, 000069, 046573, 053389</td>
</tr>
<tr>
<td>(xvii) 350 mg/head/day</td>
<td>1. Beef cattle; control of bacterial pneumonia associated with shipping fever complex caused by Pasteurella spp. susceptible to chlortetracycline.</td>
<td>Do.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by A. marginale susceptible to chlortetracycline.</td>
<td>Do.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(2) For sponsor 000004: it is used in free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approve Type A articles; such feeds are given to beef cattle and nonlactating dairy cattle to provide a daily intake of 0.5 to 2.0 milligrams of chlortetracycline per pound of body weight to aid in the control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline; the use of these Type A articles to make specific free-choice feed formulations must be approved under section 512(b) of the act and be based on a demonstration of drug stability and consumption which is consistent with the effective dose; the specific free-choice feed formulations approved in this paragraph can be manufactured under section 512(m) of the act.

(3) Chlortetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with §558.55.
(ii) Amprolium plus ethopabate in accordance with §558.58.
(iii) Bacitracin methylene disalicylate in accordance with §558.76.
(iv) Clopidol in accordance with §558.175.
(v) Decoquinate in accordance with §558.195.
(vi) Hygromycin B in accordance with §558.274.
(vii) Monensin in accordance with §558.355.
(viii) Roxarsone and salinomycin in accordance with §558.550.
(ix) Robenidine hydrochloride in accordance with §558.515.
(x) Roxarsone in accordance with §558.530.
(xi) Salinomycin in accordance with §558.550.
(xii) Zoalene in accordance with §558.680.
(xiii) Tiamulin in accordance with §558.600.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.128, see the List of Sections Affected in the Finding Aids section of this volume.

§ 558.140 Chlortetracycline and sulfamethazine.

(a) Approvals. Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 000004 in §510.600(c) of this chapter.

(b) Related tolerances. See §§556.150, 556.151, and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

1. Amount per head per day. Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

2. Indications for use. Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

3. Limitations. Feed for 28 days; withdraw 7 days prior to slaughter.


§ 558.145 Chlortetracycline, sulfathiazole, penicillin.

(a) Approvals. Type A medicated articles: (1) 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to Nos. 000004 and 046573 in §510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to Nos. 000004 in §510.600(c) of this chapter.

(b) Specifications. (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(c) Related tolerances. See §§556.150, 556.510, and 556.670 of this chapter.

(d) Conditions of use. (1) It is administered to swine in a Type C feed 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; maintenance of weight gain in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 15 days prior to slaughter.


§ 558.155 Chlortetracycline, sulfathiazole, and penicillin.

(a) Approvals. Type A medicated articles: (1) 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and procaine penicillin equivalent to 10 grams of penicillin per pound to Nos. 000004 and 000010 in §510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to Nos. 000004 and 000010 in §510.600(c) of this chapter.
§ 558.175 Clopidol.

(a) Approvals. Type A medicated articles: (i) 25 percent to 0.0125 percent of clopidol 113.5 grams in § 556.160 of this chapter.

(b) Related tolerances. See §§ 556.150, 556.510, and 556.690 of this chapter.

(c) [Reserved]

(d) Conditions of use. It is used as follows:

(i) Amount per ton. Clopidol 113.5 grams (0.0125 percent).


(b) Limitations. Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) Indications for use. Aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati; growth promotion and feed efficiency; improved pigmentation.

(b) Limitations. Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by Nos. 046573 and 046575 of § 510.600(c) of this chapter; or as zinc bacitracin provided by Nos. 000061 and 046573 in § 510.600(c) of this chapter.

(iii) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent) plus bacitracin, 4 to 25 grams.

(a) Indications for use. Aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati; growth promotion and feed efficiency; increased rate of weight gain.

(b) Limitations. Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by No. 046573 in § 510.600(c) of this chapter; or as zinc bacitracin provided by Nos. 000061 and 046573 in § 510.600(c) of this chapter.

(iv) Amount per ton. Clopidol, 113.5 grams (0.0125%) plus zinc bacitracin, 5 to 25 grams.

(a) Indications for use. For increased rate of weight gain and improved feed efficiency; aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati.

(b) Limitations. Feed continuously as sole ration. Zinc bacitracin as provided by Nos. 000061 and 046573 of § 510.600(c) of this chapter.

(b) Specifications. (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(c) Related tolerances. See §§ 556.150, 556.510, and 556.690 of this chapter.

(d) Conditions of use. It is used as follows:

(1) Amount per ton. Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) Indications for use. For reduction of incidence of cervical abscesses. Treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibrionic dysentery). Maintenance of weight gains in the presence of atrophic rhinitis. Swine 10 pounds of body weight to 6 weeks post-weaning: Increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks post-weaning: Increased rate of weight gain.

(3) Limitations. For swine raised in confinement (dry-lot) or on limited pasture. Feed as sole ration. Withdraw 7 days prior to slaughter.

MINIMUM AMOUNT OF TYPE C FEED WHICH THE ANIMAL SHOULD CONSUME

<table>
<thead>
<tr>
<th>Type of feed</th>
<th>Approximate body weight in pounds</th>
<th>Minimum desired daily feed intake in pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestarter (up to 6 weeks postweaning)</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Starter (up to 6 weeks postweaning)</td>
<td>50</td>
<td>1½</td>
</tr>
<tr>
<td>Grower (6-16 weeks postweaning)</td>
<td>80</td>
<td>2</td>
</tr>
<tr>
<td>Finisher (6-16 weeks postweaning)</td>
<td>150</td>
<td>3</td>
</tr>
</tbody>
</table>

§ 558.185

(v) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus bacitracin methylene disalicylate, 4 to 50 grams per ton.

(a) Indications for use. For increased rate of weight gain; to aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati.

(b) Limitations. 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 methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter.

(vi) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus lincomycin, 2-4 grams.

(a) Indications for use. Aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati; increase in rate of weight gain and improved feed efficiency.

(b) Limitations. As lincomycin hydrochloride monohydrate; do not feed to chickens over 16 weeks of age.

(2) Broiler chickens and replacement chickens—(i) Amount per ton. Clopidol, 113.5 or 227 grams (0.0125 or 0.025 percent).


(b) Limitations. Feed up to 16 weeks of age if intended for use as caged layers; feed continuously as the sole ration; 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.

(ii) Amount per ton. Clopidol, 113.5 grams (0.0125 percent) plus chlortetracycline 100 to 200 grams.

(a) Indications for use. Aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.

(b) Limitations. Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.

(3) [Reserved]

(4) Replacement chickens—(i) Amount per ton. Clopidol 113.5 grams (0.0125 percent).


(b) Limitations. For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age.

(ii) Amount per ton. Clopidol 113.5 grams (0.0125 percent) plus roxarsone 45.4 grams (0.005 percent).

(a) Indications for use. Aid in the prevention of coccidiosis caused by E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati; growth promotion and feed efficiency; improving pigmentation.

(b) Limitations. For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age: withdraw 5 days before slaughter; as sole source of organic arsenic.

(5) Turkeys—(i) Amount per ton. Clopidol 113.5 or 227 grams (0.0125 or 0.025 percent).

(ii) Indications for use. Aid in the prevention of leucocytozoonosis caused by Leucocytozoon smithii.

(iii) Limitations. For turkeys grown for meat purposes only; to be administered continuously in feed at 0.0125 or 0.025 percent clopidol as the sole ration depending upon management practices, degree of exposure, and amount of feed eaten; withdraw medication 5 days before slaughter.


§ 558.185 Coumaphos.

(a) Approvals. Type A medicated articles:

(1) [Reserved]

(2) 1.12 and 11.2 percent to 017800 in §510.600(c) of this chapter for use as in paragraph (d)(1)(ii) of this section.

(b) Special considerations. Adequate directions and warnings for use must be given and shall include a statement
that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment to any other cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(c) Related tolerances. See 40 CFR 180.189.

(d) Conditions of use. It is used as follows:

(1) Beef and dairy cattle—(i) Amount. Coumaphos 0.00012 lb. (0.054 gram) per 100 lb. body weight per day.

(a) Indications for use. As an aid in the reduction of fecal breeding flies through control of fly larvae.

(b) Limitations. Feed for the duration of fly season in a Type C feed containing not over 0.0066 percent coumaphos; do not feed to animals less than 3 months old; not for use in pelleted feeds.

(ii) Amount. Coumaphos, 0.0002 lb. (0.091 gram) per 100 lb. body weight per day.

(a) Indications for use. Control of gastrointestinal roundworms (Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Trichostrongylus spp.).

(b) Limitations. Feed 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days 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. Should conditions warrant, repeat treatment at 30-day intervals.

(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 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.

§ 558.195 Decoquinate.

(a) Approvals. Type A medicated articles: 6 percent to 046573 in § 510.600(c) of this chapter.

(b) Related tolerances in edible products. See § 556.170 of this chapter.

(c) Special considerations. (1) Bentonite should not be used in decoquinate feeds.

(2) Type A medicated articles containing 6 percent decoquinate may be
used to make dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraph (d) of this section.

(3) Type A medicated articles containing 6 percent decoquinate may be used to manufacture dry or liquid Type B cattle feeds as indicated in paragraph (d) of this section.

(d) Conditions of use. It is used as follows:

<table>
<thead>
<tr>
<th>Decoquinate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.6 (0.00149 pct) ..........</td>
<td>Young goats; for the prevention of coccidiosis caused by <em>Eimeria christenseni</em> and <em>E. ninakohlyakimovae</em>.</td>
<td>Feed at a rate to provide 22.7 mg per 100 lbs of body weight per day (0.5 mg per kilogram); do not feed to goats producing milk for food; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard.</td>
<td>046573</td>
<td></td>
</tr>
<tr>
<td>13.6 (0.0015 pct) ..........</td>
<td>Young sheep; for the prevention of coccidiosis caused by <em>Eimeria ovolidalis</em>, <em>E. crandallis</em>, <em>E. parva</em>, <em>E. bakuensis</em>.</td>
<td>Feed Type C feed at a rate to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kilogram) 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 sheep producing milk for food.</td>
<td>046573</td>
<td></td>
</tr>
<tr>
<td>13.6 to 27.2 (0.0015 to 0.003 pct)</td>
<td>Cattle; for the prevention of coccidiosis in ruminating and nonruminating calves and cattle caused by <em>Eimeria bovis</em> and <em>E. zuimi</em>.</td>
<td>Feed Type C feed at a rate to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kilogram) per day. May be prepared from dry or liquid Type B feed containing 0.0125 to 0.5 pct decoquinate. Liquid Type B feed must have a pH range of 5.0 to 6.5 and contain a suspending agent to maintain a viscosity of not less than 500 centipoises. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cattle producing milk for food.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.6 to 535.7 (0.0015 to 0.059 pct)</td>
<td>Cattle; prevention of coccidiosis in ruminating and nonruminating calves (including veal calves) and cattle caused by <em>Eimeria bovis</em> and <em>E. zuimi</em>.</td>
<td>Feed Type C feed (including dry milk replacer) to provide 22.7 mg per 100 lb body weight (0.5 mg per kg) per day. May be prepared from dry Type B feed containing 0.06 to 0.6 pct decoquinate or liquid Type B feed containing 0.0125 to 0.05 pct decoquinate. The liquid Type B feed must have pH 5.0 to 6.5 and contain a suspending agent to maintain a viscosity of not less than 500 centipoises. 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.</td>
<td>046573</td>
<td></td>
</tr>
</tbody>
</table>

...do ......................................... ......do

...do ......................................... ......do
### Food and Drug Administration, HHS § 558.205

<table>
<thead>
<tr>
<th>Decoquinate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.2 (0.003 pct)</td>
<td></td>
<td>Broiler chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>.</td>
<td>Do not feed to laying chickens.</td>
<td>046573</td>
</tr>
<tr>
<td>Bacitracin 10 to 50...</td>
<td></td>
<td>Broiler chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>; control of increased rate of weight gain and improved feed efficiency</td>
<td>Do not feed to laying chickens.</td>
<td>046573</td>
</tr>
<tr>
<td>Chlortetracycline 100 to 200.</td>
<td></td>
<td>Chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>.</td>
<td>Do not feed to chickens producing eggs for human consumption; in low calcium feed containing 0.8 pct. of calcium; feed continuously 7 to 14 days.</td>
<td>046573</td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400.</td>
<td></td>
<td>Chickens; for the prevention of coccidiosis caused by <em>E. tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>.</td>
<td>Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>046573</td>
</tr>
<tr>
<td>Roxarsone 45.4 (0.005 pct.)</td>
<td></td>
<td>Broiler chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.</td>
<td>046573</td>
</tr>
<tr>
<td>Lincomycin 2..................</td>
<td></td>
<td>Broiler chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>.</td>
<td>Do not feed to laying chickens; feed as sole ration; as lincomycin hydrochloride monohydrate provided by No. 000099 in sec. 510.600(c) of this chapter.</td>
<td>000099, 046573</td>
</tr>
<tr>
<td>Roxarsone 11 to 45 (0.0012–0.005 pct.) plus Bacitracin 12 to 60.</td>
<td></td>
<td>Broiler chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, and <em>E. brunetti</em>.</td>
<td>Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; as zinc bacitracin provided by No. 000061 in sec. 510.600(c) of this chapter; as roxarsone provided by No. 046573 in sec. 510.600(c) of this chapter.</td>
<td>046573</td>
</tr>
</tbody>
</table>

[40 FR 13069, Mar. 27, 1975]

**EDITORIAL NOTE:** For Federal Register citations affecting §558.195, see the List of CFR Sections Affected in the Finding Aids section of this volume.

### § 558.205 Dichlorvos.

(a) Approvals. Type A medicated articles: 3.1 and 9.6 percent to 000010 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
§ 558.235 Efrotomycin.

(a) Approvals. Type A medicated articles: 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]

§ 558.248 Erythromycin thiocyanate.

(a) Approvals. Type A medicated articles: (1) 2.2 percent to 050604 in §510.600(c) of this chapter for use as in paragraph (d) of this section. (2) 5 and 10 percent to 050604 for use in paragraphs (d)(1)(i) and (ii) of this section.

(b) Special considerations. The levels of antibiotic are expressed in terms of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(c) Related tolerances. See §556.230 of this chapter.
Food and Drug Administration, HHS  § 558.254

(d) Condition of use. (1) It is used as follows:

<table>
<thead>
<tr>
<th>Erythromycin thiocyanate in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 4.6 to 18.5</td>
<td></td>
<td>Chickens; growth promotion and feed efficiency.</td>
<td>For turkeys not over 12 weeks of age.</td>
<td>050604</td>
</tr>
<tr>
<td>(ii) 9.25 to 18.5</td>
<td></td>
<td>Turkeys; growth promotion and feed efficiency.</td>
<td>Starter ration for animals up to 35 lb body weight.</td>
<td>050604</td>
</tr>
<tr>
<td>(iii) 9.25 to 64.75</td>
<td></td>
<td>Swine; increase in weight gain, improved feed efficiency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).</td>
<td></td>
<td>050604</td>
</tr>
<tr>
<td>(iv) 18.5</td>
<td></td>
<td>Laying chickens; aids in increasing egg production.</td>
<td></td>
<td>050604</td>
</tr>
<tr>
<td>(v) 92.5</td>
<td></td>
<td>1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress.</td>
<td>Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.</td>
<td>050604</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Chickens; as an aid in the prevention of infectious coryza.</td>
<td>Feed for 7 to 14 d; withdraw 24 h before slaughter.</td>
<td>050604</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.</td>
<td>Feed for 2 d before stress and 3 to 6 d after stress.</td>
<td>050604</td>
</tr>
<tr>
<td>(vi) 185</td>
<td></td>
<td>1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.</td>
<td>050604</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes.</td>
<td>050604</td>
</tr>
</tbody>
</table>

(2) In feed for feedlot beef cattle at 37 milligrams per head per day as an aid in stimulating growth and improving feed efficiency.

(3) Erythromycin thiocyanate may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Arsanilic acid in accordance with § 558.62.

(iv) Zoalene in accordance with § 558.680.

§ 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
§ 558.258  Fenbendazole.

(a) Approvals. Type A medicated articles: 4 percent (18.1 grams per pound), 8 percent (36.2 grams per pound), and 20 percent (90.7 grams per pound) fenbendazole and all combinations provided for in this section to 012799 in § 510.600(c) of this chapter.

(b) Related tolerances. See § 556.275 of this chapter.

(c) Conditions of use. (1) It is used in swine feed as follows:

(i) Amount. Fenbendazole, 10 to 80 grams per ton (to provide 9 milligrams per kilogram of body weight) given over a 3–to-12-day period.

(A) Indications for use. 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); 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).

(B) Limitations. Feed as sole ration. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(ii) Amount. Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 20 grams per ton.

(A) Indications for use. As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for increased rate of gain in growing-finishing swine.

(B) Limitations. Feed as sole ration. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(iii) Amount. Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 40 grams per ton.

(A) Indications for use. As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) for control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred.

(B) Limitations. Feed as sole ration. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(iv) Amount. Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 100 grams per ton.

(A) Indications for use. As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for the treatment of swine dysentery.

(B) Limitations. Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(v) Amount. Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 200 grams per ton.

(A) Indications for use. As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for reduction in the severity of swine mycoplasmal pneumonia caused by Mycoplasma hyopneumoniae.

(B) Limitations. Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(2) It is used in the feed of beef and dairy cattle as follows:

(i) Amount. 5 milligrams fenbendazole per kilogram body weight (2.27 milligrams per pound).

(ii) Indications for use. For the removal and control of lungworms (Dictyocaulus viviparus); barberpole worms (Haemonchus contortus); brown stomach worms (Ostertagia ostertagi); small stomach worms (Trichostrongylus axei); hookworms (Nematodirus helvetianus); thread-necked intestinal worms (Nematodirus helvetianus); small intestinal worms (Cooperia punctata).

(iii) Limitations. Feed as sole ration for one day. Do not use within 13 days of slaughter.

(3) It is used in free-choice beef and dairy cattle feed as follows:
(i) Amount. 5 milligrams fenbendazole per kilogram body weight (2.27 milligrams per pound).

(ii) Indications for use. For the removal and control of infections of lungworms (Dictyocaulus viviparus), barberpole worms (Haemonchus contortus), brown stomach worms (Ostertagia ostertagi), small stomach worms (Trichostrongylus axei), 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) in cattle.

(iii) Limitations. Feed a total of 5 milligrams of fenbendazole per kilogram (2.27 milligrams per pound) of body weight to cattle over a 3 to 6 day period. Retreatment may be needed after 4 to 6 weeks. Do not slaughter within 13 days following last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(iv) May be fed in a Type C feed as follows:

| Ingredient | Percent | Inter-
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Ingredient:</td>
<td></td>
<td>National</td>
</tr>
<tr>
<td>Copper sulfate</td>
<td>0.45</td>
<td>feed No.</td>
</tr>
<tr>
<td>Dried Cane Molasses</td>
<td>3.12</td>
<td>6-04-695</td>
</tr>
<tr>
<td>Monosodium phosphate</td>
<td>31.16</td>
<td>6-04-298</td>
</tr>
<tr>
<td>Salt (sodium chloride)</td>
<td>59.00</td>
<td>6-04-152</td>
</tr>
<tr>
<td>Zinc sulfate</td>
<td>0.76</td>
<td>6-05-056</td>
</tr>
<tr>
<td>Fenbendazole Type A article (200 grams per kilogram)</td>
<td>5.51</td>
<td></td>
</tr>
</tbody>
</table>
| (B) Ingredient: |  | Inter-
| Dicalcium phosphate | 32.31 | national |
| Limestone | 17.13 | feed No. |
| Magnesium oxide | 9.79 | 6-02-756 |
| Zinc sulfate | 1.47 | 6-05-556 |
| Copper sulfate | 0.29 | 6-01-720 |
| Potassium iodide | 0.0098 | 6-03-759 |
| Dried Cane Molasses | 0.98 | 6-04-695 |
| Selenium | 0.0002 | |
| Salt | 35.93 | 6-04-152 |
| Fenbendazole Type A article (200 grams per kilogram) | 2.09 | |

(C) The content of any added vitamin and trace mineral 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. The amount of selenium must comply with published regulations.

(4) Zoo and wildlife animals. For removal and control of internal parasites in hoofed zoo and wildlife animals as follows:

(i) Feral swine (Sus scrofa): 3 milligrams per kilogram per day for 3 days. Treatment for kidney worm (Stephanurus dentatus), roundworm (Ascaris suum), nodular worm (Oesophagostomum dentatum).

(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae): 2.5 milligrams per kilogram per day for 3 days. Treatment for small stomach worm (Trichostrongylus spp.), thread necked intestinal worm (Nematodirus spp.), barberpole worm (Haemonchus spp.), whipworm (Trichuris spp.).

(iii) Rocky mountain bighorn sheep (Ovis c. canadensis): 10 milligrams per kilogram per day for 3 days. Treatment and control of Protostrongylus spp.

(iv) Limitations. Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not use 14 days before or during the hunting season.


§ 558.265 Halofuginone hydrobromide.

(a) Approvals. Type A medicated articles: 6 grams per kilogram (2.72 grams per pound) to 012579 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.308 of this chapter.

(c) 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) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus virginiamicin 5 to 15 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 6 days before slaughter; do not feed to layers.

(iv) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus virginiamicin 5 to 15 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.

(B) Limitations. Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) Amount per ton. Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 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 for improved feed efficiency.

(B) Limitations. Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vi) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams.

(A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, 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) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus lincomycin 2 to 4 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 and for improved feed efficiency.

(B) Limitations. Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(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 adenoides, E. meleagrimitis, and E. gallopavonis.

(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 hydrobromide 1.36 to 2.72 grams plus bacitracin methylene disalicylate 10 to 50 grams.

(A) Indications for use. For 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. Keep out of lakes, ponds, or 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.
§ 558.274 Hygromycin B.

(a) Approvals. (1) Type A medicated articles: 2.4 and 8 grams per pound to 000986, 016968, 030117, 043733, and 050639 in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(2) 2.4 grams per pound to 016968 and 043733 in § 510.600(c) of this chapter for use in swine feed as in paragraph (c)(1)(ii) of this section.

(3) 1.2 grams per pound to 016968 in § 510.600(c) of this chapter for use in swine as in paragraph (c)(1)(ii) of this section.

(b) Related tolerances. See §556.330 of this chapter.

(c) Conditions of use. (1) It may be used as follows:

<table>
<thead>
<tr>
<th>Hygromycin B in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 8 to 12 ..................</td>
<td>Bactracin 100 ..................</td>
<td>Chickens: control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata).</td>
<td>Withdraw 3 days before slaughter.</td>
<td>000986, 016968, 017519, 017790, 026186, 043733, 046573, 046573, 050639</td>
</tr>
<tr>
<td></td>
<td></td>
<td>As bacitracin methylene disalicylate or zinc bacitracin; withdraw 3 days before slaughter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination in grams per ton</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Bacitracin plus penicillin  (100 to 200 of combination)</td>
<td>1. Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</td>
<td>Feed containing not less than 25% of penicillin plus not less than 50% of bacitracin; as procaine penicillin plus bacitracin methylene disalicylate; withdraw 3 days before slaughter.</td>
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<tr>
<td></td>
<td>2. Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</td>
<td>Combination containing not less than 50% nor more than 75% of bacitracin, except that it contains not more than 125 g of penicillin; as procaine penicillin plus zinc bacitracin; withdraw 3 days before slaughter.</td>
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<td></td>
<td>3. Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</td>
<td>Combination containing 50% to 75% bacitracin, but not more than 125 g of penicillin, as procaine penicillin; withdraw 3 days before slaughter.</td>
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<td></td>
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<tr>
<td>Chlortetracycline 100 to 200</td>
<td>Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter.</td>
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<td></td>
</tr>
<tr>
<td>Chlortetracycline 200 to 400</td>
<td>Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); control of chronic respiratory disease (CRD) and airsac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to chlortetracycline.</td>
<td>As procaine penicillin; withdraw 3 days before slaughter.</td>
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<td></td>
</tr>
<tr>
<td>Penicillin 100 .............</td>
<td>Chickens; control of infestation of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</td>
<td>As tylosin phosphate; withdraw 3 days before slaughter.</td>
<td>000986</td>
<td></td>
</tr>
<tr>
<td>Tylosin 4 to 50 ............</td>
<td>Chickens: Control of infestations of large roundworms (Ascaris galli), cecal worms (Heterakis gallinae), and capillary worms (Capillaria obsignata); growth promotion and feed efficiency.</td>
<td>Withdraw 15 days before slaughter.</td>
<td>000986, 016968, 017519, 017790, 026186, 043733, 046573, 050639</td>
<td></td>
</tr>
<tr>
<td>(ii) 12 .................</td>
<td>Swine: control of infestation of large roundworms (Ascaris suis), nodular worms (Oesophagostomum dentatum), and whipworms (Trichuris suis).</td>
<td>With the above limitations.</td>
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<td></td>
</tr>
</tbody>
</table>
(2) Hygromycin B may also be used in combination with:
   (i) Amprolium in accordance with §558.55.
   (ii) Zoalene in accordance with §558.680.

[41 FR 11000, Mar. 15, 1976]

EDITORIAL NOTE: For Federal Register citations affecting §558.274, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 558.295 Iodinated casein.

(a) Approvals. See 017762 in §510.600(c) of this chapter.

(b) NAS/NRC status. The use of this drug is NAS/NRC reviewed and found effective. Applications for these uses need not include efficacy data as required by §514.111 of this chapter but may require bioequivalency or safety data.

(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 1 ½ 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]

§ 558.300 Ivermectin.

(a) Approvals. (1) Type A medicated articles: 0.6 percent (2.72 grams per pound; 6 grams per kilogram) to 050604 in §510.600(c) of this chapter, and

     (2) Type B medicated feeds for ivermectin alone or with lincomycin. See §558.4 of this chapter for maximum drug levels to 050604 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.344 of this chapter.

(c) Conditions of use. (1) It is used in swine feed as follows:

     (i) Amount. For growing-finishing swine feed 1.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day). For mature and breeding swine feed 1.8 to 11.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day).

     (ii) Indications for use. For the treatment and control of gastrointestinal roundworms (Ascaris suum, adult and fourth-stage larvae; Ascarops strongylina, adults; Hysterangylus rubidus, adult and fourth-stage larvae; Oesophagostomum spp., adult 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).

(iii) Limitations. Feed as the only feed for 7 consecutive days. For use in swine only. Withdraw 5 days before slaughter.

(2) Amount per ton. 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 20 grams of lincomycin.

(i) Indications for use. For treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Haemonchus contortus, adults; Stephanurus dentatus, 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). For increased rate of weight gain.

(ii) Limitations. For weaned, growing-finishing swine. Feed as sole ration for 7 consecutive days. Withdraw 5 days before slaughter. A separate feed containing 20 grams per ton lincomycin may be continued. Not to be fed to swine that weigh more than 250 pounds. 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) Amount per ton. 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 40 grams of lincomycin.

(i) Indications for use. For treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Haemonchus contortus, adults; Stephanurus dentatus, 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). For control of swine dysentery. For use in swine on premises with a history of swine dysentery, but where symptoms have not yet occurred.

(ii) Limitations. For weaned, growing-finishing swine. Feed as sole ration for 7 consecutive days. Withdraw 5 days before slaughter. A separate feed containing 40 grams per ton lincomycin may be continued. Not to be fed to swine that weigh more than 250 pounds. 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(4) Amount per ton. 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 100 grams of lincomycin.

(i) Indications for use. For treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Haemonchus contortus, adults; Stephanurus dentatus, 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). Treatment of swine dysentery.

(ii) Limitations. For weaned, growing-finishing swine. Feed as sole ration for 7 consecutive days followed by a separate feed containing 100 grams per ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 pounds. 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(5) Amount per ton. 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 200 grams of lincomycin.

(i) Indications for use. For treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Haemonchus contortus, adults; Stephanurus dentatus, 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). For control of swine dysentery.
Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongyulus spp., adults), lice (Haematopinus suis), and mange mites (Sarcoptes scabiei var. suis). For reduction in severity of swine mycoplasmal pneumonia caused by Mycoplasma hyopneumoniae.

(ii) Limitations. For weaned, growing-finishing swine. Feed as sole ration for 7 consecutive days followed by a separate feed containing 200 grams per ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 pounds. 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 558.305 Laidlomycin propionate potassium.

(a) Approvals. Type A medicated articles: 50 grams per pound to 000004 in §510.600(c) of this chapter.

(b) 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 Type B 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 Type B 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.

(ii) Limitations. For 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.

(c) [Reserved]

(d) Conditions of use. Used in cattle feed as follows:

(1) Amount. Laidlomycin propionate potassium, 5 grams per ton.

(i) Indications for use. For improved feed efficiency and increased rate of weight gain.

(ii) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 75 milligrams per head per day.

(2) Amount. Laidlomycin propionate potassium, 5 to 10 grams per ton.

(i) Indications for use. For improved feed efficiency.

(ii) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 150 milligrams per head per day.

(3) Additional limitations. (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.


§ 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. 000004 for use in paragraphs (e)(1)(i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 000069 as provided by No. 000004 for use in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 000004 for use in cattle feeds as
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in paragraphs (e)(1)(vi), (vii), (ix), (x), (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. 000004 for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

(5) 15 percent activity to 021930 (Type A article provided by 000004) for use in free-choice vitamin-mineral Type C cattle feeds as in paragraph (e)(1)(xi).

(6) 20 percent activity as a liquid Type A article to No. 000004 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. 000004 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).

(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 Type B 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 Type B 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 positionally stable lasalocid liquid Type B 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. Form FDA 1900 must indicate the pH and centipoises per second for such lasalocid liquid Type B feed.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (2) of this section, the manufacturer may secure approval of a positionally stable liquid Type B 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 positional 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 Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the supplement new animal drug application will be approved. Approval of the supplement will not be published in the Federal Register because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for liquid Type B feed. A manufacturer who seeks to market a positionally unstable lasalocid liquid Type B 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 Type B feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (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.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

<table>
<thead>
<tr>
<th>Lasalocid sodium activity in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 68 (0.0075 pct) to 113 (0.0125 pct)</td>
<td>Roxarsone 45.4</td>
<td>Broiler or fryer chickens; for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>; as an aid in the reduction of lesions due to <em>E. tenella</em>; and for increased rate of weight gain.</td>
<td>For broiler or fryer chickens only; feed continuously as the sole ration.</td>
<td>000004</td>
</tr>
<tr>
<td></td>
<td>Roxarsone 45.4 plus bambermycins 1 (0.00011 pct)</td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>; as an aid in the reduction of lesions due to <em>E. tenella</em>; and for increased rate of weight gain.</td>
<td>For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; Roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter.</td>
<td>000004</td>
</tr>
<tr>
<td></td>
<td>Roxarsone 45.4 plus lincomycin 2.0.</td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>; as an aid in the reduction of lesions due to <em>E. tenella</em>; and for increased rate of weight gain and improved feed efficiency.</td>
<td>For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; Roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, Lincomycin provided by No. 000004.</td>
<td>000004</td>
</tr>
<tr>
<td></td>
<td>Roxarsone 45.4 plus bacitracin 10 to 25.</td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>; as an aid in the reduction of lesions due to <em>E. tenella</em>; and for increased rate of weight gain.</td>
<td>For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; Roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, Bacitracin methylene disalicylate provided by No. 046573 and in §510.600(c) of this chapter.</td>
<td>000004</td>
</tr>
<tr>
<td></td>
<td>Roxarsone 45.4 plus bacitracin 10 or 30.</td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>; as an aid in the reduction of lesions due to <em>E. tenella</em>; and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).</td>
<td>For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; Roxarsone provided by Nos. 046573 and 011526 in §510.600(c) of this chapter, Bacitracin zinc provided by No. 000061.</td>
<td>000004</td>
</tr>
<tr>
<td>Lasalocid sodium activity in grams per ton</td>
<td>Combination in grams per ton</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
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<tr>
<td>68 (0.0075 pct) plus bacitracin</td>
<td>Broiler or fryer chickens for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>: for increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter.</td>
<td>000004</td>
<td></td>
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<tr>
<td>Roxarsone 45.5 plus bacitracin methylene disalicylate 50.</td>
<td>Roxarsone 45.5 plus bacitracin methylene disalicylate 50.</td>
<td>Prevention of coccidiosis caused by <em>Eimeria necatrix</em>, <em>E. tenella</em>, <em>E. acervulina</em>, and <em>E. maxima</em>: for increased rate of weight gain and reduced lesions due to <em>E. tenella</em>: prevention of necrotic enteritis caused or complicated by <em>Clostridium</em> spp. or other susceptible organisms.</td>
<td>046573</td>
<td></td>
</tr>
<tr>
<td>Lincomycin 2 (0.00022 pct)</td>
<td></td>
<td>For broiler and fryer chickens only; feed continuously as sole ration; withdraw 3 days before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Bacitracin 10 to 50</td>
<td></td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>: for increased rate of weight gain and improved feed efficiency.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Virginiamycin 20</td>
<td></td>
<td>For prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>: for increased rate of weight gain and improved feed efficiency.</td>
<td>000007</td>
<td></td>
</tr>
<tr>
<td>Oxytetracycline 7.5</td>
<td>Cattle; for improved feed efficiency.</td>
<td>For broiler and fryer chickens only; for increased rate of weight gain and improved feed efficiency.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Oxytetracycline 7.5</td>
<td>Cattle; for improved feed efficiency and reduced incidence and severity of liver abscesses.</td>
<td>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.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Oxytetracycline 7.5</td>
<td>Cattle; for improved feed efficiency and increased rate of weight gain.</td>
<td>In Type C feeds; for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monooalkyl (C₈₋₁₈) trimethyl ammonium oxytetracycline.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Virginiamycin 20</td>
<td>Cattle; for improved feed efficiency and increased rate of weight gain.</td>
<td>In Type C feeds; for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monooalkyl (C₈₋₁₈) trimethyl ammonium oxytetracycline.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Virginiamycin 20</td>
<td>Sheep; for the prevention of coccidiosis caused by <em>Eimeria ovina</em>, <em>E. crandallis</em>, <em>E. ovinoidalis</em> (E. ninakohlyakimovae), <em>E. parva</em>, and <em>E. intricata</em>.</td>
<td>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.</td>
<td>000004</td>
<td></td>
</tr>
<tr>
<td>Lasalocid sodium activity in grams per ton</td>
<td>Combination in grams per ton</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
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<td>-------------------------------------------</td>
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</tr>
<tr>
<td>(ix)</td>
<td></td>
<td>Cattle; for increased rate of weight gain.</td>
<td>For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day when on pastures; the drug must be contained in at least 1 pound of feed.</td>
<td>000004</td>
</tr>
<tr>
<td>(x) 68 (0.0075 pct) to 113 (0.0125 pct).</td>
<td>Bacitracin 4 to 50 ...</td>
<td>Broiler chickens; for prevention of coccidiosis caused by <em>E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,</em> and <em>E. maxima</em>; and for improved feed efficiency.</td>
<td>For broiler chickens only; feed continuously as the sole ration; withdraw 3 days before slaughter; bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter.</td>
<td>000004</td>
</tr>
<tr>
<td>(xi)</td>
<td></td>
<td>Cattle; for increased rate of weight gain.</td>
<td>For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; 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. Each use in a free-choice Type C feed must be the subject of an approved NADA or supplemental NADA as provided in §510.455 of this chapter.</td>
<td>000004, 021930</td>
</tr>
<tr>
<td>(xii)</td>
<td></td>
<td>Cattle; for control of coccidiosis caused by <em>E. bovis</em> and <em>E. zuernii</em>.</td>
<td>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.</td>
<td>000004</td>
</tr>
<tr>
<td>(xiii)</td>
<td></td>
<td>Chukar partridges; for prevention of coccidiosis caused by <em>E. legionensis</em>.</td>
<td>Feed continuously as sole ration up to 8 weeks of age.</td>
<td>000004</td>
</tr>
<tr>
<td>(xiv)</td>
<td></td>
<td>Growing turkeys; for prevention of coccidiosis caused by <em>E. meleagrimitis, E. gallopavonis,</em> and <em>E. adenoeides.</em></td>
<td>Feed continuously as sole ration</td>
<td>000004</td>
</tr>
<tr>
<td>(xv)</td>
<td></td>
<td>Replacement calves; for control of coccidiosis caused by <em>E. bovis</em> and <em>E. zuernii.</em></td>
<td>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: &quot;A withdrawal period has not been established for lasalocid in pre-uminating calves. Do not use in calves to be processed for veal&quot;.</td>
<td>000004</td>
</tr>
<tr>
<td>(xvi)</td>
<td></td>
<td>Rabbits; for prevention of coccidiosis caused by <em>E. stiedae</em>.</td>
<td>Feed continuously as sole ration up to 6 1/2 weeks of age.</td>
<td>000004</td>
</tr>
</tbody>
</table>

(2) It is used as a free-choice mineral Type C feed as follows:

(i) Specifications.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Per cent</th>
<th>International feed No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Carbonate (38 percent Calcium)</td>
<td>18.0</td>
<td>6-01-069</td>
</tr>
<tr>
<td>Cottonseed Meal</td>
<td>10.0</td>
<td>5-01-621</td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>3.0</td>
<td>6-03-755</td>
</tr>
<tr>
<td>Selenium Premix (0.02 percent Selenium)</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Dried Cane Molasses</td>
<td>2.5</td>
<td>4-04-695</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>1.7</td>
<td>6-02-758</td>
</tr>
</tbody>
</table>

Defluorinated Phosphate (20.5 percent Calcium, 18.5 percent Phosphorus) ... 35.9 6-01-060 6-04-152
Sodium Chloride (Salt) ................. 20.0 6-01-060
§ 558.315  Levamisole hydrochloride (equivalent).

(a) Approvals. Type A medicated articles: 227 grams per pound to 043781 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.350 of this chapter.

(c) Conditions of use. It is used in Type C medicated feed as follows:

(i) Cattle—(i) Amount per pound. 0.36-3.6 grams (0.08–0.8 percent).

(ii) Indications for use. Treatment of the following gastrointestinal worms and lung worm infections: stomach worms (Haemonchus, Trichostrongylus, Ostertagia), intestinal worms (Trichostrongylus Cooperia, Nematodirus, Bunostomum, Oesophagostomum), and lungworms (Dictyocaulus).

(iii) Limitations. Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated

(ii) Amount 150 grams per ton (0.17 percent).

(iii) Indications for use. Cattle: for increased rate of weight gain.

(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 200 milligrams lasalocid per head per day; each use of this Type C free-choice feed must be the subject of an approved FD-1900 as provided in §510.455 of this chapter.

(v) Sponsor. See No. 000004 in §510.600(c) of this chapter.

3 To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of Bovatec Liquid 20 (90.8 gm/lb). If dry Bovatec-68 (68 gm/lb) is used, use 2.206 lbs per ton (0.111%), replacing molasses.
feed is consumed resume normal feeding; medicated feed is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feeds only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully.'"

(2) Swine—(i) Amount per pound. 0.36 grams (0.08 percent).

(ii) Indications for use. Treatment of the following nematode infections: large roundworms (Ascaris suum), nodular worms (Oesophagostomum spp.), lungworms (Metastrongylus spp.), intestinal threadworms (Strongyloides ransomi), swine kidney worms (Stephanurus dentatus).

(iii) Limitations. It is recommended that regular feed be withheld overnight and worming feed administered the following morning; dilute supplement with nonmedicated feed as directed; feed the equivalent of 1 lb. of 0.08 percent worming feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfestation; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

(2) Swine—(i) Amount per pound. 0.36 grams (0.08 percent).

(ii) Indications for use. Treatment of the following nematode infections: large roundworms (Ascaris suum), nodular worms (Oesophagostomum spp.), lungworms (Metastrongylus spp.), intestinal threadworms (Strongyloides ransomi), swine kidney worms (Stephanurus dentatus).

(iii) Limitations. It is recommended that regular feed be withheld overnight and worming feed administered the following morning; dilute supplement with nonmedicated feed as directed; feed the equivalent of 1 lb. of 0.08 percent worming feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfestation; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

§ 558.325 Lincomycin.

(a) Approvals. Type A articles and Type B feeds approved for sponsors in §510.600(c) of this chapter for specific uses as in paragraph (c) of this section as follows:

(1) No. 000009: (i) 4 grams per pound as in paragraphs (c) (1) and (3) of this section.

(ii) 20 grams per pound as in paragraphs (c) (1) through (3) of this section.

(iii) 50 grams per pound as in paragraphs (c) (1) through (3) of this section.

(iv) 10 grams per pound as in paragraphs (c)(1) and (2) through (iv) of this section.

(2)±(4) [Reserved]

(5) No. 043733 for 8 and 20 grams per pound as in paragraphs (c)(2) (i) through (iii) of this section.

(6)±(12) [Reserved]

(13) No. 017800 for 2.5 and 8 grams per pound as in paragraphs (c)(2) (i) through (iv) of this section.

(14)±(15) [Reserved]

(b) Related tolerances in edible products. See §556.360 of this chapter.

(c) Conditions of use—(1) Broilers:

(i) Amount per ton. 2 to 4 grams.

(a) Indications for use. For control of necrotic enteritis caused by Clostridium spp. or other susceptible organisms.

(b) Limitations. As lincomycin hydrochloride monohydrate.

(ii) Amount per ton. 2 grams.

(a) Indications for use. For control of necrotic enteritis caused by Clostridium spp. or other susceptible organisms.

(b) Limitations. As lincomycin hydrochloride monohydrate.

(2) Swine—(i) Amount per ton. 40 grams.

(a) Indications for use. For control of swine dysentery.

(b) Limitations. Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more than 250 pounds.
§ 558.340 Maduramicin ammonium.

(a) Approvals. Type A medicated articles: 4.54 grams per pound to 0.000004 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).


(b) Limitations. Feed as sole ration for 3 weeks or until signs of disease disappear; not to be fed to swine weighing more than 250 pounds; withdraw 6 days before slaughter.

(c) Limitations. For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

(2) [Reserved]

§ 558.342 Melengestrol acetate.

(a) Approvals. Dry Type A medicated articles containing 100 or 200 milligrams per pound or liquid Type A articles containing 500 milligrams per pound to 0.000009 in §510.600(c) of this chapter.

(b) Tolerances. See §556.380 of this chapter.

(c) Special considerations. (1) Type B medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B medicated feeds.

(xii) Nicarbazin as in §558.366.

(xv) Salinomycin with or without roxarsone as in §558.550.

(4) Lincomycin may also be used for swine in combination with:

(i) Pyrantel tartrate as in §558.485.

(ii) Fenbendazole as provided in §558.258.

(iii) Ivermectin as in §558.300.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.325, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 558.340 Maduramicin ammonium.

(a) Approvals. Type A medicated articles: 4.54 grams per pound to 0.000004 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).

(i) Indications for use. For prevention of coccidiosis caused by Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix, and E. mivati.

(ii) Limitations. Feed as sole ration for 3 weeks or until signs of disease disappear; not to be fed to swine weighing more than 250 pounds; withdraw 6 days before slaughter.

(iv) Amount per ton. 100 grams.

(a) Indications for use. For treatment of swine dysentery.

(b) Limitations. Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; feed containing 100 grams per ton lincomycin hydrochloride should be withdrawn 6 days before slaughter.

(iii) Amount per ton. 100 grams.

(a) Indications for use. For treatment of swine dysentery.

(b) Limitations. Feed as sole ration for 3 weeks or until signs of disease disappear; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter.

(iv) Amount per ton. 200 grams.

(a) Indications for use. For reduction in the severity of swine mycoplasmal pneumonia caused by Mycoplasma hyopneumoniae.

(b) Limitations. Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter.

(v) Amount per ton. 200 grams.

(a) Indications for use. For increased rate of weight gain in growing-finish-}
which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid Type B 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 Type B 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 positionally stable melengestrol acetate liquid Type B feed will not be subject to the requirements for mixing directions prescribed in paragraphs (c)(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.

(d) Conditions of use. It is used for heifers as follows:

(1) Amount. Melengestrol acetate, 0.25 to 0.50 milligram per head per day.

(i) Indications for use. For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) Limitations. Heifers being fed for slaughter; administer 0.5 to 2.0 pounds per head per day of medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 10 to 30 grams of lasalocid per ton; or, add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate plus 25 to 720 milligrams of monensin per pound to a ration of nonmedicated feed to provide 0.25 to 0.5 milligram of melengestrol acetate and 100 to 360 milligrams of monensin per head per day. Melengestrol acetate and monensin as provided by Nos. 000009 and 000986, respectively, in §510.600(c) of this chapter.

(2) Amount. Melengestrol acetate, 0.25 to 0.50 milligram per head per day in combination with lasalocid (as lasalocid sodium), 100 to 360 milligrams per head per day.

(i) Indications for use. For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) Limitations. Heifers being fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 10 to 30 grams of lasalocid per ton; or, add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate plus 25 to 720 milligrams of lasalocid per pound to a ration of nonmedicated feed to provide 0.25 to 0.5 milligram of melengestrol acetate and 100 to 360 milligrams of lasalocid per head per day. Melengestrol acetate and lasalocid as provided by Nos. 000009 and 000004, respectively, in §510.600(c) of this chapter.

(3) Amount. Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus monensin (as tylosin phosphate), 90 milligrams per head per day.

(i) Indications for use. For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) Limitations. Heifers being fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 0.80 milligram of melengestrol acetate per pound to a feed containing 5 to 30 grams of monensin per ton; or, add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 0.80 milligram of melengestrol acetate plus 25 to 720 milligrams of monensin per pound to a nonmedicated feed to provide 0.25 to 0.40 milligram of melengestrol acetate and 50 to 360 milligrams of monensin per head per day. The liquid medicated feeds must be manufactured in accordance with §558.355(f)(3)(ii). Melengestrol acetate and monensin as provided by Nos. 000009 and 000986, respectively, in §510.600(c) of this chapter.
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provided by Nos. 000009 and 000986, respectively, in §510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate with 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate (from a dry Type A article) plus 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.

(5) Amount. Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus lasalocid (as lasalocid sodium), 100 to 360 milligrams per head per day, and tylosin (as tylosin phosphate), 90 milligrams per head per day.

(i) Indications for use. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses.

(ii) Limitations. Heifers being fed in confinement for slaughter. The liquid medicated feeds are required to be manufactured in accordance with §558.311(d). Lasalocid, melengestrol acetate, and tylosin as provided by Nos. 000004, 000009, and 000986, respectively, in §510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate plus 100 to 360 milligrams of lasalocid plus 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 10 to 30 grams of lasalocid and 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 50 to 720 milligrams of lasalocid per pound to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry pelleted medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate (from a dry Type A article), 50 to 720 milligrams of lasalocid, and 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.

(6) Amount. Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus lasalocid (as lasalocid sodium), 100 to 360 milligrams per head per day, and tylosin (as tylosin phosphate), 90 milligrams per head per day.

(i) Indications for use. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses.

(ii) Limitations. Heifers being fed in confinement for slaughter. The liquid medicated feeds are required to be manufactured in accordance with §558.355(f)(3)(i). Melengestrol acetate as provided by No. 000009 and monensin and tylosin as provided by No. 000986 in §510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate plus 100 to 360 milligrams of lasalocid plus 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 10 to 30 grams of monensin and 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 25 to 720 milligrams of monensin per pound to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry medicated feed containing 0.125 to 1.0 milligram melengestrol acetate (from a dry Type A article), 25 to 600 milligrams of monensin, and 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.
Food and Drug Administration, HHS

(i) Indications for use. For suppression of estrus (heat).

(ii) Limitation. Heifers intended for breeding. Do not exceed 24 days of feeding. Administer 0.5 to 2.0 pounds per head per day of Type C feed containing 0.25 to 1.0 milligram of melengestrol acetate per pound to provide 0.5 milligram of melengestrol acetate per head per day. Melengestrol acetate as provided by No. 000009 in §510.600(c) of this chapter.


§558.348 Mibolerone.

(a) Approvals. To No. 000009 in §510.600(c) of this chapter for a canned dog food, each 61⁄2 ounce can containing 30 or 60 micrograms of mibolerone.

(b) Conditions of use Ð (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]

§558.355 Monensin.

(a) Specifications. Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the Rf value must be comparable to a reference standard (the Rf value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

(b) Approvals. Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in §510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 36.3 (for export only), 44, 45, or 60 grams per pound, paragraphs (f) (1)(i) and (4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1)(i), (iii), (iv), (v), (ix), and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(2) of this section.

(5) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiii), (xx), and (xxi) of this section.

(6) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(5) of this section.

(7) To 000986: 20, 30, 45, 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

(8) To 000004: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 000004: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 012799: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xviii), (xix), (xxiii), (xxiv), and (xxv) of this section.
§ 558.355

(12) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.
(13) To 021930: 60 and 80 grams per pound, paragraph (f)(3)(v) of this section.
(14) To 000986: 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(6) 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) Type C cattle feeds containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.
(3) Type C goat feeds shall bear an expiration date of 30 days after date of manufacture.
(4) [Reserved]
(5) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.
(6) The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal.
(7) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:
   (i) Monensin medicated goat feed is safe for use in goats only. Consumption by unapproved species may result in toxic reactions.
   (ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin 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.
(11) The labeling of complete feeds containing monensin intended for use in goats shall bear the caution statements specified in paragraphs (d)(6) and (d)(10) (i) and (v) of this section.

(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. Do not feed to laying chickens; 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; as monensin or monensin sodium.
   (ii) Amount per ton. Monensin, 90-110 grams, plus roxarsone 45.4 grams (0.005 percent).
   (a) Indications for use. Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by E.
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necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati and E. maxima.

(b) Limitations. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(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 methylene disalicylate provided by No. 046573 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 bacitracin provided by No. 000004 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 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 provided by No. 000004 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. See § 558.95(b)(1)(vi).

(vii) Amount per ton. Monensin, 90 to 110 grams plus bambermycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See § 558.95(b)(1)(vii).

(viii) Amount per ton. Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(a) Indications for use. 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.

(b) Limitations. 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; feed continuously as sole ration; as monensin sodium.

(ix) Amount per ton. Monensin, 90 to 110 grams plus lincomycin, 2 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; to be fed as a 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 monensin sodium.

(x) Amount per ton. Monensin, 90 to 110 grams plus lincomycin, 2 grams and roxarsone, 15-45 grams.

(a) Indications for use. For increased rate of weight gain; 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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573, §510.600(c) of this chapter; as monensin sodium provided by No. 000986, §510.600(c) of this chapter; as lincomycin provided by No. 000009.
§ 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

(xi) Amount per ton. Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(a) Indications for use. For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima, E. mivati, and E. maxima.

(b) Limitations. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000009 in § 510.600(c) of this chapter; as lincomycin provided by No. 000009 in § 510.600(c) of this chapter; as chlortetracycline hydrochloride provided by No. 000004 in § 510.600(c) of this chapter.

(xii) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 10 to 25 grams, and roxarsone, 11.3 to 45.4 grams.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima, and E. mivati; for increased rate of weight gain and for improved feed efficiency.

(b) Limitations. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000009 in § 510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600 of this chapter; as roxarsone provided by No. 000009, 000004, or 046573 in § 510.600 of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(xiii) Amount per ton. Monensin, 90 to 110 grams, plus 5 grams virginiamycin.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima, and E. mivati; for increased rate of weight gain and improved feed efficiency.

(b) Limitations. Do not feed to laying chickens; feed continuously as the sole ration; as monensin sodium provided by No. 000009 in § 510.600 of this chapter; virginiamycin provided by No. 000007 in § 510.600 of this chapter.

(xiv) Amount per ton. Monensin, 90 to 110 grams, plus 500 grams chlortetracycline.

(a) Indications for use. As an aid in the reduction of mortality due to Escherichia coli infections susceptible to such treatment. 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 for 5 days as the sole ration; withdraw 24 hours before slaughter; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; not to be fed continuously for more than 5 days; as monensin sodium; as chlortetracycline; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(xv) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin zinc, 10 grams, and roxarsone, 15 grams (0.0017 percent).

(a) Indications for use. For increase in rate of weight gain; for 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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvi) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 15 to 45 grams (0.0017 percent to 0.005 percent).

(a) Indications for use. For improved feed efficiency; for improved pigmentation by enhancing carotenoid and xanthophyll utilization; for 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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as...
bacitracin zinc provided by Nos. 000004 and 046573 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xvii) Amount per ton. Monensin, 90 to 110 grams plus bambermycins, 1 to 2 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to .005 percent). See §558.95(b)(1)(x) of this chapter.

(xviii) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 34.0 grams (0.0025 percent to .00375 percent).

(a) Indications for use. For increase in 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. maxima, E. brunetti, and E. mivati; as an aid in the prevention of necrotic enteritis caused or complicated by Escherichia coli, Klebsiella spp, or other organisms susceptible to bacitracin methylene disalicylate.

(b) Limitations. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin provided by No. 000986 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xix) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to .005 percent).

(a) Indications for use. For increased rate of weight gain; as an aid in the prevention of necrotic enteritis caused or complicated by Clostridium spp or other organisms susceptible to bacitracin methylene disalicylate; 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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin provided by No. 000986 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xx) Amount per ton. Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent).

(a) Indications for use. For increase in rate of weight gain; 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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin provided by No. 000986 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xxii) Amount per ton. Monensin, 90 to 110 grams, plus oxytetracycline, 500 grams.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. maxima, E. brunetti, and E. mivati; as an aid in the reduction of mortality due to air-sacculities (air-sac infection) caused by Escherichia coli sensitive to oxytetracycline.

(b) Limitations. Feed for 5 days as sole ration. Do not feed to laying chickens. Withdraw 24 hours before slaughter. As monensin provided by No. 000986 in §510.600(c) of this chapter; as trimethylammonium oxytetracycline provided by No. 000069 in §510.600(c) of this chapter.

(xxiii) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to 0.005 percent).
(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 the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in §510.600(c) of this chapter; as bacitracin zinc provided by No. 046573 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xxiv) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

(xxv) Amount per ton. Monensin, 90 to 110 grams plus bacitracin, 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. 046573 in §510.600(c) of this chapter, as monensin sodium.

(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. Bacitracin methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter.

(iii) Amount per ton. Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 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 methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter.
(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(3)(i)(b)(1) of this section. A manufacturer may secure approval of a positionally stable liquid Type B 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 positional stability; and (iii) requesting No. 000986 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 Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the Federal Register because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(3)(i)(b)(1) of this section may also follow this procedure.

(ii) Amount per ton. Monensin, 5 to 30 grams, plus tylosin, 8 to 10 grams.

(a) Indications for use. Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomycetes (Corynebacterium) pyogenes*.

(b) Limitations. Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Feed at the rate of not less than 50 nor more than 200 milligrams per head per day in not less than 1 pound of feed or, after the fifth day feed at the rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed, as monensin sodium. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day.

(iv) Amount per ton. Monensin, 5 to 30 grams per ton (to provide 50 to 360 milligrams per head per day), plus melengestrol acetate, 0.25 to 1.6 grams per ton (to provide 0.25 to 0.40 milligram per head per day). See §558.342(c)(2).

(a) Indications for use. For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(b) Limitations. Heifers being fed in confinement for slaughter: Administer melengestrol acetate and monensin by: (1) Adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound to Type C medicated feeds containing monensin at 5 to 30 grams per ton, (2) adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound and monensin from a separate Type B feed containing 50 to 1,200 grams per ton to Type C medicated feeds, (3) adding melengestrol acetate and monensin which are contained in the same dry Type B feed at the ranges in paragraph (f)(3)(iv)(b) (1) and (2) of this section to Type C medicated feeds, or (4) using a liquid Type B feed containing 0.125 to 0.8 milligram melengestrol acetate per pound and 25 to 600 milligrams monensin per pound (50 to 1,200 grams per ton) to make Type C medicated feeds. Type C medicated feeds in paragraph (f)(3)(iv)(b) (1) and (2) of this section may be manufactured from monensin liquid Type B feeds in accordance with paragraph (f)(3)(i)(b) of this section.

(v) Amount. 150 milligrams per pound (0.033 percent).

(a) Indications for use. Increased rate of weight gain.

(b) Limitations. As protein-mineral blocks to be fed free choice to cattle (slaughter, stocker, feeder, and dairy
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Monensin may be used for heifers being fed in confinement for slaughter with melengestrol acetate with or without tylosin as in §558.342.

(i) Amount. To 000986: To make liquid Type B medicated feed containing 400 grams per ton monensin sodium with 150 grams per ton tylosin phosphate used to make a dry Type C medicated feed containing 21.4 to 26.8 grams per ton monensin plus 8 to 10 grams per ton tylosin.

(a) Indications for use. Improved feed efficiency; for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Actinomyces (Corynebacterium) pyogenes.

(b) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid Type B medicated feed must bear an expiration date of 14 days after date of manufacture. The mixing directions for this liquid Type B medicated feed stored in recirculation or agitation tank systems are: Recirculate or agitate immediately prior to use for not less than 10 minutes, moving at least 1 percent of the tanks contents per minute from the bottom of the tank to the top. Recirculate or agitate as directed daily, even when the Type B medicated feed is not used. Inadequate mixing (recirculation or agitation) of liquid Type B medicated feeds may result in increased monensin concentrations which have been fatal to cattle. Both an approved NADA and an approved medicated feed application are required to make this liquid Type B medicated feed.

(x) Amount per ton. Monensin, 1,620 grams as monensin sodium (810 milligrams per pound).

(a) Indications for use. For increased rate of weight gain.

(b) Specifications. Use as free-choice Type C medicated feed formulated as mineral granules as follows:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Percent</th>
<th>International feed no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monocalcium phosphate (21% phosphorus, 15% calcium)</td>
<td>29.49</td>
<td>6-01-082</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Percent</th>
<th>International feed no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride (salt)</td>
<td>24.25</td>
<td>6-04-152</td>
</tr>
<tr>
<td>Dried cane molasses</td>
<td>20.0</td>
<td>4-04-695</td>
</tr>
<tr>
<td>Ground limestone (33% calcium) or calcium carbonate (38% calcium)</td>
<td>13.75</td>
<td>6-02-632</td>
</tr>
<tr>
<td>Cane molasses</td>
<td>3.0</td>
<td>4-04-696</td>
</tr>
<tr>
<td>Processed grain by-products (as approved by AAFCO)</td>
<td>5.0</td>
<td></td>
</tr>
<tr>
<td>Vitamin/trace mineral premix(^1)</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>Monensin Type A article, 80 grams per pound</td>
<td>1.01</td>
<td></td>
</tr>
<tr>
<td>Antidusting oil</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\)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. Medicated mineral granules to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at the 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 water deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using this product. Do not feed to lactating dairy cattle. Do not allow horses, other equines, mature turkeys, or quail access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. The product's effectiveness in cull cows and bulls has not been established. Each use of this free-choice Type C feed must be the subject of an approved medicated feed application (MFA or Form FDA 1900) or supplemental MFA as required by §510.455 of this chapter.

(4) Replacement chickens intended for use as cage layers—(i) Amount per ton. Monensin, 90 to 110 grams.

(ii) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria crandallis, E. christensenii, and E. ninakohlyakimovae.

(iii) Limitations. Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium; do not feed to chickens over 16 weeks of age.

(5) Bobwhite quail—(i) Amount per ton. Monensin, 73 grams.

(ii) Indications for use. For the prevention of coccidiosis 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.


(a) Indications for use. For the prevention of coccidiosis caused by Eimeria crandallis, E. christensenii, and E. ninakohlyakimovae.

(b) Limitations. (1) Feed only to goats being fed in confinement. Do not feed to lactating goats. Feed continuously in Type C feed as monensin sodium. 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. Mixing directions for liquid Type B feeds stored in recirculating tank systems are: 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 directed in this paragraph, even when Type B feed is not used. Mixing directions for liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems are: Mix thoroughly with grain and/or roughage prior to feeding and must
§ 558.360 Morantel tartrate.

(a) Approvals. Type A medicated articles: 88 grams per pound to 0.00986 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 Trichostrongyulus 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.


§ 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 0.00986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) To 0.00986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.

(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 Trichostrongyulus 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.

(3) To 000986: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.

(4) To 012799: 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) To 012799: 45 grams per pound, with 4 and 10 grams per pound bambermycins, and 45.4, 90, and 227 grams per pound roxarsone, paragraph (d)(1)(vii) of this section.

(b) Tolerances. See §556.428 of this chapter.

(c) [Reserved]

(d) Conditions of use. It is used as follows:

(1) Broiler chickens—(i) Amount per ton. Narasin, 54 to 72 grams.


(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 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. 000986 in §510.600(c) of this chapter may be used in the combination.

(iv) 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.

(v) Amount per ton. Narasin 54 to 72 grams, roxarsone 22.7 to 45.4 grams, and bacitracin methylene disalicylate 10 to 50 grams.

(A) Indications for use. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, for increased rate of weight gain, and for improved feed efficiency.

(B) Limitations. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Drug overdose or lack of water may result in leg weakness. 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, 54 to 72 grams, plus roxarsone 45.4 grams (0.005 percent).

(A) Indications for use. For the prevention of coccidiosis in broiler chickens caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati including some field strains of E. tenella which are more susceptible to roxarsone combined with narasin than to narasin alone.

(B) Limitations. For broiler chickens only; feed continuously as the sole ration; do not feed to laying chickens; may be fatal if accidentally fed to adult turkeys or to horses; withdraw 5 days before slaughter; as sole source of organic arsenic; not approved for use with pellet binders.

(iii) 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. 000986 in §510.600(c) of this chapter may be used in the combination.

For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency.
§ 558.365 Nequinate.

(a) Approvals. Type A medicated articles: 4 percent to 017800 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.

(b) Limitations. For broiler chickens only. Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

§ 558.366 Nicarbazin.

(a) Type A medicated articles; 25 percent to 000986, 060728, and 063271 in §510.600(c) of this chapter for use as indicated in the table in paragraph (c) of this section.

(b) Related tolerances. See §556.445 of this chapter.

(c) Conditions of use. It is used in chicken feed as follows:
## § 558.369 Nitarsone

(a) Approvals. Type A medicated articles: 50 percent to 046573 in § 510.600(c) of this chapter.

(b) Related tolerances. See § 556.60 of this chapter.

(c) NAS/NRC status. These conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses may not require effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use. It is used for chickens and turkeys as follows:

1. **Amount.** Nitarsone, 0.01875 percent.
2. **Indications for use.** As an aid in the prevention of blackhead.
3. **Limitations.** Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeder at all times. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 days. Discontinue use 5 days before slaughtering animals for human consumption to allow elimination of the residue in the body.

## Table

<table>
<thead>
<tr>
<th>Nitarsone in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>27 to 45</td>
<td>Narasin 27 to 45</td>
<td>Broiler chickens; prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, <em>E. brunetti</em>, and <em>E. mivati</em>.</td>
<td>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.</td>
<td>000986</td>
</tr>
<tr>
<td>113.5 (0.0125 pct)</td>
<td>Bacitracin methylene disalicylate 30.</td>
<td>Broiler chickens; aid in preventing outbreaks of cecal (<em>Eimeria tenella</em>) and intestinal (<em>E. acervulina</em>, <em>E. maxima</em>, <em>E. necatrix</em>, and <em>E. brunetti</em>) coccidiosis; for increased rate of weight gain and improved feed efficiency.</td>
<td>do .........................................</td>
<td>060728 063271</td>
</tr>
<tr>
<td>0.00044 pct.</td>
<td>Lincomycin 2</td>
<td>Broiler chickens; aid in preventing outbreaks of cecal (<em>Eimeria tenella</em>) and intestinal (<em>E. acervulina</em>, <em>E. maxima</em>, <em>E. necatrix</em>, and <em>E. brunetti</em>) coccidiosis; for increased rate of weight gain.</td>
<td>do .........................................</td>
<td>060728 063271</td>
</tr>
<tr>
<td>0.0023%</td>
<td>Roxarsone 22.7</td>
<td>Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; as sole source of organic arsenic; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 5 days before slaughter.</td>
<td>do .........................................</td>
<td>060728 063271</td>
</tr>
<tr>
<td>0.0004%</td>
<td>Roxarsone 22.7 plus lincomycin 2</td>
<td>do .........................................</td>
<td>do .........................................</td>
<td>060728 063271</td>
</tr>
</tbody>
</table>
§ 558.376 Nitromide and sulfanitran.

(a) Approvals. Type A medicated articles: 25 percent nitromide, 30 percent sulfanitran, with or without 5 percent roxarsone to 0.05 percent in § 510.600(c) of this chapter.

(b) Related tolerances. See §§ 556.220 and 556.680 of this chapter.

(c) Conditions of use. It is used for chickens as follows:

(1) Amount. 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (0.03 percent).
   (i) Indications for use. As an aid in the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, and E. acervulina.
   (ii) Limitations. Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide and 30 percent sulfanitran.

(2) Amount. 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (0.03 percent), plus 45.4 grams per ton roxarsone (0.005 percent).
   (i) Indications for use. Prevention of coccidiosis caused by Eimeria tenella, E. necatrix, and E. acervulina; growth promotion and feed efficiency; improving pigmentation.
   (ii) Limitations. Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide, 30 percent sulfanitran, and 5 percent roxarsone; as sole source of organic arsenic.

§ 558.415 Novobiocin.

(a) Approvals. Type A medicated articles: 25 grams of activity per pound to 0.00009 in § 510.600(c) of this chapter.

Type B medicated feeds: 17.5 grams per pound to 0.00009 in § 510.600(c) of this chapter.

(b) Related tolerances. See § 556.460 of this chapter.

(c) 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.

(2) Turkeys—(i) Amount. Novobiocin, 4-5 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 turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) Turkeys—(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.

(2) Turkeys—(iii) Amount. Novobiocin, 7-8 mgs. per lb. body weight per day.
Food and Drug Administration, HHS  

§ 558.450 Oxytetracycline.

(a) Approvals. Type A medicated articles: 20 grams of activity per pound to 000069 in § 510.600(c) of this chapter.

(b) Related tolerances. See § 556.470 of this chapter.

(c) Special considerations. (1) In accordance with § 558.5 labeling shall bear the statement: "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-al(8±18)trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline.
§ 558.450

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amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(c) Related tolerances. See §556.500 of this chapter.

(d)(1) Conditions of use. It is used in feed as follows:

<table>
<thead>
<tr>
<th>Oxytetracycline amount</th>
<th>Combination</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 10 to 20 grams per ton (g/ton)</td>
<td>Sheep; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to chickens producing eggs for human consumption.</td>
<td>000069, 053389</td>
<td></td>
</tr>
<tr>
<td>(ii) 10 to 50 g/ton</td>
<td>1. Chickens; increased rate of weight gain and improved feed efficiency.</td>
<td>Do not feed to turkeys producing eggs for human consumption.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Growing turkeys; increased rate of weight and improved feed efficiency.</td>
<td>Do not feed to turkeys producing eggs for human consumption.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Swine; increased rate of weight and improved feed efficiency.</td>
<td>Feed continuously for 7 to 14 days.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>(iii) 100 g/ton</td>
<td>Turkeys; control of hexamitiasis caused by Hexamita meleagridis susceptible to oxytetracycline.</td>
<td>Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>(iv) 100 to 200 g/ton</td>
<td>Chickens; control of infectious synovitis caused by Mycoplasma synoviae; control of fowl cholera caused by Pasteurella multocida susceptible to oxytetracycline.</td>
<td>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.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nequinate 18.16 g/ton (0.002%)</td>
<td></td>
<td>000069</td>
<td></td>
</tr>
<tr>
<td>(v) 200 g/ton</td>
<td>Chickens; control of infectious synovitis caused by M. synoviae; control of fowl cholera caused by P. multocida susceptible to oxytetracycline; as an aid in the control of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati.</td>
<td>Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.</td>
<td>000069, 053389</td>
<td></td>
</tr>
<tr>
<td>(vi) 400 g/ton</td>
<td>Turkeys; control of infectious synovitis caused by M. synoviae susceptible to oxytetracycline.</td>
<td>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.</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>Oxytetracycline amount</td>
<td>Combination</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsor</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Monensin 90 to 110 g/ton</td>
<td>Chickens; control of CRD and air sac infection caused by <em>M. gallisepticum</em> and <em>E. coli</em> susceptible to oxytetracycline; and as an aid in the prevention of coccidiosis caused by <em>E. necatrix</em>, <em>E. tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima.</em></td>
<td>......do ................................ 000069</td>
<td>Do.</td>
<td>000069</td>
</tr>
<tr>
<td>Nequinate 18.16 g/ton (0.002%)</td>
<td>Chickens; control of CRD and air sac infection caused by <em>M. gallisepticum</em> and <em>E. coli</em> susceptible to oxytetracycline; as an aid in prevention of coccidiosis caused by <em>E. tenella</em>, <em>E. acervulina</em>, <em>E. maxima</em>, <em>E. brunetti</em>, and <em>E. mivati.</em></td>
<td>......do ................................ Do.</td>
<td>000069, 053389</td>
<td></td>
</tr>
<tr>
<td>(vii) 500 g/ton</td>
<td>Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <em>E. coli</em> susceptible to oxytetracycline.</td>
<td>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.</td>
<td>000069, 053389</td>
<td></td>
</tr>
<tr>
<td>Monensin 90 to 110 g/ton</td>
<td>Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <em>E. coli</em> susceptible to oxytetracycline; as an aid in the prevention of coccidiosis caused by <em>E. necatrix</em>, <em>E. tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima.</em></td>
<td>......do ................................ 000069</td>
<td>Do.</td>
<td>000069</td>
</tr>
<tr>
<td>Salinomycin 40 to 60 g/ton</td>
<td>Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <em>E. coli</em> susceptible to oxytetracycline; prevention of coccidiosis caused by <em>E. necatrix</em>, <em>E. tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima.</em></td>
<td>......do ................................ 000069, 012799</td>
<td>Do.</td>
<td>000069, 053389</td>
</tr>
<tr>
<td>(vii) 0.05 to 0.1 milligram/pound (mg/lb) of body weight daily.</td>
<td>Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.</td>
<td>Feed continuously; in milk replacers or starter feed.</td>
<td>000069, 053389</td>
<td></td>
</tr>
<tr>
<td>(ix) 10 mg/lb of body weight daily.</td>
<td>1. Calves and beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <em>E. coli</em> and bacterial pneumonia (shipping fever complex) caused by <em>P. multocida</em> susceptible to oxytetracycline.</td>
<td>Feed continuously for 7 to 14 d; in feed or milk replacers; withdraw 5 d before slaughter.</td>
<td>Do.</td>
<td>000069, 053389</td>
</tr>
<tr>
<td></td>
<td>2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <em>E. coli</em> susceptible to oxytetracycline.</td>
<td>Feed continuously for 7 to 14 d; in milk replacers or starter feed; withdraw 5 d before slaughter.</td>
<td>Do.</td>
<td>000069, 053389</td>
</tr>
</tbody>
</table>
3. Sheep; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.

4. Swine: treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.

5. Breeding swine: control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.

(x) 25 mg/lb of body weight

Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.

(xi) 25 mg/head/day

Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.

(xii) 75 mg/head/day

Growing cattle (over 400 lb); increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.

(xiii) 0.5 to 2.0 g/head/day

Cattle; prevention and treatment of the early stages of shipping fever complex.

(xiv) 200 mg/colony

Honey bees; control of American foulbrood caused by *Bacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.

Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.

Feed continuously for not more than 14 d; withdraw 5 d before slaughter.

Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.

(2) It is used in fish feed as follows:
Table 2

<table>
<thead>
<tr>
<th>Oxytetracycline amount</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 250 mg/kilogram of fish/d (1.15 g/100 lb of fish/d)</td>
<td>Pacific salmon for marking of skeletal tissue.</td>
<td>For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in feed containing oxytetracycline hydrochloride or mono-alkyl (C_8-C_18) trimethyl ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of medicated feed.</td>
<td>000069</td>
<td></td>
</tr>
<tr>
<td>(ii) 1 to 3.75 g/100 lb of fish/day</td>
<td>1. Salmonids; control of ulcer disease caused by Hemophilus piscium, furunculosis caused by Aeromonas salmonicida, bacterial hemorrhagic septicemia caused by A. liquefaciens, and pseudomonas disease.</td>
<td>Administer as mono-alkyl (C_8-C_18) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 °C (48.2 °F).</td>
<td>000069</td>
<td></td>
</tr>
<tr>
<td>2. Catfish; control of bacterial hemorrhagic septicemia caused by A. liquefaciens and pseudomonas disease.</td>
<td>Lobsters; control of gaffkemia caused by Aerococcus viridans.</td>
<td>Administer as sole ration for 5 consecutive days in feed containing monoalkyl (C_8-C_18) trimethyl ammonium oxytetracycline; withdraw medicated feed 30 d before harvesting lobsters.</td>
<td>000069</td>
<td></td>
</tr>
</tbody>
</table>

(3) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Robenidine hydrochloride in accordance with § 558.515.
(ii) Lasalocid as in § 558.311.

[61 FR 51590, Oct. 3, 1996]

§ 558.460 Penicillin.

(a) Specifications. As penicillin procaine G or feed grade penicillin procaine.

(b) Related tolerances. See § 556.510 of this chapter.

(c) Conditions of use. (1) It is used as follows:

<table>
<thead>
<tr>
<th>Penicillin in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 2.4 to 50</td>
<td>chickens, turkeys, and pheasants; growth promotion and feed efficiency.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ii) 5 to 20</td>
<td>quail; growth promotion and feed efficiency.</td>
<td>Quail, not over 5 weeks of age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(iii) 10 to 50</td>
<td>swine; growth promotion and feed efficiency.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Penicillin in grams per ton</th>
<th>Combination in grams per ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(iv) 50 to 100</td>
<td></td>
<td>1. Chickens; prevention of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).&lt;br&gt;2. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).</td>
<td>........................................................................</td>
<td>..........</td>
</tr>
<tr>
<td>(v) 100</td>
<td></td>
<td>1. Chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis).&lt;br&gt;2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).</td>
<td>........................................................................</td>
<td>..........</td>
</tr>
</tbody>
</table>

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with §558.55.
(ii) Amprolium plus ethopatbate in accordance with §558.58.
(iii) (v) [Reserved]
(vi) Hygromycin B in accordance with §558.274.
(vii) Roxarsone and zoalene in accordance with §558.680.
(viii) Zoalene in accordance with §558.680.

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with §558.55.
(ii) Amprolium plus ethopatbate in accordance with §558.58.
(iii) (v) [Reserved]
(vi) Hygromycin B in accordance with §558.274.
(vii) Roxarsone and zoalene in accordance with §558.680.
(viii) Zoalene in accordance with §558.680.

§ 558.465 Poloxalene free-choice liquid Type C feed.

(a) Approvals. (1) Dry Type A medicated articles: 53 percent to 000069 in §510.600(c) of this chapter.
(2) Liquid Type A medicated articles: 99.5 percent to 000069 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. 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.
(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.

(§ 558.485 Pyrantel tartrate.

(a) Approvals. Type A medicated articles containing pyrantel tartrate to firms identified by drug labeler codes in §510.600(c) of this chapter for the specific usage indicated in paragraph (e) of this section:

(1) To 000069: 9.6, 19.2, 48 and 80 grams per pound, paragraph (e)(1)(i) of this section; 48 grams per pound, paragraph (e)(2) of this section.

(2) To 017800: 19.2 and 48 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(3) To 016968: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(4) [Reserved]

(5) To 017790: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) [Reserved]

(7) To 051359: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(8) To 014900: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(9) To 017490: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(10) To 043733: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(11) To 017519: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(12) To 046877: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(13) To 034936: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(14) [Reserved]

(15) To 049685: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(16) [Reserved]

(17) To 047427: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(18) To 011800: 9.6 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(19) To 050568: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(20) To 050639: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(21) [Reserved]

(22) To 017473: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(23) To 021676: 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(24) [Reserved]

(25) To 010439: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(26) [Reserved]

(27) To 017490: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(28) To 021640: 48 grams per pound, paragraph (e)(2) of this section.

(b) [Reserved]

(c) Related tolerances. See §556.560 of this chapter.

(d) Special considerations. (1) Consult 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
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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.

(iv) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

(A) 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 spp.) infections.

(B) Limitations. Do not feed to swine weighing 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 Type C feeds containing less than 15 percent crude protein.

(v) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin, 40 to 100 grams, as tylosin phosphate.

(A) Indications for use. Treatment and control of swine dysentery (vibrionic); 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.

(B) Limitations. Administer tylosin in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 grams per gallon in drinking water for 3 to 10 days, 40 to 100 grams tylosin per ton in feed for 2 to 6 weeks; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vi) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 40 grams, as lincomycin hydrochloride monohydrate.

(A) Indications for use. For control of swine dysentery; 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.

(B) Limitations. Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vii) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, then 40 grams, as
lincomycin hydrochloride monohydrate.

(A) Indications for use. For treatment and control of swine dysentery; 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.

(B) Limitations. Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ix) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, as lincomycin hydrochloride monohydrate.

(A) Indications for use. For treatment of swine dysentery; 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.

(B) Limitations. Feed 100 grams per ton 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(x) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 or 40 grams.

(A) Indications for use. For treatment and/or control of swine dysentery; for removal and control of large roundworm (Ascaris suum) infections; aid in the prevention of migration and establishment of nodular worm (Oesophagostomum spp.) infections.

(B) Limitations. Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(iii)(B) of this section.

(xi) Amount per ton. Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 200 grams as lincomycin hydrochloride monohydrate.

(A) Indications for use. For the reduction in severity of swine mycoplasma pneumonia caused by Mycoplasma hyopneumoniae; aid in the prevention of migration and establishment of large roundworms (Ascaris suum) infections; aid in the prevention of establishment of nodular worm (Oesophagostomum spp.) infections.

(B) Limitations. Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter; consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(C) Sponsor. See No. 000009 in § 510.600(c) of this chapter.

(2) Horses—(i) Amount. 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, S. edentatus, and Triodontophorus spp.), adult and 4th stage larvae small strongyles (Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp., Cylicodontophorus spp., Poteriostrongylus 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 12,000 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.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For Federal Register citations affecting § 558.485, see the List of CFR Sections Affected.
§ 558.515  **Robenidine hydrochloride.**

(a) Approvals. Type A medicated articles: 30 grams per pound to 000.004 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 in edible products. See §556.500 of this chapter.

(d) Conditions of use. It is used in feed for chickens as follows:

(i) For broiler and fryer chickens—(i) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.

(b) Limitations. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(ii) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus roxarsone, 22.5–45.4 grams (.005 percent).

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; increased rate of weight gain; in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(b) Limitations. Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as zinc bacitracin provided by Nos. 000004, 000061, and 046573 in §510.600(c) of this chapter.

(iii) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 to 200 grams.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.

(b) Limitations. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(iv) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 to 400 grams.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline.

(b) Limitations. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(v) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 500 grams.

(a) Indications for use. 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 reduction of mortality due to E. coli susceptible to chlortetracycline.

(b) Limitations. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously up to 5 days.

(vi) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus bacitracin, 4 to 50 grams (as zinc bacitracin).

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; and: in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(b) Limitations. Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as zinc bacitracin provided by Nos. 000004, 000061, and 046573 in §510.600(c) of this chapter.

(vii) Amount per ton. Robenidine hydrochloride, 30 grams (0.0033 percent) plus bacitracin, 4 to 50 grams (as bacitracin methylene disalicylate).

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix; and: in the presence of 4 to 30 grams...
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§ 558.530 Roxarsone.

(a) Approvals. Type A medicated articles: (1) 10, 20, and 50 percent to 046573 in §510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

(2) 10, 20, 50, and 80 percent to 046573 in §510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(b) Related tolerances. See §556.60 of this chapter.

(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. NADA’s for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use—(1) Growing chickens and growing turkeys—(i) Grams per ton. Roxarsone 22.7 and 45.4 (0.0025 to 0.005 percent).

(ii) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) Limitations. Withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(2) Growing chickens—(i) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) Limitations. Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(ii) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) Limitations. Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(iii) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 100 to 200.

(A) Indications for use. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.

(B) Limitations. See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 200 to 400.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

(B) **Limitations.** See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 500.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.

(B) **Limitations.** See paragraph (d)(2)(i)(B) of this section except feed for 5 days.

(3) **Growing turkeys—(i) Grams per ton.** Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) **Limitations.** Do not feed to turkeys producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing season.

(ii) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline 200.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(B) **Limitations.** See paragraph (d)(3)(i)(B) of this section except the drug should only be fed continuously for 7 to 14 days.

(iii) Grams per ton. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 400.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline. Turkey poult not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.

(B) **Limitations.** See paragraph (d)(3)(ii)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iv) **Amount.** Roxarsone 22.7 to 45.4 grams per ton (0.0025 to 0.005 percent) plus chlortetracycline, 25 milligrams per pound of body weight daily.

(A) **Indications for use.** For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(B) **Limitations.** See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(4) **Growing-finishing swine—(i) Grams per ton.** Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent).

(A) **Indications for use.** For increased rate of weight gain and improved feed efficiency.

(B) **Limitations.** Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) Grams per ton. Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) **Indications for use.** For increased rate of weight gain and improved feed efficiency; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) **Limitations.** Withdraw 5 days before slaughter; as sole source of organic arsenic; feed for not more than 14 days.

(iii) Grams per ton. Roxarsone 181.5 (0.02 percent).

(A) **Indications for use.** For the treatment of swine dysentery.

(B) **Limitations.** Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.
(iv) Grams per ton. Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) Indications for use. For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) Limitations. See paragraph (d)(4)(iii)(B) of this section.

(v) Grams per ton. Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) Indications for use. For the treatment of swine dysentery; treatment of bacterial enteritis caused by E. coli and S. choleraesuis and bacterial pneumonia caused by P. multocida susceptible to chlortetracycline.

(B) Limitations. See paragraph (d)(4)(iii)(B) of this section.

(5) Permitted combinations. It may be used in accordance with this section in combination as follows:

(i) Aklomide as in §558.35.

(ii) Amprolium as in §558.55.

(iii) Amprolium and ethopabate as in §558.58.

(iv) Bacitracin methylene disalicylate as in §558.76.

(v) Bacitracin zinc as in §558.78.

(vi) Bambermycins and bambermycins plus certain anticoccidials as in §558.95.

(vii) [Reserved]

(viii) Chlortetracycline as in §558.128.

(ix) Clopido as in §558.175.

(x) Dequorin as in §558.195.

(xi) Monensin as in §558.355.

(xii) Nequinate as in §558.356.

(xiii) Nicarbazin as in §558.366.

(xiv) Nitromide and sulfanitran as in §558.376.

(xv) Robenidine hydrochloride as in §558.515.

(xvi) Sulfaethoxine, ormetoprim as in §558.575.

(xvii) Zoalene as in §558.680.

(xviii) Penicillin and zoalene as in §558.680.

(xix) Lasalocid as in §558.311.

(xx) Lasalocid sodium and lincomycin as in §558.311.

(xxii) Monensin and virginiamycin as in §558.355.

(xxii) Monensin and bacitracin zinc as in §558.355.

(xxii) Narasin with bacitracin methylene disalicylate as in §558.363.

(xxiv) Semduramicin with bacitracin methylene disalicylate as in §558.555.

(6) Additional combinations. (i) Roxarsone may be used in combination as an aid in the reduction of lesions due to E. tenella as follows:

(A) Lasalocid as in §558.311.

(B) Lasalocid plus bacitracin methylene disalicylate as in §558.311.

(C) Lasalocid plus lincomycin as in §558.311.

(D) Lasalocid and bacitracin zinc as in §558.311.

(ii) Roxarsone may be used in combination with salinomycin as in §558.550.

(iii) Roxarsone may be used in combination with salinomycin and bacitracin methylene disalicylate as in §558.550.

(iv) Roxarsone may be used in combination with salinomycin and bacitracin zinc as in §558.550.

(v) Roxarsone may be used in combination with halofuginone hydrobromide and bacitracin methylene disalicylate as in §558.265.

(vi) Roxarsone may be used in combination with narasin as in §558.363 of this part.

(vii) Roxarsone may be used in combination with salinomycin and chlortetracycline as in §558.550.

(46 FR 52331, Oct. 27, 1981)

EDITORIAL NOTE: For Federal Register citations affecting §558.530, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§558.550 Salinomycin.

(a) Approvals. Type A medicated articles—30 or 60 grams of salinomycin activity per pound from salinomycin sodium biomass:

(1) To 000004 in §510.600(c) of this chapter for use of 30 and 60 grams per pound as in paragraph (b) of this section.

(2) To 012799 for use of 30 and 60 grams per pound as in paragraphs (b)(1)(i), (b)(1)(ii) through (b)(1)(xxi), and (b)(3)(i) through (b)(3)(iii) of this section.

(b)(c) [Reserved]

(d) Conditions of use. (1) Broilers: It is used as follows:

(i)(a) Amount per ton. Salinomycin 40 to 60 grams.
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(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 layers. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(iii)(a) Amount per ton. Salinomycin 40 to 60 grams and roxarsone 45.4 grams.

(b) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. acervulina, E. maxima, E. brunetti, and E. mivati, including some field strains of E. tenella which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone and bacitracin as provided by No. 046573 in §510.600(c) of this chapter.

(vi)(a) Amount per ton. Salinomycin 40 to 60 grams per ton with roxarsone 22.7 to 45.4 grams per ton.

(b) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima and for improved feed efficiency.

(c) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in §510.600(c) of this chapter.

(vi)(a) Amount per ton. Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 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 MD as provided by No. 046573 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. 000004 in §510.600(c) of this chapter.

(viii)(a) Amount per ton. Salinomycin 40 to 60 grams and bacitracin zinc 4 to 50 grams.
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(b) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, including some field strains of E. tenella which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain and improved feed efficiency.

(c) Limitations. See paragraph (b)(1)(iv)(c) of this section.

(xi) (a) Amount per ton. Salinomycin 40 to 60 grams, virginiamycin 5 grams, and roxarsone 45.4 grams.

(b) Indications for use. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, including some field strains of E. tenella which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(c) Limitations. Feed continuously as sole ration. Withdraw 5 days prior to slaughter. Use as sole source of organic arsenic. Do not approved for use with pelleted binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 046573 in §510.600(c) of this chapter. Roxarsone as provided by No. 046573 in §510.600(c) of this chapter.

(xiii) (a) Amount per ton. Salinomycin 40 to 60 grams and lincomycin 2 to 4 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 pelleted binders. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Lincomycin hydrochloride monohydrate as provided by No. 000009 in §510.600(c) of this chapter.

(xiv) (a) Amount per ton. Salinomycin 40 to 60 grams, roxarsone 45.4 grams, and lincomycin 2 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, including some field strains of E. tenella that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(c) Limitations. Feed continuously as sole ration. Not approved for use with pelleted binders. Drug overdose or lack of water may result in leg weakness. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits,
hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Withdraw 5 days before slaughter. Lincomycin hydrochloride monohydrate as provided by No. 000009 in §510.600(c) of this chapter. Roxarsone as provided by No. 046573 in §510.600(c) of this chapter.

(xvi)(a) Amount per ton. Salinomycin 40 to 60 grams, chlortetracycline 500 grams, and roxarsone 45.4 grams.

(b) Indications for use. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, including some field strains of E. tenella which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and as an aid in the reduction of mortality due to E. coli infections susceptible to such treatment.

(c) Limitations. Do not feed to layers. In feeds containing 0.8 percent dietary calcium, not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 5 days before slaughter. May be fatal if accidentally fed to adult turkeys or to horses. Chlortetracycline as provided by No. 000004 and roxarsone as provided by No. 046573 in §510.600(c) of this chapter.

(xvii)(a) Amount per ton. Salinomycin 40 to 60 grams and chlortetracycline 500 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 reduction of mortality due to E. coli infections susceptible to such treatment.

(c) Limitations. Do not feed to layers. In feeds containing 0.8 percent dietary calcium. Not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by No. 000004 in §510.600(c) of this chapter.

(xviii)(a) Amount per ton. Salinomycin 40 to 60 grams with roxarsone 34.1 or 45.4 grams and bacitracin methylene disalicylate 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, including some field strains of E. tenella that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain. Use of 34.1 or 45.4 grams per ton roxarsone is indicated to meet the E. tenella challenge which varies with environmental and management conditions.

(C) Limitations. Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to laying chickens. May be fatal if accidentally fed to adult turkeys or horses. Poultry should have access to drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Salinomycin as provided by No. 000004 in §510.600(c) of this chapter. Roxarsone and bacitracin as provided by No. 046573 in §510.600(c) of this chapter.

(2) Quail—(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.

(ii) [Reserved]

(3) Roaster and replacement (breeder and layer) chickens: It is used as follows:

(i) Amount per ton. Salinomycin 40 to 60 grams.


(iii) 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.

(4) Permitted combinations. Salinomycin may be used as in this section in combinations as follows:

(i) Bambermycins and roxarsone as in §558.95.

(ii) Bambermycins as in §558.95.

(iii) Oxytetracycline as in §558.450.
Sections Affected in the Finding Aids section of this volume.

**EDITORIAL NOTE:** At 62 FR 23034, May 29, 1997, in §558.550, paragraph (b) was redesignated as paragraph (d). At 62 FR 60781, Nov. 13, 1997, paragraph (b)(1)(vii)(c) was amended by removing “No. 000004” and adding in its place “Nos. 000004 and 046573” and at 62 FR 66985, Dec. 23, 1997, paragraph (b)(1)(ix)(c) was amended by removing “No. 000004” and adding in its place “Nos. 000004 and 046573”. Since §558.550(b) does not exist, these amendments could not be incorporated.

§558.555 Semduramicin.

(a) Approvals. Type A medicated article containing 5.13 percent semduramicin sodium (equivalent to 50 grams semduramicin per kilogram or 22.7 grams per pound) to 000069 in §510.600(c) of this chapter.

(b) Conditions of use. (1) Broilers: (i) Amount. Semduramicin: 25 parts per million.

(ii) Indications for use. For the prevention of coccidiosis caused by *Eimeria* tenella, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/E. mitis*.

(iii) Limitations. Do not feed to laying hens.

(2) Amount. Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams and roxarsone 45.4 grams per ton.

(i) Indications for use. For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, and for improved feed efficiency in broiler chickens.

(ii) Limitations. Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Semduramicin as provided by 000069, bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter.

(4) Amount. Semduramicin 22.7 grams with roxarsone 45.4 grams per ton.

(i) Indications for use. For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.

(ii) Limitations. Feed continuously as sole ration. Withdraw 5 days before slaughter. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Roxarsone as provided by 046573, semduramicin as provided by 000069 in §510.600(c) of this chapter.


§558.575 Sulfadimethoxine, ormetoprim.

(a) Approvals. Type A medicated articles to sponsors as identified in §510.600(c) of this chapter for uses as in paragraph (c) of this section as follows:

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim to 000004 for use for poultry as in paragraphs (c)(1), (2), (3), and (4) of this section.

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim to 000004 for use for fish as in paragraphs (c)(5) and (6) of this section.

(b) Related tolerances. See §§556.490 and 556.640 of this chapter.

(c) 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). |

| (2) Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent). |

| (3) Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent). |

| (4) Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent). |

| (5) Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent). |

| (6) 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) 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); growth promotion and feed efficiency; improving pigmentation.

(b) Limitations. Withdraw 5 days before slaughter; as sole source of organic arsenic.

(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. meleagritidis_ 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 (0.03 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, P. 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 for 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.

§ 558.586 Sulfaquinoxoline.

(a) Approvals. Type A medicated articles: 40 percent to 050749 in §510.600(c) of this chapter.
(b) Related tolerances. See §556.660 of this chapter.
(c) Conditions of use. It is used as follows:
   (1) Chickens—(i) Amount. 0.015 percent.
      (a) Indications for use. 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.
      (b) Limitations. 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.

(ii) Amount. 0.0175 percent.
(a) Indications for use. 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.
(b) Limitations. 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.

(iii) Amount. 0.05 to 0.1 percent.
(a) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, and E. brunetti.
(b) Limitations. 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.

(2) Turkeys—(i) Amount. 0.0175 percent.
(a) Indications for use. As an aid in preventing outbreaks of coccidiosis caused by Eimeria meleagrimitis and E. adenoeides.
(b) Limitations. Feed 0.0175 percent continuously during time birds are closely confined. May be continued for 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.

(ii) Amount. 0.05 percent.
(a) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by Eimeria meleagrimitis, and E. adenoeides.
(b) Limitations. Feed 0.05 percent 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 till 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.

(3) Chickens and turkeys—(i) Amount. 0.05 or 0.1 percent.
(a) Indications for use. 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.
(b) Limitations. 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.

(ii) [Reserved]
(4) Rabbits—(i) Amount. 0.025 percent.
(a) Indications for use. As an aid in preventing coccidiosis caused by Eimeria stiedae.
(b) Limitations. Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2
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(iii) Amount. 0.1 percent.

(a) Indications for use. As an aid in controlling outbreaks of coccidiosis caused by *Eimeria stiedae*.

(b) Limitations. Feed for 2 weeks. Do not treat within 10 days of slaughter.


§ 558.600 Tiamulin.

(a) Approvals. Type A article containing 5, 10, or 113.4 grams of tiamulin (as tiamulin hydrogen fumarate) per pound to 000010 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.738 of this chapter.

(c) Conditions of use in swine—(1) Amount. 35 grams of tiamulin per ton.

(i) Indications for use. For control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) Limitations. 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. Not for use in swine over 250 pounds body weight. Use as only source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, semduramicin, or salinomycin) as adverse reactions may occur.

(2) Amount. 10 grams of tiamulin per ton.

(i) Indications for use. For increased rate of weight gain and improved feed efficiency.

(ii) Limitations. Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds. Use as sole source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, or salinomycin) as adverse reactions may occur.

(3) Amount. 200 grams of tiamulin per ton.

(i) Indications for use. Treatment of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) Limitations. Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter. Not for use in swine over 113.40 kilograms (250 pounds) body weight. Use as the only source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, semduramicin, or salinomycin) as adverse reactions may occur.

(4) Amount per ton. 35 grams of tiamulin (as tiamulin hydrogen fumarate), plus the equivalent of approximately 400 grams of chlortetracycline hydrochloride varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline per pound of body weight daily.

(i) Indications for use. Treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) Limitations. Feed continuously as sole ration for 14 days. Not for use in swine weighing over 250 pounds. Use as only source of chlortetracycline and tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., monensin, salinomycin, narasin, semduramicin, and lasalocid) as adverse reactions may occur. If signs of toxicity occur, discontinue use. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 000004 and 046573 in §510.600(c) of this chapter.


§ 558.615 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...
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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., 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 Trichostrongylus colubriformis and axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.; less effective against those of Haemonchus contortus and Oesophagostomum spp.).

(ii) Limitations. Use 3 grams per 100 lb. body weight at a single dose; 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.

(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.

(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., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp., and Oesophagostomum spp.).

(b) Limitations. 5 grams per 100 lb. body weight at a single dose; do not treat animals within 3 days of slaughter.

(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.

§ 558.618 Tilmicosin.

(a) Approvals. Type A medicated articles: 90.7 grams of tilmicosin (as tilmicosin phosphate) per pound (200 grams per kilogram) to 000986 in §510.600(c) of this chapter.

(b) Special considerations. Do not use in any feed containing bentonite.

(c) Related tolerances. See §556.735 of this chapter.

(d) Conditions of use. It is used in swine feed as follows:

(1) Amount per ton. 181 grams to 363 grams tilmicosin.

(2) Indications for use. For the control of swine respiratory disease associated with Actinobacillus pleuropneumoniae and Pasteurella multocida.

(3) Limitations. For use in swine feed only. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Withdraw 7 days before slaughter. Federal law restricts this drug to use under the professional supervision of a licensed veterinarian. Any animal feed bearing or containing this drug shall be fed to animals only by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian’s professional practice. VFD’s for tilmicosin phosphate shall not be refilled.

(4) VFD Requirements. This drug and any article or feed manufactured from it shall bear the following cautionary statements: “Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian’s professional practice.” A VFD shall contain the following information: The name, address, and phone number of the veterinarian and the client; identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals; date of treatment and, if different, date of prescribing the VFD drug; the condition or disease being diagnosed or treated; name of the animal drug; level of animal drug in feed and amount of feed; feeding instructions with withdrawal time; any special instructions and cautionary statements necessary for use of the drug in conformance with the approval; expiration date of VFD; number of refills, if permitted by approval; signature of the veterinarian; veterinarian’s license number and name of the State issuing the license.


§ 558.625 Tylosin.

(a) Specifications. Tylosin is the antibiotic substance produced by growth of Streptomyces fradiae or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled “Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,” which is incorporated by reference.

(b) Approvals. Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in §510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(2) To 051359: 1, 2, 4, 5, 8, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(v)(a) of this section; 10 and 40 grams per pound,
(6) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(7) To 043727: 4 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(8) To 017519: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(9) To 035393: 0.4 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1)(i), (ii), (iii), (iv), and (vi) of this section.

(10) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(11) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(12) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(13) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(14) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1)(i), (ii), (iii), (iv), and (vi) of this section.

(15) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(16) To 029341: 5 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(17) To 010439: 0.4, 0.5, and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

(18) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(19) To 028459: 0.4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(20) (22) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(21) (24) To 017139: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(22) To 025282: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(23) (25) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(24) (26) To 017519: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(25) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(26) (28) To 018930: 1 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(27) To 000069: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(28) (30) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(29) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(30) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.
(68) To 017473: 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(69)–(72) [Reserved]
(73) To 050998: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi)(a) of this section; 0.8, 1, 2, and 10 grams per pound, paragraphs (f)(1) (i) and (vi) (a), (b) and (d) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(74)–(76) [Reserved]
(77) To 050695: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (a), (b), and (d) of this section.
(79) To 012286: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(80) To 049665: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(81)–(82) [Reserved]
(83) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(84) [Reserved]
(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
(86)–(88) [Reserved]
(89) To 053389: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.
(c) Limitations. As tylosin phosphate: withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24-48 hours at 3 to 5 weeks of age.
(iii) Chickens—(a) Amount per ton. Tylosin, 4-50 grams.
(1) Indications for use. For increased rate of weight gain and improved feed efficiency.
(2) Limitations. As tylosin phosphate.
(iv) Laying chickens—(a) Amount per ton. Tylosin, 20-50 grams.
(b) Indications for use. For improved feed efficiency.
(c) Limitations. As tylosin phosphate.
(v) Replacement chickens—(a) Amount per ton. Tylosin, 1,000 grams.
(b) Indications for use. To aid in the control of chronic respiratory disease caused by Mycoplasma gallisepticum.
(c) Limitations. As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.
(vi) Swine—(a) Amount per ton. Tylosin, 10-100 grams.
(1) Indications for use. For increased rate of weight gain and improved feed efficiency.
(2) Limitations. As tylosin phosphate; continuous use as follows: Grams per ton: 20-100, prestarter or starter; 20-40, grower; 10-20, finisher.
(b) Amount per ton. Tylosin, 40-100 grams.
(1) Indications for use. Prevention of swine dysentery (vibricon).
§ 558.630 Tylosin and sulfamethazine.

(1) Indications for use. Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) Limitations. As tylosin phosphate.

(2) Tylosin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Hygromycin B as in §558.274.

(ii) Melengestrol acetate alone or in combination with certain ionophores in accordance with §558.342.

(iii) [Reserved]

(iv) Monensin in accordance with §558.355.

(v) Pyrantel tartrate in accordance with §558.485.

(e) Amount per ton. Tylosin 100 grams.

Indications for use. Prevention and/or control of procine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis.

(2) Limitations. As tylosin phosphate, administer for 21 days.

[40 FR 13959, Mar. 27, 1975]

Editorial Note: For Federal Register citations affecting §558.625, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 558.635 Virginiamycin.

(a) [Reserved]

(b) Approvals. Type A medicated articles, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in §510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section.

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i) of this section.

(2) To 000986: 10 grams per pound each, paragraph (f)(2)(i) of this section.

(3) To 017519: 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(4) To 021780: 2 grams per pound each, paragraph (f)(2)(ii) of this section.

(5) To 017800: 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(6) To 017139: 4, 10, or 20 grams per pound each, paragraph (f)(2)(ii) of this section.

(7) To 021930: 2 grams per pound each, paragraph (f)(2)(ii) of this section; 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(8) To 017519, 026186: 5 or 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(9) [Reserved]

(10) To 010439, 011749, 016968, 017473, 017519, 017790, 021780, 024174, 030841, 034596, 035098, 043727, 043733, 046573, 046987, 050568, 050639, and 051359, 053389: 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(c)–(d) [Reserved]

(e) Related tolerances. See §§556.670 and 556.740 of this chapter.

(f) Conditions of use. It is used in feed for swine as follows:

(1) Amount per ton. Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) Indications for use. (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of Bordetella bronchiseptica rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (Pasteurella multocida and/or Corynebacterium pyogenes); for 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.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of Bordetella bronchiseptica rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (Pasteurella multocida and/or Corynebacterium pyogenes).

(3) Limitations. As tylosin phosphate; withdraw 15 days before slaughter.

[40 FR 13959, Mar. 27, 1975]

Editorial Note: For Federal Register citations affecting §558.630, see the List of CFR Sections Affected in the Finding Aids section of this volume.
Food and Drug Administration, HHS

§ 558.680

Zoalene.

(a) Approvals. Type A medicated articles: 25 percent to 046573 in §510.600(c) of this chapter.

(b) Related tolerances. See §556.770 of this chapter.

(c) Conditions of use—(1) Chickens and turkeys:

(i) 10 to 20 grams per ton for increased rate of weight gain and improved feed efficiency in growing turkeys.

(ii) 16.0 to 22.5 grams per ton to provide 100 to 340 milligrams per head per day for increased rate of weight gain.

(iii) 13.5 to 16.0 grams per ton to provide 85 to 240 milligrams per head per day for reduced incidence of liver abscesses.

(iv) 11.0 to 16.0 grams per ton to provide 70 to 240 milligrams per head per day for improved feed efficiency.

(v) Feed continuously as sole ration to cattle fed in confinement for slaughter. Not for use in animals intended for breeding.

(vi) Virginiamycin may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Monensin sodium in accordance with §558.355.

(ii) Lasalocid sodium in accordance with §558.311.

(iii) Monensin and roxarsone as in §558.355.

(iv) Amprolium and ethopabate as in §558.38.

(v) Halofuginone as in §558.265.

(vi) Salinomycin alone or with roxarsone as in §558.550.

[40 FR 13959, Mar. 27, 1975]
<table>
<thead>
<tr>
<th>Zoalene in grams/ton</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
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</thead>
<tbody>
<tr>
<td>(i) 36.3–113.5 (0.004–0.0125%)</td>
<td>Replacement chickens; development of active immunity to coccidiosis.</td>
<td>Grower ration not to be fed to birds over 14 weeks of age; as follows: Growing condition: severe exposure; Starter ration: 113.5 (0.0125%) grams per ton; Grower ration: 75.4–113.5 (0.0083%–0.0125%) grams per ton. Growing condition: light to moderate exposure; Starter ration: 75.4–113.5 (0.0083%–0.0125%) grams per ton; Grower ration: 36.3–75.4 (0.004%–0.0083%) grams per ton.</td>
<td></td>
</tr>
<tr>
<td>Arsanilate sodium 90 (0.01%)</td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days (d) before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%)</td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5</td>
<td>Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.</td>
<td>As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 92.5</td>
<td>1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
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<tr>
<td></td>
<td>2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Feed for 7 to 14 d; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 185.</td>
<td>Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.</td>
<td>Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.</td>
<td>As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td>Bacitracin 100 to 500.</td>
<td>Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.</td>
<td>As bacitracin zinc; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
<td></td>
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</tbody>
</table>
### Food and Drug Administration, HHS § 558.680

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Chlortetracycline</strong> 100 to 200.</td>
<td>Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
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<tr>
<td><strong>Chlortetracycline</strong> 200 to 400.</td>
<td>Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and Escherichia coli susceptible to chlortetracycline.</td>
<td>Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
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<tr>
<td><strong>Erythromycin</strong> 4.6 to 18.5.</td>
<td>Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.</td>
<td>As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td><strong>Erythromycin</strong> 92.5.</td>
<td>1. Replacement chickens, as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis.</td>
<td>Feed for 2 d before stress and 3 to 6 after stress; withdraw 24 hours (h) before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
<td></td>
</tr>
<tr>
<td><strong>Erythromycin</strong> 185.</td>
<td>Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
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<tr>
<td><strong>Erythromycin</strong> 92.5.</td>
<td>2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis.</td>
<td>Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
<td></td>
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<tr>
<td><strong>Hygromycin B</strong> 8 to 12.</td>
<td>Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (Ascaris galli) cecal worms (Heterakis gallinae) and capillary worms (Capillaria esbiniae).</td>
<td>Grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
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<td><strong>Penicillin</strong> 2.4 to 50.</td>
<td>Replacement chickens; development of active immunity to coccidiosis.</td>
<td>As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).</td>
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<tr>
<td><strong>Penicillin</strong> 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).</td>
<td>Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.</td>
<td>As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
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<tr>
<td><strong>Roxarsone</strong> 22.7 to 45.5 (0.0025% to 0.005%).</td>
<td>Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).</td>
<td></td>
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<tr>
<td>(ii) 113.5 (0.0125%).</td>
<td>Broiler chickens; prevention and control of coccidiosis.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
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<tr>
<td><strong>Arsanilate sodium</strong> 90 (0.01%).</td>
<td>Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td><strong>Arsanilic acid</strong> 90 (0.01%).</td>
<td>Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
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<tr>
<td>Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.</td>
<td>Broiler chickens; growth prevention and control of coccidiosis; improving pigmentation.</td>
<td>As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td>Do.</td>
</tr>
</tbody>
</table>
| Arsanilic acid 90 (0.01%) plus erythromycin 92.5. | 1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis.  
2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza. | Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic. | Do. |
| Arsanilic acid 90 (0.01%) plus erythromycin 185. | Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation. | As procaine penicillin; withdraw 5 d before slaughter; as sole source of organic arsenic. | As bacitracin methylene disalicylate or zinc bacitracin. |
| Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50. | Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation. | Withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate. | As bacitracin methylene disalicylate or zinc bacitracin. |
| Arsanilic acid 90 (0.01%) plus bacitracin 4 to 50. | Broiler chickens; prevention and control of coccidiosis; improving pigmentation; growth promotion and feed efficiency. | As bacitracin methylene disalicylate or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic. | As bacitracin methylene disalicylate or zinc bacitracin. |
| Bacitracin 4 to 50. | Broiler chickens; treatment of chronic respiratory disease (air sac infection); blue comb (non-specific infectious enteritis); prevention and control of coccidiosis. | As bacitracin methylene disalicylate or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic. | As zinc bacitracin. |
| Bacitracin 100 to 500. | As chlortetracycline. | Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d. | As chlortetracycline. |
| Chlortetracycline 100 to 200 | Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by M. synoviae susceptible to chlortetracycline. | Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d. | As chlortetracycline. |
| Chlortetracycline 200 to 400 | Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and E. coli susceptible to chlortetracycline. | Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d. | As chlortetracycline. |
| Erythromycin 4.6 to 18.5. | Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis. | Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate. | As erythromycin thiocyanate. |
| Erythromycin 92.5. | 1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis.  
2. Broiler chicken; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis. | Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate. | Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate. |
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<table>
<thead>
<tr>
<th>Zoalene in grams/ton</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin 185.</td>
<td>Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis.</td>
<td>Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.</td>
<td></td>
</tr>
<tr>
<td>Hygromycin B 8 to 12.</td>
<td>Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms (Ascaris galli) cecal worms (Heterakis gallinae) and capillary worms (Capillaria obtuigata).</td>
<td>Do not feed to laying chickens; to be fed as the sole ration; as hygromycin hydrochloride monohydrate provided by No. 000009 in § 510.600(c) of this chapter.</td>
<td></td>
</tr>
<tr>
<td>Lincomycin 2.</td>
<td>Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis.</td>
<td>As procaine penicillin.</td>
<td></td>
</tr>
<tr>
<td>Penicillin 2.4 to 50.</td>
<td>Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic; as procaine penicillin.</td>
<td></td>
</tr>
<tr>
<td>Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%).</td>
<td>Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>Withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Roxarsone 22.7 to 45.4 (0.0025 to 0.005%).</td>
<td>Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanilate sodium 90 (0.01%).</td>
<td>Turkeys; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.</td>
<td>For turkeys grown for meat purposes only; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
<tr>
<td>Arsanilic acid 90 (0.01%), Carbamone (not U.S.P.) 277 to 340.5 (0.025% to 0.0375%).</td>
<td>Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead.</td>
<td>For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.</td>
<td></td>
</tr>
</tbody>
</table>

(ii) 113.5 to 170.3 (0.0125 to 0.01875%).

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Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).

Turkeys; growth promotion and feed efficiency; improving pigmentation.

Withdraw 5 d before slaughter; as sole source of organic arsenic.

Partial 564—Definitions and Standards for Animal Food

Subpart A—General Provisions

Sec. 564.3 Definitions and interpretations.

564.5 Procedure for establishing a food standard.

564.6 Review of Codex Alimentarius Food Standards.

564.8 Conformity to definitions and standards of identity.

564.12 General methods for water capacity and fill of container.
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564.14 General statements of substandard quality and substandard fill of container.
564.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

Subpart B—Food Additives in Standardized Animal Food

564.20 Food additives proposed for use in animal foods for which definitions and standards of identity are established.


Source: 41 FR 38641, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 564.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 of the act contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

(d) Safe and suitable means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

(3) Is not a food additive or color additive as defined in section 201(s) or (t) of the act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 721 of the act.

§ 564.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by part 10 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.


§ 564.6 Review of Codex Alimentarius Food Standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without
change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the Federal Register as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the Federal Register the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the Federal Register for review and informal comment. Interested persons shall be requested to comment on the desirability and need for the standard, on the specific provisions of the standard, on additional or different provisions that should be included in the standard, and on any other pertinent points. After reviewing all such comments, the Commissioner either shall publish a proposal to establish a food standard pursuant to section 401 of the act covering the food involved, or shall publish a notice terminating consideration of such a standard.

(c) All interested persons are encouraged to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating petitions or comments pursuant to paragraph (b) of this section. All such petitions or comments are requested to include a statement of any meetings and discussions that have been held with other interest groups. Appropriate weight will be given by the Commissioner to petitions or comments that reflect a consensus of different interest groups.

§ 564.8 Conformity to definitions and standards of identity.

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in §501.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

§ 564.12 General methods for water capacity and fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term general method for water capacity of containers means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68 °F to 3⁴⁄₁₆ inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in paragraph (a)(2) of this section from the weight found in paragraph (a)(3) of this section. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraph (a)(2) to (4) of this section, except that under paragraph (a)(3) of this section, fill the container to the level of the top thereof.
§ 564.14 General method for fill of containers

(b) The term general method for fill of containers means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to \( \frac{3}{16} \) inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by subtracting the weight of the container found in paragraph (b)(3) of this section.

(5) Maintaining the water at the temperature recorded in paragraph (b)(4) of this section, draw off water from the container as filled in paragraph (b)(4) of this section to the level of the food found in paragraph (b)(2) of this section, weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in paragraph (b)(3) of this section.

(6) Divide the weight of water found in paragraph (b)(5) of this section by the weight of water found in paragraph (b)(4) of this section, and multiply by 100. The result shall be considered to be the percent of the total capacity of the container occupied by the food.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraph (b)(2) to (6) of this section, except that under paragraph (b)(4) of this section, fill the container to the level of the top thereof.

§ 564.14 General statements of substandard quality and substandard fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term general statement of substandard quality means the statement “Below Standard in Quality Good Food—Not High Grade” printed in two lines of Cheltenham bold condensed caps. The words “Below Standard in Quality” constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is on a strongly contrasting, uniform background, and is so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

(b) The term general statement of substandard fill means the statement “Below Standard in Fill” printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, uniform background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

§ 564.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(a) The Food and Drug Administration recognizes that before petitions to amend food standards can be submitted, appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of experimental packs of food varying from applicable definitions and standards of identity prescribed under section 401 of the act.
(b) It is the purpose of the Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards, that the tests are necessary to the completion or conclusiveness of an otherwise adequate investigation, and that the interests of consumers are adequately safeguarded; permits for such tests shall normally be for a period not to exceed 15 months. The Commissioner, for good cause shown by the applicant, may provide for a longer test market period. The Administration will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Commissioner providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity. The test period will begin on the date the person holding an effective permit from the Commissioner introduces or causes the introduction of the food covered by the permit into interstate commerce but no later than 3 months after notice of the issuance of the permit is published in the Federal Register. The Commissioner shall be notified in writing of the date on which the test period begins as soon as it is determined.

(c) Any person desiring a permit may file with the Commissioner a written application in triplicate containing as part thereof the following:

1. Name and address of the applicant.
2. A statement of whether or not the applicant is regularly engaged in producing the food involved.
3. A reference to the applicable definition and standard of identity (citing applicable section of regulations).
4. A full description of the proposed variation from the standard.
5. The basis upon which the food so varying is believed to be wholesome and nondeleterious.
6. The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.
7. The purpose of effecting the variation.
8. A statement of how the variation is of potential advantage to consumers. The statement shall include the reasons why the applicant does not consider the data obtained in any prior investigations which may have been conducted sufficient to support a petition to amend the standard.
9. The proposed label (or an accurate draft) to be used on the food to be market tested. The label shall conform in all respects to the general requirements of the act and shall provide a means whereby the consumer can distinguish between the food being tested and such food complying with the standard.
10. The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the need for such period. If a period longer than 15 months is requested, a detailed explanation of why a 15-month period is inadequate shall be provided.
11. The probable amount of such food that will be distributed. The amount distributed should be limited to the smallest number of units reasonably required for a bona fide market test. Justification for the amount requested shall be included.
12. The areas of distribution.
13. The address at which such food will be manufactured.
14. A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.
15. If it has not been or is not to be so distributed, a statement showing why.
16. If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Commissioner may require the applicant to furnish samples of the
§ 564.20 Food additives proposed for use in animal foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the Federal Register granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market test shall notify the Commissioner in writing that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the Federal Register.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the Federal Register. Such disclosure shall be in accordance with the rules established in part 20 of this chapter.

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

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provisions of the regulations in this subchapter E shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this Subchapter E.

PART 570—FOOD ADDITIVES

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.


(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 in the United States.

(g) The word substance in the definition of the term food additive of foods, food or feed or a component of a food or feed consisting of one or more ingredients.

(h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.
§ 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


§ 570.6 Opinion letters on food additive status.

\[21 CFR Ch. I (4-1-98 Edition)\]
§ 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.

§ 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.

§ 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.

§ 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.
§ 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
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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 about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

(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 regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, 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.

(d) The food ingredients listed as GRAS in part 582 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 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.
§ 570.35  Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, either on his initiative or on the petition of an interested person, may affirm the GRAS status of substances that directly or indirectly become components of food.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS, he will place all of the data and information on which he relies on public file in the office of the Dockets Management Branch 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 Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch’s office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS as defined in § 570.3(k), he will publish a notice in the Federal Register listing the substance in this subchapter E as GRAS.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the Federal Register in accordance with § 570.38.

(c)(1) Persons seeking the affirmation of GRAS status of substances as provided for in § 570.30(e), except those subject to the NAS-NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to part 10 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 570.30(b) have been met, in the following form:

(i) Description of the substance, including:

(a) Common or usual name.
(b) Chemical name.
(c) Chemical Abstract Service (CAS) registry number.
(d) Empirical formula.
(e) Structural formula.
(f) Specifications for food grade material, including arsenic and heavy metals. (Recommendation for any change in the Food Chemicals Codex monograph should be included where applicable.)

(g) Quantitative compositions.

(h) Manufacturing process (excluding any trade secrets).

(i) Use of the substance, including:
   (a) Date when use began.
   (b) Information and reports or other data on past uses in food.
   (c) Foods in which used, and levels of use in such foods, and for what purposes.

(iii) Methods for detecting the substance in food, including:
   (a) References to qualitative and quantitative methods for determining the substance(s) in food, including the type of analytical procedures used.
   (b) Sensitivity and reproducibility of such method(s).

(iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evidence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions 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.

(vii) [Reserved]

(viii) A claim for categorical exclusion under §25.30 or 25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

(2) Within 30 days after the date of filing the petition, the Commissioner will place the petition on public file in the Dockets Management Branch and will publish a notice of filing in the Federal Register giving the name of the petitioner and a brief description of the petition including the name of the substance, its proposed use, and any limitations proposed for reasons other than safety. A copy of the notice will be mailed to the petitioner at the time the original is sent to the Federal Register.

(3) The notice of filing in the Federal Register will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch.

(4) The Commissioner will evaluate the petition and all available information including all comments received. If the petition and such information provide convincing evidence that the substance is GRAS as defined in §570.3, he will publish an order in the Federal Register listing the substance in this subchapter E as GRAS.

(5) If, after evaluation of the petition and all available information, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the Federal Register in accordance with §570.3.

(6) The notice of filing in the Federal Register will request submission of proof of any applicable prior sanction for use of the ingredient under conditions different from those proposed to be determined to be GRAS. The failure of any person to come forward with proof of such an applicable prior sanction in response to the notice of filing will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice of filing will also constitute a proposal to establish a regulation under this subchapter.
§ 570.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 570.35 (b)(4) or (c)(5), publish a notice in the Federal Register determining that a substance is not GRAS and is a food additive subject to section 409 of the 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 Dockets Management Branch 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.

(b)(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 Dockets Management Branch. Copies of all comments shall be made available for examination in the Dockets Management Branch.

(b)(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.

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(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.
§ 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:

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<thead>
<tr>
<th>(Date)</th>
</tr>
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<tbody>
<tr>
<td>Name of petitioner</td>
</tr>
<tr>
<td>Post office address</td>
</tr>
<tr>
<td>Date</td>
</tr>
</tbody>
</table>
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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
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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 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.

(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
§ 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 for the noncompliance.


§ 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.


§ 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 require-
ments of subpart E of part 500 of this chapter.

[52 FR 40588, 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.


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.

573.180 Anhydrous ammonia.

573.200 Condensed animal protein hydrolysate.

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.

573.310 Crambe meal, heat toasted.

573.320 Di ammonium phosphate.

573.340 Diatomaceous earth.

573.360 Disodium EDTA.

573.380 Ethoxyquin in animal feeds.

573.400 Ethoxyquin in certain dehydrated forage crops.
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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.

(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 \( \text{k} \mathrm{an} \) gene originally isolated from transposon \( \text{Tn}5 \) 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 \( \text{k} \mathrm{an} \) 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

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protein and/or as a source of non-protein 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 non-protein 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."

§ 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.
§ 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.

§ 573.220 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biuret</td>
<td>55 minimum.</td>
</tr>
<tr>
<td>Urea</td>
<td>15 maximum.</td>
</tr>
<tr>
<td>Cyanuric acid and triuret</td>
<td>30 maximum.</td>
</tr>
<tr>
<td>Mineral oil</td>
<td>0.5 maximum.</td>
</tr>
<tr>
<td>Total nitrogen (equivalent to 218.75 pct crude protein)</td>
<td>35 minimum.</td>
</tr>
</tbody>
</table>

(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:

(1) The name of the additive.

(ii) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(iii) The statement "Do not feed to animals producing milk for human consumption."

(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.

§ 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.

§ 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
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§ 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.
3. The additives are manufactured so that in aqueous solution they are exposed for 1 hour or longer to temperature in excess of 100°F.
4. 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.

[63 FR 8573, Feb. 20, 1998]

§ 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 X 6.25) and 20 percent phosphorus. It contains not more than the following:

1 part fluorine to 100 parts phosphorus.
75 parts per million of 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.

§ 573.340 Choline xanthate. (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 epi-progoitrin, 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]
§ 573.340 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 dihydride (C7H14O7N2Na2.2H2O).

(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:

- The name of the additive; and
- 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:

- The name of the additive, ethoxyquin.
- A statement of the concentration or strength contained therein.
- 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 albus.
  - Yellow sweetclover: Melilotus officinalis.
  - Coastal Bermudagrass: Cynodon dactylon.
- Corn: Zea mays.
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§ 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, 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.

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(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, 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.

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(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.

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(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, 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.
§ 573.460 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a)(1) The additive is used, or intended for use, to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing therefrom a dry, free-flowing product as follows:

(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., 1976 ed., pages 86, 103, and 109.

(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.

(2) The dried mixture described in paragraph (a) of this section is used, or intended for use, as a component of dry, nonpelleted feeds for beef and non-lactating dairy cattle.

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling of the dried mixture described in paragraph (a) of this section shall bear:

(i) The name of the additive.

(ii) Adequate directions for use providing that feed as consumed is not to contain more than 25 percent of the mixture.

(b)(1) The food additive is formaldehyde (37 percent aqueous solution). It is used at the rate of 5.4 pounds (2.5 kilograms) per ton of poultry feed. At this level, it is an antimicrobial agent used to maintain complete poultry feeds salmonella negative for up to 14 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 poultry feeds.

(iii) Adequate directions for use including a statement that formaldehyde should be thoroughly mixed into complete poultry feed and that the finished poultry feed shall be labeled as containing formaldehyde.

(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 National Environmental Protection Act (NEPA), 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).


§ 573.480 Formic acid.

Formic acid may be safely used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of
§ 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.

§ 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.

§ 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.


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 (C₁₇H₁₈O₆N₂S).

(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) Product. 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) Conditions of use. As a nutritional supplement in chicken and turkey feeds for both the prevention of vitamin K deficiency and as a source of supplemental niacin.

(c) Limitations. Not to exceed 2 grams per ton of complete feed. To assure safe use, the label and labeling shall bear adequate directions for use.

[61 FR 5, Jan. 2, 1996]

§ 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...
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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:


\[
t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{\left(\frac{s_t^2}{n_t}\right) + \left(\frac{s_c^2}{n_c}\right)}}
\]

where:

\[
x_t \text{ and } x_c \text{ are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;}
\]

\[
n_t \text{ and } n_c \text{ are the number of chicks in the respective groups;}
\]

\[
s_t^2 \text{ and } s_c^2 \text{ are the variances of the test and control groups, respectively.}
\]

The variances are calculated as follows:

\[
s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}
\]

where:

\[
\sum x \text{ is the sum of the logs of the pericardial fluid volumes;}
\]

\[
\sum x^2 \text{ is the sum of the squares of the logs of the pericardial fluid volumes for either the test or control group data.}
\]

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 1.146.

(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:

(i) 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:

(ii) The designation “feed grade” in juxtaposition with the name and equally as prominent.
§ 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.

§ 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.

<table>
<thead>
<tr>
<th>Ultraviolet absorbance per centimeter path length:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Millimicrons</td>
</tr>
<tr>
<td>280 to 289</td>
</tr>
<tr>
<td>290 to 299</td>
</tr>
<tr>
<td>300 to 359</td>
</tr>
<tr>
<td>360 to 400</td>
</tr>
</tbody>
</table>

(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:

\[
\text{HO(CH\text{\textsubscript{2}}-\text{CH}\text{\textsubscript{2}}-\text{O})\text{\textsubscript{32-36}}(\text{CH\text{\textsubscript{2}}-\text{CH\text{\textsubscript{2}}-O})\text{\textsubscript{11-13}}}H
\]

(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:

\[0.9\pm0.1 \times 0.8\pm0.1 \times 1.2\pm0.1\]

(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
§ 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:

<table>
<thead>
<tr>
<th>Component/property</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inherent viscosity</td>
<td>1.0-1.6 deciliter per gram.¹</td>
</tr>
<tr>
<td>Styrene moiety</td>
<td>40 percent maximum.</td>
</tr>
<tr>
<td>2-Vinylpyridine moiety</td>
<td>90 percent maximum.</td>
</tr>
<tr>
<td>Residual styrene</td>
<td>200 parts per billion maximum.</td>
</tr>
<tr>
<td>Residual 2-vinylstyrene</td>
<td>200 parts per billion maximum.</td>
</tr>
<tr>
<td>Heavy metals such as lead</td>
<td>&gt;10 parts per million.</td>
</tr>
<tr>
<td>Arsenic</td>
<td>&gt;3 parts per million.</td>
</tr>
</tbody>
</table>

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 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]

§ 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:

<table>
<thead>
<tr>
<th>Components</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium salts of mixed 5-carbon acids</td>
<td>48 to 54 percent.</td>
</tr>
<tr>
<td>(as identified in paragraph (a) of this section).</td>
<td></td>
</tr>
<tr>
<td>Ammonium salt of isobutyric acid</td>
<td>22 to 26 percent.</td>
</tr>
<tr>
<td>Water</td>
<td>28 percent maximum.</td>
</tr>
<tr>
<td>Ammonia</td>
<td>0.3 percent maximum.</td>
</tr>
<tr>
<td>Arsenic</td>
<td>&gt;3 parts per million.</td>
</tr>
<tr>
<td>Heavy metals as lead</td>
<td>&gt;10 parts per million.</td>
</tr>
</tbody>
</table>

(2) Calcium salts:

<table>
<thead>
<tr>
<th>Components</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium salts of mixed 5-carbon acids</td>
<td>58 to 72 percent.</td>
</tr>
<tr>
<td>(as identified in paragraph (a) of this section).</td>
<td></td>
</tr>
<tr>
<td>Calcium salt of isobutyric acid</td>
<td>26 to 34 percent.</td>
</tr>
<tr>
<td>Calcium hydroxide</td>
<td>3 percent maximum.</td>
</tr>
<tr>
<td>Water</td>
<td>14 percent maximum.</td>
</tr>
</tbody>
</table>

(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]

§ 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
§ 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) 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.”

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, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989; 60 FR 53703, Oct. 17, 1995

§ 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) 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.

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§ 573.940  Silicon dioxide.

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(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) 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.”

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§ 573.940  Silicon dioxide.

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(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) 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.”

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, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989; 60 FR 53703, Oct. 17, 1995

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(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) 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.”

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, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989; 60 FR 53703, Oct. 17, 1995

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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) 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.
Feed component & Limitations (percent)
--- & ---
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.

§ 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:

(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 in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal 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 1.5 percent of the dog feed or 5 percent of the final feed for other animals.

(ii) 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.

(iii) 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.

(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 an 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 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:

(i) In calf milk replacers at a maximum use level of 0.1 percent, as fed.
§ 573.1020

(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: Na₄Fe(Cn)₆°-10H₂O) 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 laboratory animal diets.

579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.


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.

[51 FR 5993, Feb. 19, 1986]

Subpart B—Radiation and Radiation Sources

§ 579.22 Ionizing radiation for treatment of laboratory animal diets.

Ionizing radiation for treatment of complete diets for laboratory animals (mice, rats, and hamsters) 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. The ionizing radiation is used or intended for use in single treatment as follows:

<table>
<thead>
<tr>
<th>Food for irradiation</th>
<th>Limitations</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bagged complete diets for laboratory animals (mice, rats, hamsters, rabbits, and guinea pigs).</td>
<td>Absorbed dose: Not to exceed 50 kiloGrays (5 megarads). Feeds treated by irradiation should be formulated to account for nutritional loss.</td>
<td>Microbial disinfection.</td>
</tr>
</tbody>
</table>

[51 FR 5993, Feb 19, 1986; 51 FR 8315, Mar. 11, 1986, as amended at 58 FR 18148, Apr. 8, 1993]

§ 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 gamma rays from sealed units of cobalt-60.

(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 ini-
tial 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]

PART 582—SUBSTANCES
GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.
582.1 Substances that are generally recog-
nized 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 conjunc-
tion 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, es-
ternal oils, oleoresins, and natural ex-
tracts.
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—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.
582.1196 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 Dextrins.
582.1301 Glycerin.
582.1324 Glyceryl monostearate.
582.1355 Helium.
582.1366 Hydrogen peroxide.
582.1400 Lecithin.
582.1423 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.
582.2347 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 Sorbic acid.
- 582.3089 Propionic acid.
- 582.3109 Thiodipropionic acid.
- 582.3149 Ascorbyl palmitate.
- 582.3169 Butylated hydroxyanisole.
- 582.3173 Butylated hydroxytoluene.
- 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.
- 582.3680 Potassium sorbate.
- 582.3731 Sodium ascorbate.
- 582.3733 Sodium benzoate.
- 582.3739 Sodium bisulfite.
- 582.3740 Sodium metabisulfite.
- 582.3744 Sodium propionate.
- 582.3795 Sodium sulfate.
- 582.3798 Sodium sulfite.
- 582.3813 Stannous chloride.
- 582.3820 Sulfer dioxide.
- 582.3890 Tocopherols.
- 582.3900 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.
- 582.5149 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.
- 582.5533 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.
- 582.5685 Riboflavin.
- 582.5697 Riboflavin-5-phosphate.
- 582.5701 Serine.
- 582.5772 Sodium pantothenate.
- 582.5778 Sodium phosphate.
- 582.5795 Sorbitol.
- 582.5875 Thiamine hydrochloride.
- 582.5878 Thiamine mononitrate.
- 582.5881 Threonine.
- 582.5880 Tocopherols.
- 582.5890 a-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 B₁₂.
- 582.5950 Vitamin D₂.
- 582.5953 Vitamin D₃.
- 582.5985 Zinc chloride.
- 582.5998 Zinc gluconate.
- 582.5991 Zinc oxide.
- 582.5994 Zinc stearate.
- 582.5997 Zinc sulfate.
- 582.6038 Citric acid.
- 582.6085 Sodium acid phosphate.

Subpart G—Sequestrants

- 582.6038 Citric acid.
- 582.6085 Sodium acid phosphate.
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 of 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.
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:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa herb and seed ................................</td>
<td>Medicago sativa L.</td>
</tr>
<tr>
<td>Alfalfa root ............................................</td>
<td>Pimenta officinalis L.</td>
</tr>
<tr>
<td>Ambrette seed ...........................................</td>
<td>Hibiscus abelmoschus L.</td>
</tr>
<tr>
<td>Angelica ..................................................</td>
<td>Angelica archangelica L. or other spp. of Angelica.</td>
</tr>
<tr>
<td>Angelica seed ...........................................</td>
<td>Do.</td>
</tr>
<tr>
<td>Angostura (usaha bark) ................................</td>
<td>Galipea officinalis L.</td>
</tr>
<tr>
<td>Anise ................................................................</td>
<td>Pimpinella anisum L.</td>
</tr>
<tr>
<td>Anise, star ................................................</td>
<td>Illicium verum Hook. f.</td>
</tr>
<tr>
<td>Balm (lemon balm) .......................................</td>
<td>Melissa officinalis L.</td>
</tr>
<tr>
<td>Basil, bush ................................................</td>
<td>Ocimum minimum L.</td>
</tr>
<tr>
<td>Basil, sweet ...............................................</td>
<td>Ocimum basilicum L.</td>
</tr>
<tr>
<td>Bay ..................................................................</td>
<td>Laurus nobilis L.</td>
</tr>
<tr>
<td>Calendula ..................................................</td>
<td>Calendula officinalis L.</td>
</tr>
<tr>
<td>Camomile (chamomile), English or Roman ............</td>
<td>Anthemis nobilis L.</td>
</tr>
<tr>
<td>Camomile (chamomile), German or Hungarian .......</td>
<td>Matricaria chamomilla L.</td>
</tr>
<tr>
<td>Capers ......................................................</td>
<td>Capparis spinosa L.</td>
</tr>
<tr>
<td>Capsicum ...................................................</td>
<td>Capsicum frutescens L.or Capsicum annuum L.</td>
</tr>
<tr>
<td>Caraway .....................................................</td>
<td>Carum carvi L.</td>
</tr>
<tr>
<td>Caraway, black (black cumin) .........................</td>
<td>Nigella sativa L.</td>
</tr>
<tr>
<td>Cardamom (cardamon) ...................................</td>
<td>Elettaria cardamomum Maton.</td>
</tr>
<tr>
<td>Cassia, Chinese ..........................................</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cassia, Padang or Batavia .............................</td>
<td>Cinnamomum burmannii Blume.</td>
</tr>
<tr>
<td>Cassia, Saigon ...........................................</td>
<td>Cinnamomum loureani Nees.</td>
</tr>
<tr>
<td>Cayenne pepper ...........................................</td>
<td>Capsicum frutescens L. or Capsicum annuum L.</td>
</tr>
<tr>
<td>Celery seed ................................................</td>
<td>Apium graveolens L.</td>
</tr>
<tr>
<td>Chervil .....................................................</td>
<td>Anthriscus cerefolium (L.) Hoffm.</td>
</tr>
<tr>
<td>Chives ................................................................</td>
<td>Allium schoenoprasum L.</td>
</tr>
<tr>
<td>Cinnamon, Ceylon ........................................</td>
<td>Cinnamomum zeylanicum Nees.</td>
</tr>
<tr>
<td>Cinnamon, Chinese ........................................</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cinnamon, Saigon .........................................</td>
<td>Cinnamomum loureani Nees.</td>
</tr>
<tr>
<td>Clary (clary sage) ......................................</td>
<td>Salvia sclarea L.</td>
</tr>
<tr>
<td>Clover ................................................................</td>
<td>Trifolium spp.</td>
</tr>
<tr>
<td>Cumin (cuminum) ..........................................</td>
<td>Eugenia caryophyllata Thunb.</td>
</tr>
<tr>
<td>Cumin, black (black caraway) ........................</td>
<td>Nigella sativa L.</td>
</tr>
<tr>
<td>Dill ..................................................................</td>
<td>Cuminum cyminum L.</td>
</tr>
<tr>
<td>Elder flowers ............................................</td>
<td>Nigella sativa L.</td>
</tr>
<tr>
<td>Fennel, common ................................ ..........</td>
<td>Anethum graveolens L.</td>
</tr>
<tr>
<td>Fennel, sweet (finochio, Florence fennel) ........</td>
<td>Foeniculum vulgare Mill.</td>
</tr>
<tr>
<td>Fenugreek ...................................................</td>
<td>Foeniculum vulgare Mill. var. dulce (DC.) Alex.</td>
</tr>
<tr>
<td>Galanga (galangal) ......................................</td>
<td>Trigonella foenum-graecum L.</td>
</tr>
<tr>
<td>Garlic .......................................................</td>
<td>Alium sativum L.</td>
</tr>
<tr>
<td>Geranium ....................................................</td>
<td>Pelargonium spp.</td>
</tr>
<tr>
<td>Ginger .......................................................</td>
<td>Zingiber officinale Rosc.</td>
</tr>
<tr>
<td>Glycyrhiza ................................................</td>
<td>Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.</td>
</tr>
<tr>
<td>Grains of paradise .....................................</td>
<td>Anomum melegueta Rosc.</td>
</tr>
<tr>
<td>Horehound (hoarhound) ..................................</td>
<td>Marrubium vulgare L.</td>
</tr>
<tr>
<td>Horseradish ................................................</td>
<td>Armoracia lapathifolia Gilib.</td>
</tr>
<tr>
<td>Hyssop .......................................................</td>
<td>Hyssopus officinalis L.</td>
</tr>
<tr>
<td>Lavender ....................................................</td>
<td>Lavandula officinalis Chaix.</td>
</tr>
<tr>
<td>Licorice .....................................................</td>
<td>Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.</td>
</tr>
<tr>
<td>Linden flowers ............................................</td>
<td>Tilia spp.</td>
</tr>
<tr>
<td>Mace ................................................................</td>
<td>Myristica fragrans Houtt.</td>
</tr>
<tr>
<td>Marjoram, pot ............................................</td>
<td>Calendula officinalis L.</td>
</tr>
<tr>
<td>Marjoram, sweet ..........................................</td>
<td>Majorana onites (L.) Benth.</td>
</tr>
<tr>
<td>Mustard, black or brown ................................</td>
<td>Majorana hortensis Moench.</td>
</tr>
<tr>
<td>Mustard, brown ...........................................</td>
<td>Brassica nigra (L.) Koch.</td>
</tr>
<tr>
<td>Mustard, white or yellow ................................</td>
<td>Brassica juncea (L.) Coss.</td>
</tr>
<tr>
<td>Nutmeg .......................................................</td>
<td>Brassica foetida Moench.</td>
</tr>
<tr>
<td>Oregano (oregano, Mexican oregano, Mexican sage,</td>
<td>Myristica fragrans Houtt.</td>
</tr>
<tr>
<td>Paprika .....................................................</td>
<td>Capsicum annuum L.</td>
</tr>
<tr>
<td>Parsley ......................................................</td>
<td>Capsicum frutescens L. or Capsicum annuum L.</td>
</tr>
<tr>
<td>Pepper, black .............................................</td>
<td>Do.</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS

§ 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:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pepper, white</td>
<td>Piper nigrum L.</td>
</tr>
<tr>
<td>Pepper mint</td>
<td>Mentha piperita L.</td>
</tr>
<tr>
<td>Poppy seed</td>
<td>Papaver somniferum L.</td>
</tr>
<tr>
<td>Pot marigold</td>
<td>Calendula officinalis L.</td>
</tr>
<tr>
<td>Pot marjoram</td>
<td>Majorana hortensis (L.) Benth.</td>
</tr>
<tr>
<td>Rosemary</td>
<td>Rosmarinus officinalis L.</td>
</tr>
<tr>
<td>Rue</td>
<td>Ruta graveolens L.</td>
</tr>
<tr>
<td>Saffron</td>
<td>Crocus sativus L.</td>
</tr>
<tr>
<td>Sage</td>
<td>Salvia officinalis L.</td>
</tr>
<tr>
<td>Sage, Greek</td>
<td>Salvia fruticosa L.</td>
</tr>
<tr>
<td>Savory, summer</td>
<td>Satureja hortensis L. (Satureja).</td>
</tr>
<tr>
<td>Savory, winter</td>
<td>Satureja montana L. (Satureja).</td>
</tr>
<tr>
<td>Sesame</td>
<td>Sesamum indicum L.</td>
</tr>
<tr>
<td>Spearmint</td>
<td>Mentha spicata L.</td>
</tr>
<tr>
<td>Star anise</td>
<td>Illicium verum Hook. f.</td>
</tr>
<tr>
<td>Tarragon</td>
<td>Artemisia dracunculus L.</td>
</tr>
<tr>
<td>Thyme</td>
<td>Thymus vulgaris L.</td>
</tr>
<tr>
<td>Thyme, wild or creeping</td>
<td>Thymus serpyllum L.</td>
</tr>
<tr>
<td>Turmeric</td>
<td>Curcuma longa L.</td>
</tr>
<tr>
<td>Vanilla</td>
<td>Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.</td>
</tr>
<tr>
<td>Zedoary</td>
<td>Curcuma zedoaria Rosc.</td>
</tr>
<tr>
<td>Cinnamon bark, Saigon</td>
<td>Cinnamomum loureirii Nees.</td>
</tr>
<tr>
<td>Cinnamon bark, Chinese</td>
<td>Cinnamomum zeylanicum Nees.</td>
</tr>
<tr>
<td>Cinnamon bark, Ceylon</td>
<td>Cinnamomum zeylanicum Nees.</td>
</tr>
<tr>
<td>Cinnamon bark, Saigon</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cinnamon bark, Chinese</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cinnamon bark, Saigon</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa</td>
<td>Medicago sativa L.</td>
</tr>
<tr>
<td>Alfalfa</td>
<td>Pimenta officinalis Lind.</td>
</tr>
<tr>
<td>Almond, bitter (free from prussic acid)</td>
<td>Prunus amygdalus Batsch.</td>
</tr>
<tr>
<td>Angelica root</td>
<td>Prunus armeniaca L. or Prunus</td>
</tr>
<tr>
<td>Angelica seed</td>
<td>Hibiscus moschatus Moench.</td>
</tr>
<tr>
<td>Angelica stem</td>
<td>Angelica archangelica L.</td>
</tr>
<tr>
<td>Angostura (cuminum bark)</td>
<td>Angostura (cuminum bark)</td>
</tr>
<tr>
<td>Acorus root</td>
<td>Galium officinale Hick.</td>
</tr>
<tr>
<td>Acorus stem</td>
<td>Angelica archangelica L.</td>
</tr>
<tr>
<td>Adsorbed</td>
<td>Pimpinella anisum L.</td>
</tr>
<tr>
<td>Asafetida</td>
<td>Veratrum viride L. or related spp. of Veratrum.</td>
</tr>
<tr>
<td>Balm (lemon balm)</td>
<td>Melissa officinalis L.</td>
</tr>
<tr>
<td>Balsam of Peru</td>
<td>Myrtus communis L.</td>
</tr>
<tr>
<td>Basil</td>
<td>Oenanthe asafoedita L.</td>
</tr>
<tr>
<td>Bay leaves</td>
<td>Thymus vulgaris L.</td>
</tr>
<tr>
<td>Bay (myrrh oil)</td>
<td>Thymus vulgaris L.</td>
</tr>
<tr>
<td>Bergamot (bergamot orange)</td>
<td>Thymus vulgaris L.</td>
</tr>
<tr>
<td>Bitter almond (free from prussic acid)</td>
<td>Prunus persica (L.) Batsch.</td>
</tr>
<tr>
<td>Boys de rose</td>
<td>Prunus persica (L.) Batsch.</td>
</tr>
<tr>
<td>Cacao</td>
<td>Camellia sinensis L.</td>
</tr>
<tr>
<td>Camomile (chamomile) flowers, Hungarian</td>
<td>Matricaria chamomilla L.</td>
</tr>
<tr>
<td>Camomile (chamomile) flowers, Roman or English</td>
<td>Anthemis nobilis L.</td>
</tr>
<tr>
<td>Cananga</td>
<td>Cananga odorata Hook. f. and Thoms.</td>
</tr>
<tr>
<td>Capsicum</td>
<td>Capsicum frutescens L. or Capsicum annuum L.</td>
</tr>
<tr>
<td>Caraway</td>
<td>Carum carvi L.</td>
</tr>
<tr>
<td>Cardamom seed (cardamon)</td>
<td>Elettaria cardamomum Maton.</td>
</tr>
<tr>
<td>Carob bean</td>
<td>Carum carvi L.</td>
</tr>
<tr>
<td>Carrot</td>
<td>Carum carvi L.</td>
</tr>
<tr>
<td>Cascarilla bark</td>
<td>Croton eluteria Benn.</td>
</tr>
<tr>
<td>Cassia bark, Chinese</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cassia bark, Padang or Batavia</td>
<td>Cinnamomum burmanni Blume.</td>
</tr>
<tr>
<td>Cassia bark, Saigon</td>
<td>Cinnamomum loureirii Nees.</td>
</tr>
<tr>
<td>Celery seed</td>
<td>Apium graveolens L.</td>
</tr>
<tr>
<td>Cherry, wild, bark</td>
<td>Pyrus serotina Ehrh.</td>
</tr>
<tr>
<td>Chervil</td>
<td>Anthriscus cerefolium (L.) Hoffm.</td>
</tr>
<tr>
<td>Chicory</td>
<td>Cichorium intybus L.</td>
</tr>
<tr>
<td>Cinnamon bark, Ceylon</td>
<td>Cinnamomum zeylanicum Nees.</td>
</tr>
<tr>
<td>Cinnamon bark, Chinese</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cinnamon bark, Saigon</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
</tbody>
</table>

485
<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cinnamon leaf, Ceylon</td>
<td>Cinnamomum zeylanicum Nees.</td>
</tr>
<tr>
<td>Cinnamon leaf, Chinese</td>
<td>Cinnamomum cassia Blume.</td>
</tr>
<tr>
<td>Cinnamon leaf, Saigon</td>
<td>Cinnamomum loureiri Nees.</td>
</tr>
<tr>
<td>Citronella</td>
<td>Cymbopogon nardus Rendle.</td>
</tr>
<tr>
<td>Clove bud</td>
<td>Salvia sclarea L.</td>
</tr>
<tr>
<td>Clove leaf</td>
<td>Eugenia caryophyllata Thumb.</td>
</tr>
<tr>
<td>Clove stem</td>
<td>Do.</td>
</tr>
<tr>
<td>Cardio</td>
<td>Trifolium spp.</td>
</tr>
<tr>
<td>Cocoa (decoykanized)</td>
<td>Erythroxylum coca Lam. and other spp. of Erythroxylum.</td>
</tr>
<tr>
<td>Coffee</td>
<td>Coffea spp.</td>
</tr>
<tr>
<td>Cola sin</td>
<td>Cola acuminata Schott and Endl. and other spp. of Cola.</td>
</tr>
<tr>
<td>Coriander</td>
<td>Coriandrum sativum L.</td>
</tr>
<tr>
<td>Corn silk</td>
<td>Zea mays L.</td>
</tr>
<tr>
<td>Cumin (cumum)</td>
<td>Cuminum cyminum L.</td>
</tr>
<tr>
<td>Curacao orange peel (orange, bitter peel)</td>
<td>Citrus aurantium L.</td>
</tr>
<tr>
<td>Cuspania bark</td>
<td>Gauloisa officinalis Hancock.</td>
</tr>
<tr>
<td>Dandelion</td>
<td>Taraxacum officinale Weber and T. laevigatum DC.</td>
</tr>
<tr>
<td>Dandelion root</td>
<td>Do.</td>
</tr>
<tr>
<td>Dit</td>
<td>Do.</td>
</tr>
<tr>
<td>Dog grass (quackgrass, triticum)</td>
<td>Do.</td>
</tr>
<tr>
<td>Elder flowers</td>
<td>Sambucus canadensis L. and S. nigra L.</td>
</tr>
<tr>
<td>Estragol (esdrogol, esdragon, tarragon)</td>
<td>Artemisia dracunculus L.</td>
</tr>
<tr>
<td>Estragon (tarragon)</td>
<td>Do.</td>
</tr>
<tr>
<td>Fenugreek</td>
<td>Trigonella foenum-graecum L.</td>
</tr>
<tr>
<td>Fibergreek</td>
<td>Alpinia officinarum Hayne.</td>
</tr>
<tr>
<td>Galanga (galangal)</td>
<td>Alsium sativum L.</td>
</tr>
<tr>
<td>Geranium</td>
<td>Pelargonium spp.</td>
</tr>
<tr>
<td>Geranium, East Indian</td>
<td>Cymbopogon martini Stapf.</td>
</tr>
<tr>
<td>Geranium, Rose</td>
<td>Pelargonium graveolens L. Her.</td>
</tr>
<tr>
<td>Ginger</td>
<td>Zingiber officinales Rosc.</td>
</tr>
<tr>
<td>Glycyrrhiza</td>
<td>Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.</td>
</tr>
<tr>
<td>Glycyrrhiza, ammoniated</td>
<td>Do.</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>Citrus paradisi Macf.</td>
</tr>
<tr>
<td>Guava</td>
<td>Psidium spp.</td>
</tr>
<tr>
<td>Hickory bark</td>
<td>Carya spp.</td>
</tr>
<tr>
<td>Horehound (hearhound)</td>
<td>Manonti umbilical L.</td>
</tr>
<tr>
<td>Hops</td>
<td>Humulus lupuluis L.</td>
</tr>
<tr>
<td>Horsemint</td>
<td>Monanda punctata L.</td>
</tr>
<tr>
<td>Hysop</td>
<td>Hyssopus officinalis L.</td>
</tr>
<tr>
<td>Immertelle</td>
<td>Helichrysum auxifolium DC.</td>
</tr>
<tr>
<td>Jasmine</td>
<td>Jasminum officinale L. and other spp. of Jasminum.</td>
</tr>
<tr>
<td>Juniper (berries)</td>
<td>Juniperus communis L.</td>
</tr>
<tr>
<td>Kola nut</td>
<td>Cola acuminata Schott and Endl. and other spp. of Cola.</td>
</tr>
<tr>
<td>Laurel berrys</td>
<td>Laurus nobilis L.</td>
</tr>
<tr>
<td>Laurel leaves</td>
<td>Laurus spp.</td>
</tr>
<tr>
<td>Lavender</td>
<td>Lavandula officinalis Chax.</td>
</tr>
<tr>
<td>Lavender, spike</td>
<td>Lavandula latifolia Vill.</td>
</tr>
<tr>
<td>Lavandin</td>
<td>Hybrids between Lavandula officinalis Chax and Lavandula latifolia Vill.</td>
</tr>
<tr>
<td>Lemon</td>
<td>Citrus limon (L.) Burm. f.</td>
</tr>
<tr>
<td>Lemon balm (see balm)</td>
<td>Cymbopogon citratus DC. and Cymbopogon flexuosus Stapf.</td>
</tr>
<tr>
<td>Lemon peel</td>
<td>Citrus limon (L.) Burm. f.</td>
</tr>
<tr>
<td>Licorice</td>
<td>Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.</td>
</tr>
<tr>
<td>Lime</td>
<td>Citrus aurantiaria Swingle.</td>
</tr>
<tr>
<td>Linden flowers</td>
<td>Tilia spp.</td>
</tr>
<tr>
<td>Locust bean</td>
<td>Ceratonia silique L.</td>
</tr>
<tr>
<td>Lupulin</td>
<td>Humulus lupuluis L.</td>
</tr>
<tr>
<td>Mace</td>
<td>Myristica fragrans Houtt.</td>
</tr>
<tr>
<td>Malt (extract)</td>
<td>Hordeum vulgare L. or other grains.</td>
</tr>
<tr>
<td>Mandarin</td>
<td>Citrus reticulata Blanco.</td>
</tr>
<tr>
<td>Marjoram, sweet</td>
<td>Majorana hortensis Moench.</td>
</tr>
<tr>
<td>Mate 1</td>
<td>Illex paraguayensis St. Hil.</td>
</tr>
<tr>
<td>Melissa (see balm)</td>
<td>Do.</td>
</tr>
<tr>
<td>Menthol</td>
<td>Mentha spp.</td>
</tr>
<tr>
<td>Menthol acetate</td>
<td>Do.</td>
</tr>
<tr>
<td>Molasses (extract)</td>
<td>Saccharum officinarum L.</td>
</tr>
<tr>
<td>Mustard</td>
<td>Brassica spp.</td>
</tr>
<tr>
<td>Naringin</td>
<td>Citrus paradisi Macf.</td>
</tr>
<tr>
<td>Neroli, bigarade</td>
<td>Citrus aurantium L.</td>
</tr>
<tr>
<td>Nutmeg</td>
<td>Myristica fragrans Houtt.</td>
</tr>
<tr>
<td>Common name</td>
<td>Botanical name of plant source</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Onion</td>
<td>Allium cepa L.</td>
</tr>
<tr>
<td>Orange, bitter, flowers</td>
<td>Citrus sinensis (L.) Osbeck.</td>
</tr>
<tr>
<td>Orange, bitter, peel</td>
<td>Do.</td>
</tr>
<tr>
<td>Orange leaf</td>
<td>Citrus sinensis (L.) Osbeck.</td>
</tr>
<tr>
<td>Orange, sweet</td>
<td>Do.</td>
</tr>
<tr>
<td>Orange, sweet, flowers</td>
<td>Do.</td>
</tr>
<tr>
<td>Orange, sweet, peel</td>
<td>Do.</td>
</tr>
<tr>
<td>Origanium</td>
<td>Origanum spp.</td>
</tr>
<tr>
<td>Palmarosa</td>
<td>Cymbopogon martini Stapf.</td>
</tr>
<tr>
<td>Paprika</td>
<td>Capsicum annuum L.</td>
</tr>
<tr>
<td>Parsley</td>
<td>Petrosideum crispum (Mill.) Mansf.</td>
</tr>
<tr>
<td>Pepper, black</td>
<td>Piper nigrum L.</td>
</tr>
<tr>
<td>Pepper, white</td>
<td>Piper nigrum L.</td>
</tr>
<tr>
<td>Peruvian balsam</td>
<td>Mentha piperita L.</td>
</tr>
<tr>
<td>Petitgrain</td>
<td>Citrus reticulata Blanco.</td>
</tr>
<tr>
<td>Petitgrain lemon</td>
<td>Citrus imon (L.) Burm. f.</td>
</tr>
<tr>
<td>Petitgrain mandarin or tangerine</td>
<td>Pimenta officinalis Lind.</td>
</tr>
<tr>
<td>Pimento leaf</td>
<td>Prunus spinosa L.</td>
</tr>
<tr>
<td>Pipsissewa leaves</td>
<td>Chimaphila umbellata Nutt.</td>
</tr>
<tr>
<td>Pomegranate</td>
<td>Punica granatum L.</td>
</tr>
<tr>
<td>Prickly ash bark</td>
<td>Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clava-herculis L.</td>
</tr>
<tr>
<td>Rose absolute</td>
<td>Do.</td>
</tr>
<tr>
<td>Rose (otto of roses, attar of roses)</td>
<td>Do.</td>
</tr>
<tr>
<td>Rose buds</td>
<td>Do.</td>
</tr>
<tr>
<td>Rose flowers</td>
<td>Do.</td>
</tr>
<tr>
<td>Rose fruit (hips)</td>
<td>Do.</td>
</tr>
<tr>
<td>Rose geranium</td>
<td>Pelargonium graveolens L'Her.</td>
</tr>
<tr>
<td>Rose leaves</td>
<td>Rosa spp.</td>
</tr>
<tr>
<td>Rosemary</td>
<td>Rosmarinus officinalis L.</td>
</tr>
<tr>
<td>Rue</td>
<td>Ruta graveolens L.</td>
</tr>
<tr>
<td>Saltor</td>
<td>Crocus sativus L.</td>
</tr>
<tr>
<td>Sage</td>
<td>Salvia officinalis L.</td>
</tr>
<tr>
<td>Sage, Greek</td>
<td>Salvia fruticans L.</td>
</tr>
<tr>
<td>Sage, Spanish</td>
<td>Salvia lavandulaefolia Vahl.</td>
</tr>
<tr>
<td>St. John's bread</td>
<td>Ceratonia siliquifolia L.</td>
</tr>
<tr>
<td>Savory, summer</td>
<td>Satureia montana L.</td>
</tr>
<tr>
<td>Savory, winter</td>
<td>Satureia hortensis L.</td>
</tr>
<tr>
<td>Schinus molle</td>
<td>Schinus molle L.</td>
</tr>
<tr>
<td>Sloe berries (blackthorn berries)</td>
<td>Prunus spinosa L.</td>
</tr>
<tr>
<td>Spearmint</td>
<td>Mentha spicata L.</td>
</tr>
<tr>
<td>Spike lavender</td>
<td>Lavandula latifolia Vill.</td>
</tr>
<tr>
<td>Tamarind</td>
<td>Tamarindus indica L.</td>
</tr>
<tr>
<td>Tangerine</td>
<td>Citrus reticulata Blanco.</td>
</tr>
<tr>
<td>Tannic acid</td>
<td>Nuttalls of Quercus infectoria Oliver and related spp. of Quercus. Also in many other plants.</td>
</tr>
<tr>
<td>Tarragon</td>
<td>Artemisia dracunculus L.</td>
</tr>
<tr>
<td>Tea</td>
<td>Thea sinensis L.</td>
</tr>
<tr>
<td>Thyme</td>
<td>Thymus vulgaris L. and Thymus zygis var. gracilis Boiss.</td>
</tr>
<tr>
<td>Thyme, wild or creeping</td>
<td>Thymus serpyllum L.</td>
</tr>
<tr>
<td>Triticum (see dog grass)</td>
<td></td>
</tr>
<tr>
<td>Tuberosa</td>
<td>Polianthes tuberosa L.</td>
</tr>
<tr>
<td>Turmeric</td>
<td>Curcuma longa L.</td>
</tr>
<tr>
<td>Vanilla</td>
<td>Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.</td>
</tr>
<tr>
<td>Violet flowers</td>
<td>Vanilla odorata L.</td>
</tr>
<tr>
<td>Violet leaves</td>
<td>Do.</td>
</tr>
<tr>
<td>Violet leaves absolute</td>
<td>Do.</td>
</tr>
<tr>
<td>Wild cherry bark</td>
<td>Prunus serotina Erh.</td>
</tr>
<tr>
<td>Yang-yang</td>
<td>Cananga odorata Hopk. f. and Thoms.</td>
</tr>
<tr>
<td>Zedoary bark</td>
<td>Curcuma zedoaria Rosc.</td>
</tr>
</tbody>
</table>
§ 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:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae, brown (kelp)</td>
<td>Laminaria spp. and Nereocystis spp.</td>
</tr>
<tr>
<td>Algae, red</td>
<td></td>
</tr>
<tr>
<td>Dulse</td>
<td>Rhodymenia palmata (L.) Grev.</td>
</tr>
</tbody>
</table>

§ 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:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Botanical name of plant source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae, brown</td>
<td>Laminaria spp. and Nereocystis spp.</td>
</tr>
<tr>
<td>Algae, red</td>
<td></td>
</tr>
<tr>
<td>Apricot kernel (persic oil)</td>
<td>Prunus armeniaca L.</td>
</tr>
<tr>
<td>Dulse</td>
<td>Rhodymenia palmata (L.) Grev.</td>
</tr>
<tr>
<td>Kelp (see algae, brown)</td>
<td></td>
</tr>
<tr>
<td>Peach kernel (persic oil)</td>
<td></td>
</tr>
<tr>
<td>Peanut stearine</td>
<td></td>
</tr>
<tr>
<td>Persic oil (see apricot kernel and peach kernel)</td>
<td></td>
</tr>
<tr>
<td>Quince seed</td>
<td>Cydonia oblonga Miller</td>
</tr>
</tbody>
</table>

§ 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:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Derivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambergris</td>
<td>Physeter macrocephalus L.</td>
</tr>
<tr>
<td>Castoreum</td>
<td>Castor fiber L. and C. canadensis Kuhl.</td>
</tr>
<tr>
<td>Civet (zibeth, zibet, zibetum)</td>
<td>Civet cats, Viverra civetta Schreber and Viverra zibetha Schreber.</td>
</tr>
<tr>
<td>Cognac oil, white and green</td>
<td>Ethyl oenanthate, so-called.</td>
</tr>
<tr>
<td>Musk (Tonquin musk)</td>
<td>Musk deer, Moschus moschiferus L.</td>
</tr>
</tbody>
</table>

§ 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, citric acid, achiillic acid).
- Anethole (parapropenyl anisole).
- Benzaldehyde (benzoic aldehyde).
- N-Butyric acid (butanoic acid).
- d- or l-Carvone (carvol).
- Cinnamaldehyde (cinnamic aldehyde).
- Citral (2,6-dimethyl-octadien-2,6-al-8, geranial, neral).
- Decanal (N-decyl aldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).
- Diacetyl (2,3-butane-dione). 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.
- Geranial (3,7-dimethyl-2,6 and 3,6-octadien-1-ol).
- Geranyl acetate (geraniol acetate).
Food and Drug Administration, HHS

§ 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.

§ 582.99 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.

---

§ 582.80 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

<table>
<thead>
<tr>
<th>Element</th>
<th>Source compounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt</td>
<td>Cobalt acetate.</td>
</tr>
<tr>
<td></td>
<td>Cobalt carbonate.</td>
</tr>
<tr>
<td></td>
<td>Cobalt chloride.</td>
</tr>
<tr>
<td></td>
<td>Cobalt oxide.</td>
</tr>
<tr>
<td></td>
<td>Cobalt sulfate.</td>
</tr>
<tr>
<td>Copper</td>
<td>Copper carbonate.</td>
</tr>
<tr>
<td></td>
<td>Copper chloride.</td>
</tr>
<tr>
<td></td>
<td>Copper gluconate.</td>
</tr>
<tr>
<td></td>
<td>Copper hydroxide.</td>
</tr>
<tr>
<td></td>
<td>Copper orthophosphate.</td>
</tr>
<tr>
<td></td>
<td>Copper oxide.</td>
</tr>
<tr>
<td></td>
<td>Copper pyrophosphate.</td>
</tr>
<tr>
<td></td>
<td>Copper sulfate.</td>
</tr>
<tr>
<td>Iodine</td>
<td>Calcium iodate.</td>
</tr>
<tr>
<td></td>
<td>Calcium iodobehenate.</td>
</tr>
<tr>
<td></td>
<td>Cuprous iodide.</td>
</tr>
<tr>
<td></td>
<td>3,5-Diodosalicylic acid.</td>
</tr>
<tr>
<td></td>
<td>Ethylenediamine dihydroiodide.</td>
</tr>
<tr>
<td></td>
<td>Potassium iodate.</td>
</tr>
<tr>
<td></td>
<td>Potassium iodide.</td>
</tr>
<tr>
<td></td>
<td>Sodium iodate.</td>
</tr>
<tr>
<td></td>
<td>Sodium iodide.</td>
</tr>
<tr>
<td></td>
<td>Thymol iodide.</td>
</tr>
<tr>
<td>Iron</td>
<td>Iron ammonium citrate.</td>
</tr>
<tr>
<td></td>
<td>Iron carbonate.</td>
</tr>
<tr>
<td></td>
<td>Iron chloride.</td>
</tr>
<tr>
<td></td>
<td>Iron gluconate.</td>
</tr>
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<td>Iron oxide.</td>
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<td>Iron phosphoric acid.</td>
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<td>Iron pyrophosphate.</td>
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<td>Iron sulfate.</td>
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<td>Reduced iron.</td>
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<td>Manganese</td>
<td>Manganese acetate.</td>
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<td>Manganese citrate (soluble).</td>
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<td>Manganese chloride.</td>
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<td>Manganese gluconate.</td>
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<td>Manganese orthophosphate.</td>
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<td>Manganese phosphate (dibasic).</td>
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<td>Manganese sulfate.</td>
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<td>Manganese oxide.</td>
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<td>Zinc</td>
<td>Zinc acetate.</td>
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<td>Zinc carbonate.</td>
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<td>Zinc chloride.</td>
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<td>Zinc oxide.</td>
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</table>

1All substances listed may be in anhydrous or hydrated form.
§ 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.

§ 582.1103 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.

§ 582.1125 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.

§ 582.1127 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.

§ 582.1133 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.

§ 582.1135 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
§ 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.
§ 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 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 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 Thiiodipropionic acid.
(a) Product. Thiiodipropionic 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
§ 582.3336  

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 B₁.

§ 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 B₁.

§ 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 B₁.

§ 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 B₁.

§ 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 B1.

§ 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 B1.

§ 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

§ 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]

1Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.
§ 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 used 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 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.

§ 582.5118 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.

§ 582.5145 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.

§ 582.5191 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.

§ 582.5191 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.

§ 582.5201 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.
§ 582.5260 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.
§ 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.

§ 582.5434  **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.

§ 582.5443  **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.

§ 582.5446  **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.

§ 582.5449  **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.

§ 582.5452  **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.

§ 582.5455  **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.

§ 582.5458  **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.

§ 582.5461  **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.

§ 582.5470  **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.

§ 582.5470  **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.

§ 582.5477  **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.

§ 582.5477  **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.

§ 582.5530  **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.

§ 582.5535  **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.

§ 582.5597 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
§ 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.

§ 582.5938 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 B₁₂.
(a) Product. Vitamin B₁₂.
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5950 Vitamin D₃.
(a) Product. Vitamin D₃.
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.5953 Vitamin D₃.
(a) Product. Vitamin D₃.
(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.
For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

Subpart G—Sequestrants

§ 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.
§ 582.6625  
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 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.  

§ 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.  

§ 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) Conditions 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 (carrageenan).
(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.


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 212.45, 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]

§ 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) Precipitated 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 9 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]

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Subpart A—General Provisions

§ 589.1 Substances prohibited from use in animal food or feed.

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 effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

§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.

§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; 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...
§ 589.2000

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.

(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 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.

(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
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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.

(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.


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.

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