

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of virginiamycin is 250 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*. Tolerances are established for residues of virginiamycin in uncooked edible tissues of 0.4 part per million (ppm) in kidney, skin, and fat, 0.3 ppm in liver, and 0.1 ppm in muscle.

(2) *Broiler chickens and cattle*. A tolerance for residues of virginiamycin is not required.

[64 FR 48296, Sept. 3, 1999]

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances*. The tolerances for residues of zeranol in edible tissues are:

(1) *Cattle*. A tolerance is not needed.

(2) *Sheep*. 20 parts per billion.

(c) *Related conditions of use*. See § 522.2680 of this chapter.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989; 67 FR 6867, Feb. 14, 2002; 70 FR 15759, Mar. 29, 2005]

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of zilpaterol is 0.083 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for zilpaterol (the marker residue) is 12 parts per billion (ppb).

(ii) *Muscle*. The tolerance for zilpaterol (the marker residue) is 10 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 558.665 of this chapter.

[71 FR 53005, Sept. 8, 2006, as amended at 81 FR 17608, Mar. 30, 2016]

§ 556.770 Zoalene.

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**Subpart A—General Provisions**

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AUTHORITY: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each 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 of 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 of this chapter or an index listing granted under § 516.151 of this chapter.

(3) A “Type B medicated feed” is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term “highest continuous use level” means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(4) A “Type C medicated feed” is intended as the complete feed for the animal or may be fed “top dressed” (added on top of usual ration) on or offered “free-choice” (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed

from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or “drum-run” (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(6) A “veterinary feed directive (VFD) drug” is a drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed pursuant to section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian. Use of animal feed bearing or containing a VFD drug must be authorized by a lawful veterinary feed directive.

(7) A “veterinary feed directive” is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration.

(8) A “medicated feed” means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a “distributor” means any person who distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD.

(10) An “animal production facility” is a location where animals are raised for any purpose, but does not include

the specific location where medicated feed is made.

(11) An “acknowledgment letter” is a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee). An acknowledgment letter must be provided either in hardcopy or through electronic media and must affirm:

(i) That the distributor will not ship such VFD feed to an animal production facility that does not have a VFD,

(ii) That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and

(iii) That the distributor has complied with the distributor notification requirements of § 558.6(c)(5).

(12) A “combination veterinary feed directive (VFD) drug” is a combination new animal drug (as defined in § 514.4(c)(1)(i) of this chapter) intended for use in or on animal feed which is limited by an approved application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed under section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug. Use of animal feed bearing or containing a combination VFD drug must be authorized by a lawful VFD.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007; 80 FR 31733, June 3, 2015]

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

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(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to

the conditions of use provided for in subpart B of this part and in §558.15 of this chapter.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

Drug	Assay limits percent ¹ type A	Type B maximum (200x)	Assay limits percent ¹ type B/C ²
Amprolium with Ethopabate	94–114	22.75 g/lb (5.0%)	80–120.
Avilamycin	90–110	3.65 g/lb (0.8%)	80–110.
Bacitracin methylenedisalicylate	85–115	25.0 g/lb (5.5%)	70–130.
Bacitracin zinc	84–115	5.0 g/lb (1.1%)	70–130.
Bambermycins	90–110	800 g/ton (0.09%)	80–120/70–130.
Chlortetracycline	85–115	40.0 g/lb (8.8%)	80–115/70–130.
Coumaphos	95–115	6.0 g/lb (1.3%)	80–120.
Decoquinat	90–105	2.72 g/lb (0.6%)	80–120.
Dichlorvos	100–115	33.0 g/lb (7.3%)	90–120/80–130.
Diclazuril	90–110	182 g/t (0.02%)	85–115/70–120.
Efrotomycin	94–113	1.45 g/lb (0.32%)	80–120.
Erythromycin (thiocyanate salt)	85–115	9.25 g/lb (2.04%)	<20g/ton 70–115/150–50;>20g/ton 75–125.
Iodinated casein	85–115	20.0 g/lb (4.4%)	75–125.
Laidlomycin propionate potassium	90–110	1 g/lb (0.22%)	90–115/85–115.
Lasalocid	95–115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin	90–115	20.0 g/lb (4.4%)	80–130.
Melengestrol acetate	90–110	10.0 g/ton (0.0011%)	70–120.
Monensin	85–115	40.0 g/lb (8.8%)	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin	90–110	7.2 g/lb (1.6%)	85–115/75–125.
Nequinat	95–112	1.83 g/lb (0.4%)	80–120.
Nystatin	85–125	5.0 g/lb (1.1%)	75–125.
Oleandomycin	85–120	1.125 g/lb (0.25%)	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline	90–120	20.0 g/lb (4.4%)	75–125/65–135.
Penicillin	80–120	10.0 g/lb (2.2%)	65–135.
Poloxalene	90–110	54.48 g/lb (12.0%)	Liq. feed: 85–115.
Ractopamine	85–105	2.46 g/lb (0.54%)	80–110/75–125.
Salinomycin	90–110	6.0 g/lb (1.3%)	80–120.
Semduramicin (as semduramicin sodium).	90–110	2.27 g/lb (0.50%)	80–110
Semduramicin (as semduramicin sodium biomass).	90–110	2.27 g/lb (0.50%)	80–120
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Virginiamycin	85–115	10.0 g/lb (2.2%)	70–130.
Zoalene	92–104	11.35 g/lb (2.5%)	85–115.

¹ Percent of labeled amount.

² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

CATEGORY II

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
Carbadox	90–110	2.5 g/lb (0.55%)	75–125.
Clopidol	94–106	11.4 g/lb (2.5%)	90–115/80–120.
Famphur	100–110	5.5 g/lb (1.21%)	90–115/80–120.
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125

CATEGORY II—Continued

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
Florfenicol	90–110	9.1 g/lb (2.0%)	Swine feed: 85–115 Catfish feed: 80–110 Salmonid feed: 80–110
Halofuginone hydrobromide	90–115	272.0 g/ton (.03%)	75–125.
Hygromycin B	90–110	1,200 g/ton (0.13%)	75–125.
Ivermectin	95–105	1,180 g/ton (0.13%)	80–110.
Maduramicin ammonium	90–110	545 g/ton (.06%)	80–120.
Morantel tartrate	90–110	66.0 g/lb (14.52%)	85–115.
Neomycin	80–120	7.0 g/lb (1.54%)	70–125.
Oxytetracycline	80–120	10.0 g/lb (2.2%)	65–135.
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125.
Nicarbazin (granular)	90–110	5.675 g/lb (1.25%)	85–115/75–125
Narasin	90–110	5.675 g/lb (1.25%)	85–115/75–125
Nicarbazin (powder)	98–106	5.675 g/lb (1.25%)	85–115/80–120
Novobiocin	85–115	17.5 g/lb (3.85%)	80–120.
Pyrantel tartrate	90–110	36 g/lb (7.9%)	75–125.
Robenidine	95–115	1.5 g/lb (0.33%)	80–120.
Sulfadimethoxine	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Ormetoprim (5/3)	90–110	3.405 g/lb (0.75%)	85–115.
Ormetoprim (5/1)	90–110	17.0 g/lb (3.75%)	85–115.
Sulfamerazine	85–115	18.6 g/lb (4.0%)	85–115.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Penicillin	85–115	5.0 g/lb (1.1%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Sulfaquinoxaline	98–106	11.2 g/lb (2.5%)	85–115.
Thiabendazole	94–106	45.4 g/lb (10.0%)	>7% 85–115; <7% 90–110.
Tiamulin hydrogen fumarate	90–115	10 g/lb	90–115/70–130
Tilmicosin	90–110	37.9 g/lb (8.35%)	85–115.
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

¹ Percent of labeled amount.

² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

EFFECTIVE DATE NOTE: At 81 FR 11665, Mar. 7, 2016, § 558.4, paragraph (c) was amended by removing the phrase “and in § 558.15 of this chapter”, effective Apr. 6, 2016.

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section?* This section covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:

(2) Type C feed that is intended for the following:

(i) Further manufacture of another Type C feed, or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).

(b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medicated feed is covered by this section and by § 510.455.

(c) *What is required for new animal drugs intended for use in liquid feed?* Any new animal drug intended for use in liquid feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) or index listed under section 572 of the act. Such approvals under section 512 of the act must be:

(1) An original NADA,

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- (2) A supplemental NADA, or
- (3) An abbreviated NADA.

(d) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in liquid feed?* An approval under section 512 of the act for a new animal drug intended for use in liquid feed must contain the following information:

(1) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and

(2) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(3) Feed labeling with recirculation or agitation directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted?* The data must be submitted as follows:

- (1) Directly in the NADA,
- (2) By a sponsor, or

(3) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed?* The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include the following requirements:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of a liquid medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All liquid medicated feeds that contain a Category II drug, and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds?* Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: “FOR USE IN _____ ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.” The blank may be filled in with the words: “DRY FEEDS”, “DRINKING WATER”, or “DRY FEEDS AND DRINKING WATER”.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for a waiver?* (1) The labeling provisions of paragraph (h) of this section may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Office of New Animal Drug Evaluation (HFV-100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section?* The labeling provisions of paragraph (h) of this section may be implemented without prior approval as

provided for in § 514.8(c)(3) of this chapter.

[69 FR 30197, May 27, 2004, as amended at 71 FR 74785, Dec. 13, 2006; 72 FR 69131, Dec. 6, 2007]

§ 558.6 Veterinary feed directive drugs.

(a) *General requirements related to veterinary feed directive (VFD) drugs.* (1) Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

(2) A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

(3) Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request.

(6) All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."

(b) *Responsibilities of the veterinarian issuing the VFD.* (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

(i) Be licensed to practice veterinary medicine; and

(ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice re-

quirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in § 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter.

(2) The veterinarian must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.

(3) The veterinarian must ensure that the following information is fully and accurately included on the VFD:

(i) The veterinarian's name, address, and telephone number;

(ii) The client's name, business or home address, and telephone number;

(iii) The premises at which the animals specified in the VFD are located;

(iv) The date of VFD issuance;

(v) The expiration date of the VFD. This date must not extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD must not exceed 6 months after the date of issuance;

(vi) The name of the VFD drug(s);

(vii) The species and production class of animals to be fed the VFD feed;

(viii) The approximate number of animals to be fed the VFD feed by the expiration date of the VFD. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of VFD drug in the VFD feed and duration of use;

(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug

approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted;

(xiii) The statement: “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.”;

(xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6) of this section; and

(xv) The veterinarian’s electronic or written signature.

(4) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the VFD feed:

(i) A more specific description of the location of animals (*e.g.*, by site, pen, barn, stall, tank, or other descriptor that the veterinarian deems appropriate);

(ii) The approximate age range of the animals;

(iii) The approximate weight range of the animals; and

(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

(5) For VFDs intended to authorize the use of an approved, conditionally approved, or indexed combination VFD drug that includes more than one VFD drug, the veterinarian must include the drug-specific information required in paragraphs (b)(3)(vi), (ix), (x), and (xi) of this section for each VFD drug in the combination.

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

(i) “This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.”

(ii) “This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.” [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]

(iii) “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.”

(7) The veterinarian must issue a written (nonverbal) VFD.

(8) The veterinarian must send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client.

(9) The veterinarian must provide a copy of the VFD to the client.

(c) *Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug.* (1) The distributor is permitted to fill a VFD only if the VFD contains all the information required in paragraph (b)(3) of this section.

(2) The distributor is permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug.

(3) The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years.

(4) In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

(5) A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes

animal feed containing a VFD drug. The notification is required one time per distributor and must include the following information:

- (i) The distributor's complete name and business address;
- (ii) The distributor's signature or the signature of the distributor's authorized agent; and
- (iii) The date the notification was signed.

(6) A distributor must also notify FDA within 30 days of any change in ownership, business name, or business address.

(7) The notifications cited in paragraphs (c)(5) and (c)(6) of this section must be submitted to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855, FAX: 240-453-6882.

(8) A distributor is permitted to distribute a VFD feed to another distributor only if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in §558.3(b)(11), from the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor's acknowledgment letter for 2 years.

[80 FR 31733, June 3, 2015; 80 FR 35841, June 23, 2015]

§ 558.15 Antibiotic, nitrofurans, 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 nitrofurans 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 nitrofurans drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofurans 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, nitrofurans, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, 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, 1973; and for the nitrofurans drugs by March 4, 1974. 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, 1974, 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 nitrofurans 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

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antibiotic, nitrofurantoin, 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, nitrofurantoin, 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:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co.	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76	Sec. 558.76.

(2) [Reserved]

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999; 71 FR 16221, Mar. 31, 2006; 75 FR 16002, Mar. 31, 2010]

EFFECTIVE DATE NOTE: At 81 FR 11665, Mar. 7, 2016, §558.15 was removed, effective Apr. 6, 2016.

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) *Approvals.* Type A medicated articles: 25 percent to No. 016592 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

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

(d) *Conditions of use—(1) Cattle.* It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal.	016592
(ii) 113.5 to 11, 350; to provide 10 milligrams per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal.	016592

(2) *Chickens.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously until onset of production as follows:	016592

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylenedisalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed according to subtable in item (i). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 72.6 to 113.5	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> only.	Feed continuously as the sole ration; as sole source of amprolium.	016592
(iv) 72.6 to 113.5	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> only; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(v) 113.5	1. Laying chickens: For prevention of coccidiosis.	Feed continuously as the sole ration; as the sole source of amprolium.	016592

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Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vi) 113.5 to 227	2. Laying chickens: For treatment of coccidiosis in moderate outbreaks.	Feed for 2 weeks.	016592
(vii) 113.5 to 227	Bambermycins 1 to 2.	1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired. 2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously from day-old until onset of production; as the sole source of amprolium.	
(viii) 227	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency. Laying chickens: For treatment of coccidiosis in severe outbreaks..	Feed continuously as the sole ration; as sole source of amprolium. Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	

(3) *Turkeys*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(ii) 113.5 to 227	Turkeys: For prevention of coccidiosis.	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) *Pheasants*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159	Growing pheasants: For the prevention of coccidiosis caused by <i>Eimeria colchici</i> , <i>E. duodenalis</i> , and <i>E. phasiani</i> .	Feed continuously as sole ration. Use as sole source of amprolium.	016592
(ii) [Reserved]				

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.58 Amprolium and ethopabate.

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. It is used in chicken feed as follows:

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Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6.	Broiler chickens: As an aid in the prevention of coccidiosis.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens.	016592
(2) Amprolium 113.5 and ethopabate 3.6.	Lincomycin 2 to 4 ...	Broiler chickens: As an aid in the prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens. Lincomycin as provided by No. 054771 in §510.600(c) of this chapter.	054771
(3) Amprolium 113.5 and ethopabate 36.3.	Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur.	Feed continuously as sole ration; as sole source of amprolium. Not for chickens over 16 weeks of age.	016592
(4) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	1. Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis. Bacitracin as bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	016592
(5) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for improved feed efficiency.	Feed as the sole ration from the time chickens are placed on litter until market weight. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter.	054771
(6) Amprolium 113.5 and ethopabate 3.6.	Bambermycins 1 to 3.	Broiler chickens: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain, improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter.	016592
(7) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 15	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in §510.600(c) of this chapter.	066104
(8) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 5 to 15.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in §510.600(c) of this chapter.	066104
(9) Amprolium 227 and ethopabate 3.6.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying chickens	016592

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(10) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 days.	054771
(11) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption.	054771

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.58, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.59 Apramycin.

(a) *Approvals*. Type A articles to sponsors identified in § 510.600(c) of this chapter as follows:

(1) 000986 for 75 grams apramycin (as apramycin sulfate) per pound for use as in paragraph (d)(1) of this section.

(2) [Reserved]

(b) [Reserved]

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

(d) *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]

§ 558.68 Avilamycin.

(a) *Specifications*. Each pound of Type A medicated article contains 90.7 grams of avilamycin.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for avilamycin medicated feeds must not exceed 90 days from the date of

issuance. VFDs for avilamycin shall not be refilled.

(d) *Related tolerances*. See § 556.68 of this chapter.

(e) *Conditions of use in swine*—(1) *Amount*. Feed at 73 grams avilamycin per ton of Type C medicated feed (80 ppm) as the sole ration for 21 consecutive days. The veterinarian may direct feeding for up to a total of 42 consecutive days, based on the clinical assessment.

(2) *Indications for use*. Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.

[80 FR 61297, Oct. 13, 2015, as amended at 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016]

§ 558.76 Bacitracin methylenedisalicylate.

(a) *Specifications*. (1) Type A medicated articles containing 10, 25, 30, 40, 50, 60, or 75 grams bacitracin methylenedisalicylate per pound.

(2) Type A medicated article containing 50 grams bacitracin methylenedisalicylate per pound.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use of products in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(iii), (e)(1)(v) through (xiii), and (e)(1)(xv) of this section.

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(2) No. 069254 for use of products in paragraph (a)(2) of this section as in paragraphs (e)(1)(ii), (e)(1)(iv), (e)(1)(xiv), and (e)(1)(xvi) of this section.

terms of the equivalent amount of antibiotic standard.

(d) *Related tolerances.* See §556.70 of this chapter.

(c) *Special considerations.* The quantities of antibiotics are expressed in

(e) *Conditions of use.* (1) It is used as follows:

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
(i) 4 to 50 g/ton	Chickens, turkeys, and pheasants: For increased rate of weight gain and improved feed efficiency.	054771
(ii) 4 to 50 g/ton	Broiler and replacement chickens, growing turkeys, and growing pheasants: For increased rate of weight gain and improved feed efficiency.	069254
(iii) 5 to 20 g/ton	Quail not over 5 weeks of age: For increased rate of weight gain and improved feed efficiency.	054771
(iv) 5 to 20 g/ton	Growing quail: For increased rate of weight gain and improved feed efficiency.	For use in quail not over 5 weeks of age.	069254
(v) 10 to 25 g/ton	Chickens: For increased egg production and improved feed efficiency for egg production.	For first 7 months of production	054771
(vi) 10 to 30 g/ton	Swine: For increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	054771
(vii) 10 to 30 g/ton	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams (mg) per pound of body weight per day.	Swine: For increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed for not more than 14 days; bacitracin methylenedisalicylate provided by No. 054771; chlortetracycline provided by Nos. 054771 and 069254 in §510.600(c) of this chapter.	054771 069254
(viii) 10 to 30 g/ton	Swine: For control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	054771
(ix) 50 g/ton	Broiler chickens: As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration	054771
(x) 100 to 200 g/ton	Broiler chickens: As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/ton).	054771

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Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
(xi) 200 g/ton		Turkeys: As an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylenedisalicylate. Quail: For the prevention of ulcerative enteritis in growing quail due to <i>Clostridium colinum</i> susceptible to bacitracin methylenedisalicylate.	Feed continuously as the sole ration.	054771
(xii) 250 g/ton		1. Growing/finishing swine: For control of swine dysentery <i>Treponema hyodysenteriae</i> on premises with history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition. 2. Pregnant sows: For control of clostridial enteritis caused by <i>C. perfringens</i> in suckling piglets.	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. As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by veterinarian when results are not satisfactory.	054771
(xiii) To provide 70 mg per head per day.		Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	054771
(xiv) To provide 70 mg per head per day.		Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	069254
(xv) To provide 250 mg per head per day.		Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	054771
(xvi) To provide 250 mg per head per day.		Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	069254

(2) Bacitracin methylenedisalicylate may also be used in combination with:

- (i) Amprolium as in § 558.55.
- (ii) Amprolium and ethopabate as in § 558.58.
- (iii) Clopidol as in § 558.175.
- (iv) Decoquinatate as in § 558.195.
- (v) Diclazuril as in § 558.198.
- (vi) Fenbendazole as in § 588.258.
- (vii) Halofuginone hydrobromide as in § 558.265.
- (viii) Ivermectin as in § 558.300.
- (ix) Lasalocid as in § 558.311.
- (x) Monensin as in § 588.355.
- (xi) Narasin as in § 558.363.
- (xii) Nicarbazine alone and with narasin as in § 558.366.
- (xiii) Robenidine as in § 558.515.

- (xiv) Salinomycin as in § 558.550.
- (xv) Semduramicin as in § 558.555.
- (xvi) Zoalene as in § 558.680.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTES 1. For FEDERAL REGISTER citations affecting § 558.76, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

2. At 80 FR 78970, Dec. 18, 2015, § 558.76 was amended by removing and reserving paragraph (d)(3)(xiii); however, the amendment could not be incorporated because the paragraph did not exist.

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§ 558.78 Bacitracin zinc.

(a) *Specifications.* Type A medicated articles containing bacitracin zinc equivalent to 10, 25, 40, or 50 grams per pound bacitracin.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Chickens: for increased rate of weight gain and improved feed efficiency.	Growing chickens	054771
(ii) 4 to 50	Turkeys and pheasants: for increased rate of weight gain and improved feed efficiency.	Growing turkeys and pheasants	054771
(iii) 5 to 20	Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as the Type C feed to starting quail through 5 weeks of age.	054771
(iv) 10 to 25	Laying chickens; improved feed efficiency and increased egg production.	054771
(v) 10 to 50	Swine; increased rate of weight gain and improved feed efficiency.	Growing and finishing swine	054771
(vi) 20	Growing-finishing swine; increased rate of weight gain.	In Type C feed	054771
(vii) 20 to 40	Growing-finishing swine; improved feed efficiency.do	054771

(2) It is used in feed for growing cattle at 35 to 70 milligrams per head per day as follows:

(i) To aid in stimulating growth and improving feed efficiency.

(ii) For increased rate of weight gain and improved feed efficiency; see sponsor 054771.

(3) Bacitracin zinc may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Clopidol as in § 558.175.

(iii) Decoquinat as in § 558.195.

(iv) Lasalocid as in § 558.311.

(v) Monensin as in § 558.355.

(vi) Naracin as in § 558.363.

(vii) [Reserved]

(viii) Robenidine as in § 558.515.

(ix) Salinomycin as in § 558.550.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.95 Bambermycins.

(a) *Approvals.* See sponsors in § 510.600(c) of this chapter for use of Type A medicated articles as in paragraph (d) of this section:

(1) No. 016592: 2, 4, and 10 grams per pound for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) No. 012286: 2 grams for use as in paragraph (d)(2) of this section and 0.4 and 2 grams per pound for use as in paragraph (d)(3).

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) *Conditions of use*—(1) *Chickens.* Use in medicated feed as follows:

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Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Broiler chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	016592.
(ii) [Reserved].			

(2) *Turkeys*. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Growing turkeys: For improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.
(ii) 2	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.

(3) *Swine*. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Growing-finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592.
(ii) 2 to 4	Growing-finishing swine: For increased rate of weight.	Feed continuously as the sole ration.	012286, 016592.

(4) *Cattle*.

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 4	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592.
(ii) 2 to 80	Pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.	016592.

(iii) Used as a free-choice Type C medicated loose-mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

(a) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.24
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix *	3.72
Mineral oil	1.00
Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)	0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Selenium premix (270 mg/lb) *	0.21
Copper sulfate	6-01-720	0.18

Ingredient	International Feed No.	Percent
Potassium sulfate (0.33%)	6-06-098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

- (b) *Amount per ton.* 120 grams.
- (c) *Indications for use.* For increased rate of weight gain.
- (d) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.
- (iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

- (a) *Amount.* Feed continuously to provide 10 to 40 milligrams of bambermycins per head per day.
- (b) *Indications for use.* For increased rate of weight gain.
- (c) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.
- (v) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) as follows:

(A) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.45
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix*	3.72
Mineral oil	1.00
Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)	0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Copper sulfate	6-01-720	0.18
Potassium sulfate (0.33%)	6-06-098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

- (B) *Amount per ton.* 120 grams.
- (C) *Indications for use.* For increased rate of weight gain.
- (D) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers). Feed a non-medicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not

- been shown to be more effective than 20 mg/head/day.
- (5) Bambermycins may also be used in combination with:
 - (i) Amprolium as in § 558.55.
 - (ii) Amprolium and ethopabate as in § 558.58.
 - (iii) Clopidal as in § 558.175.
 - (iv) Diclazuril as in § 558.198.
 - (v) Halofuginone as in § 558.265.
 - (vi) Lasalocid as in § 558.311.
 - (vii) Monensin as in § 558.355.
 - (viii) Narasin alone or with nicarbazin as in § 558.363.
 - (ix) Nicarbazin as in § 558.366.

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- (x) Salinomycin as in § 558.550.
- (xi) Zoalene as in § 558.680.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2 percent (10 grams per pound) to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.100 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

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

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10

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weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004]

§ 558.128 Chlortetracycline.

(a) *Specifications.* Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 054771, 066104, and 069254: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 069254: 50, 90, or 100 grams per pound of Type A medicated article.

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

(d) *Special considerations.* (1) In milk replacers or starter feed; include on labeling the warning: “A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.”

(2) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

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(3) When manufactured for use as in paragraph (e)(5)(iv) of this section, include on labeling the warning: “Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and

domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.”

(e) *Conditions of use*—(1) *Chickens*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Chickens: For increased rate of weight gain and improved feed efficiency.. Do not feed to chickens producing eggs for human consumption..	054771 054771, 066104, 069254, 054771.
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	054771, 066104, 069254, 054771.
(iii) 200 to 400 g/ton	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d. 2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	054771, 066104, 069254, 054771.
(iv) 500 g/ton	Chickens: For the reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	1. Feed for 5 d. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: zero withdrawal time. 2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.	054771, 066104, 069254.

(2) *Turkeys*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Do not feed to turkeys producing eggs for human consumption..	054771, 066104, 069254.
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	054771, 066104, 069254.
(iii) 400 g/ton	1. Turkeys: For control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline.. 2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	054771, 066104, 069254.
(iv) 25 mg/lb of body weight.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	054771, 066104, 069254.

(3) *Swine*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing swine: For increased rate of weight gain and improved feed efficiency..	054771, 066104, 069254.
(ii) 50 to 100 g/ton	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group <i>E. Streptococci</i> susceptible to chlortetracycline..	054771, 066104, 069254.

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Chlortetracycline amount	Indications for use	Limitations	Sponsor
(iii) 400 g/ton	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline..	Feed continuously for not more than 14 d..	054771, 066104, 069254.
(iv) 10 mg/lb of body weight.	1. Swine: For the treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.. 2. Swine: For the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline..	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 069254.. Feed for not more than 14 d.	054771, 066104, 069254. 054771.

(4) *Cattle*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.1 mg/lb of body weight daily..	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	054771, 066104, 069254.
(ii) 0.5 mg/lb of body weight daily..	Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor Nos. 054771 and 069254: zero withdrawal time..	054771, 066104, 069254.
(iii) 0.5 to 2.0 mg/lb of body weight daily..	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline..	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(2) of this section..	054771.
(iv) 10 mg/lb of body weight daily.	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.. 2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to chlortetracycline..	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter. To sponsor No. 069254: zero withdrawal time. See paragraph (d)(1) of this section.. See paragraph (d)(1) of this section. ..	066104, 069254. 054771, 066104, 069254.
(v) 500 to 4,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline.	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046–699: 24-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal time.	054771 069254
(vi) 4,000 to 20,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(1) of this section..	054771.
(vii) 25 to 70 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	054771, 066104, 069254.
(viii) 70 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	See paragraph (d)(1) of this section. ..	054771, 066104, 069254.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(ix) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline. 2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046-699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: Zero withdrawal time. Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046-699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: zero withdrawal time.	054771, 066104, 069254. 054771, 066104, 069254.

(5) *Minor species.* It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 20 to 50 g/ton	Growing sheep; increased rate of weight gain and improved feed efficiency..	054771, 066104, 069254.
(ii) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibronic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline..	054771, 066104, 069254.
(iii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by <i>P. multocida</i> susceptible to chlortetracycline..	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption..	054771.
(iv) 10 mg/g of finished feed daily..	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline..	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight.. See paragraph (d)(3) of this section. ...	054771.

(6) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International Feed No.
Dicalcium Phosphate	46.20	6-26-335
Sodium Chloride (Salt)	15.00	6-04-152
Magnesium Oxide	10.67	6-02-756
Cottonseed Meal	10.00	5-01-625
Trace Mineral/Vitamin Premix ¹	3.80	
Calcium Carbonate	3.50	6-01-069
Dried Cane Molasses	3.00	4-04-695
Potassium Chloride	2.00	6-03-755
Mineral Oil	2.00	8-03-123
Iron Oxide	0.50	6-02-431
Chlortetracycline Type A medicated article (90 gram/lb)	3.33	

¹Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(ii) *Amount.* 6,000 grams per ton.

(iii) *Indications for use.* Beef and non-lactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 0.5 to 2.0 mg chlortetracycline per pound of body weight per day.

(v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(7) Chlortetracycline may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Bacitracin methylenedisalicylate as in § 558.76.

(iii) Clopidol as in § 558.175.

(iv) Decoquinat as in § 558.195.

(v) Hygromycin B as in § 558.274.

(vi) Laidlomycin as in § 558.305.

(vii) Lasalocid as in § 558.311.

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- (viii) Monensin as in § 558.355.
- (ix) Robenidine as in § 558.515.
- (x) Salinomycin as in § 558.550.
- (xi) Tiamulin as in § 558.600.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.128, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing:

- (1) 35 grams (g) per pound (lb) each, chlortetracycline and sulfamethazine.
- (2) 40 g/lb each, chlortetracycline and sulfamethazine.

(b) *Sponsors.* See sponsors numbers in § 510.600(c) of this chapter as follow:

- (1) Nos. 054771 and 069254 for use of product described in paragraph (a)(1) as in paragraph (d)(1) of this section.
- (2) No. 054771 for use of product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

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

(d) *Conditions of use*—(1) *Cattle.* It is used in feed for beef cattle as follows:

(i) *Amount.* 350 milligrams per head per day each, chlortetracycline and sulfamethazine.

(ii) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(iii) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(2) *Swine.* It is used in swine feed as follows:

(i) *Amount.* 100 g/ton each, chlortetracycline and sulfamethazine.

(ii) *Indications for use.* For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); prevention of these diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis.

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(iii) *Limitations.* Feed as the sole ration. Withdraw 15 days prior to slaughter.

[79 FR 37622, July 2, 2014, as amended at 80 FR 13231, Mar. 13, 2015]

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(a) *Approvals.* Type A medicated articles: (1) 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to 054771 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 No. 069254 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.

(3) Type C medicated feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

(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 vibronic dysentery); prevention of these diseases during times of stress; maintenance of weight gains 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.

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 19385, May 5, 1978; 47 FR 39814, Sept. 10, 1982; 48 FR 30615, July 5, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 56 FR 14019, Apr. 5, 1991; 61 FR 18082, Apr. 24, 1996; 62 FR 14300, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 47237, Aug. 8, 2003; 69 FR 62407, Oct. 26, 2004; 79 FR 13544, Mar. 11, 2014; 79 FR 37623, July 2, 2014; 80 FR 13231, Mar. 13, 2015]

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§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) [Reserved]

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

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 113.5	Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Do not feed to chickens over 16 weeks of age.	016592
(2) 113.5	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(3) 113.5	Bacitracin zinc 5 to 25.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771 016592
(4) 113.5	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age	016592
(5) 113.5	Chlortetracycline 100 to 200.	Broiler and replacement chickens: As in paragraph (d)(1) of this section; for control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.	016592
(6) 113.5	Lincomycin 2 to 4	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Do not feed to chickens over 16 weeks of age; as lincomycin hydrochloride monohydrate.	054771
(7) 227	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section.	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	016592
(8) 227	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age	016592
(9) 113.5 or 227	Turkeys: As an aid in the prevention of leucocytozoonosis caused by <i>Leucocytozoon smithi</i> .	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	016592

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[68 FR 17882, Apr. 14, 2003, as amended at 72 FR 60551, Oct. 25, 2007; 74 FR 61028, Nov. 23, 2009; 79 FR 10965, 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016]

§ 558.185 Coumaphos.

(a) *Specifications.* Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000859 for use of Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

(2) No. 051311 for use of Type A medicated articles containing 1.12 percent coumaphos as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See 40 CFR 180.189.

(d) *Special considerations.* Labeling shall bear the following caution statement: “The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.” Also, see § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Beef and dairy cattle*—(i) *Amount.* 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) *Indications for use.* Control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Trichostrongylus* spp.).

(iii) *Limitations.* Feed in the normal grain ration to which the animals are accustomed, but not in rations containing more than 0.1 percent coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with oral drenches or with feeds containing phenothiazine.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common

round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as total feed ration for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 1463, Jan. 7, 1977; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 34729, July 3, 1996; 69 FR 70056, Dec. 2, 2004; 70 FR 32489, June 3, 2005; 75 FR 24394, May 5, 2010]

§ 558.195 Decoquinate.

(a) *Specifications.* Type A medicated article containing 6 percent decoquinate.

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(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Special considerations.* (1) Bentonite should not be used in decoquinatate feeds.

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep,

and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

(3) Type C cattle feeds may be manufactured from decoquinatate liquid Type B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

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

(1) *Chickens.*

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ..	Do not feed to laying chickens.	054771
(ii) 27.2	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(iii) 27.2	Bacitracin zinc 10 to 50.	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(iv) 27.2	Chlortetracycline 100 to 200.	Chickens: As in paragraph (e)(1)(i) of this section; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline..	Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption..	054771
(v) 27.2	Chlortetracycline 200 to 400.	Chickens: As in paragraph (e)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline..	As in paragraph (e)(1)(vi) of this section..	054771
(vi) 27.2	Lincomycin 2	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Feed as sole ration; do not feed to laying chickens; lincomycin provided by No. 000009 in § 510.600(c) of this chapter..	054771 054771

(2) *Cattle.*

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	Cattle (including ruminating and non-ruminating calves and veal calves): For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section..	054771

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Decoquinat in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 12.9 to 90.8 ...	Chlortetracycline 500 to 4,000..	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline..	Feed Type C feed to provide 22.7 mg decoquinat and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinat per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AU-REOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter..	054771
(iii) 12.9 to 90.8 ..	Monensin 5 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for improved feed efficiency..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinat per 100 lb body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and § 558.355(d)(8). Monensin as provided by No. 000986 in § 510.600(c) of this chapter..	054771

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 13.6 to 27.2 ..	Chlortetracycline approximately 400 (varying with body weight and feed consumption to provide 10 mg/lb of body weight per day).	Calves, beef and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>E. coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline..	Feed Type C feed to provide 22.7 mg decoquinatate and 1 gram (g) chlortetracycline per 100 lb body weight (0.5 mg/kg) per day for not more than 5 days. Type C feed may be prepared from Type B feed containing 535.8 to 5,440 g/ton decoquinatate and 6,700 to 80,000 g/ton chlortetracycline. When consumed, feed 22.7 mg decoquinatate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from chlortetracycline Type A medicated articles under NADA 141-147 and ANADA 200-359. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141-185. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by Nos. 054771 and 069254 in §510.600(c) of this chapter..	054771 069254
(v) 13.6 to 27.2 ...	Monensin 5 to 30 plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for improved feed efficiency; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Actinomyces</i> (<i>Corynebacterium</i>) <i>pyogenes</i> ..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinatate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and §558.355(d)(8). Monensin as provided by No. 000986, and tylosin as provided by Nos. 000986 and 016592 in §510.600(c) of this chapter.	016592, 054771
(vi) 90.9 to 535.7	Cattle (including ruminating and non-ruminating calves and veal calves): As in paragraph (e)(2)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section..	054771

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Decoquinat in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vii) 90.9 to 535.7	Chlortetracycline 4,000 to 20,000..	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg decoquinat and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinat per 100 lb body weight per day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 054771 in §510.600(c) of this chapter..	054771

(3) *Minor species.*

Decoquinat in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	1. Young sheep: For the prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. crandallis</i> , <i>E. parva</i> , and <i>E. bakuensis</i> ..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food..	054771
.....	2. Young goats: For the prevention of coccidiosis caused by <i>E. christenseni</i> and <i>E. ninakohlyakimovae</i> ..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food..	
(ii) 90.9 to 535.7	1. Young sheep: As in item 1 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food..	054771

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Decoquinat in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
.....	2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food..	

[67 FR 72370, Dec. 5, 2002; 68 FR 15372, Mar. 31, 2003; 69 FR 26499, May 13, 2004; 69 FR 52816, Aug. 30, 2004; 69 FR 62407, Oct. 26, 2004; 69 FR 67264, Nov. 17, 2004; 70 FR 2567, Jan. 14, 2005; 78 FR 25183, Apr. 30, 2013; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 79 FR 17860, Mar. 31, 2014; 80 FR 13231, Mar. 13, 2015; 81 FR 17609, Mar. 30, 2016]

§ 558.198 **Diclazuril.**

(a) *Specifications.* Type A medicated article containing 0.2 percent diclazuril.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.185 of this chapter.

(d) *Conditions of use—(1) Chickens.* For chickens it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 part per million (ppm)).	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> . Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> ..	Feed continuously. Not for use in hens producing eggs for human food..	016592
(ii) 0.91 (1 ppm) ..	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bacitracin methylenedisalicylate provided by 054771..	016592
(iii) 0.91 (1 ppm)	Bambermycins 1 to 2	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bambermycins provided by 057926..	016592
(iv) 0.91 (1 ppm)	Virginiamycin 5	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table; Virginiamycin provided by 066104..	016592
(v) 0.91 (1 ppm)	Virginiamycin 5 to 15	Broiler chickens: As in item (i) of this table; for increased rate of weight gain..	As in item (i) of this table. Virginiamycin provided by 066104..	016592

(2) *Turkeys.* For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 ppm)	Growing turkeys: For the prevention of coccidiosis caused by <i>E. adenoides</i> , <i>E. gallopavonis</i> and <i>E. meleagrimitis</i> ..	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption..	016592
(ii) 0.91 (1 ppm).	Bacitracin methylenedisalicylate 4 to 50..	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter..	016592

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Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(iii) 0.91 (1 ppm).	Bambermycins 1 to 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592
(iv) 0.91 (1 ppm).	Bambermycins 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592

[64 FR 35923, July 2, 1999, as amended at 65 FR 50134, Aug. 17, 2000; 66 FR 47962, 47963, Sept. 17, 2001; 66 FR 62917, Dec. 4, 2001; 67 FR 34830, May 16, 2002; 67 FR 47257, July 18, 2002; 67 FR 48549, July 25, 2002; 69 FR 9947, Mar. 3, 2004; 72 FR 60552, Oct. 25, 2007; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016]

§ 558.205 Dichlorvos.

(a) *Approvals.* Type A medicated articles: 3.1 and 9.6 percent to 054628 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician or a veterinarian. Atropine is antidotal.

(3) Labeling for Type A articles and Type B feeds must include a statement that containers or materials used in packaging such Type A articles and Type B feeds are not to be reused and all such packaging materials must be destroyed after the product has been used.

(c) *Related tolerances.* See § 556.180 of this chapter.

(d) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Dichlorvos, 348 grams (0.0384 percent).

(i) *Indications for use.* For the removal and control of mature, imma-

ture, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.

(2) *Amount per ton.* Dichlorvos, 479 grams (0.0528 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

(3) *Amount per ton.* Dichlorvos, 334–500 grams (0.0366–0.0550 percent).

(i) *Indications for use.* An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum supp.*), large roundworm (*Ascaris suum*), and the

thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.

(ii) *Limitations.* For pregnant swine; mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 50258, Oct. 29, 1975; 48 FR 46515, Oct. 13, 1983; 51 FR 7397, Mar. 3, 1986; 51 FR 28547, Aug. 8, 1986; 52 FR 2684, Jan. 26, 1987; 62 FR 35077, June 30, 1997; 78 FR 21060, Apr. 9, 2013]

§ 558.235 Eftromycin.

(a) *Approvals.* Type A medicated article: 14.5 grams per pound to 050604 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3.6 grams per ton.

(A) *Indications for use.* For improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(ii) *Amount.* 3.6 to 14.5 grams per ton.

(A) *Indications for use.* For increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(2) [Reserved]

[57 FR 38442, Aug. 25, 1992, as amended at 62 FR 63271, Nov. 28, 1997]

§ 558.248 Erythromycin.

(a) *Approvals.* Type A medicated articles: (1) 2.2 percent to 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 5 and 10 percent to 061623 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.

(d) *Condition of use.* (1) It is used as follows:

Erythromycin thiocyanate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 18.5	Chickens; growth promotion and feed efficiency.	061623
(ii) 9.25 to 18.5	Turkeys; growth promotion and feed efficiency.	For turkeys not over 12 weeks of age.	061623
(iii) 9.25 to 64.75	Swine; increase in weight gain, improved feed efficiency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).	Starter ration for animals up to 35 lb body weight.	061623
(iv) 18.5	Laying chickens; aids in increasing egg production.	061623
(v) 92.5	1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Chickens; as an aid in the prevention of infectious coryza. 3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.	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. Feed for 2 d before stress and 3 to 6 d after stress.	061623
(vi) 185	1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease. 2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed for 5 to 8 d; do not use in birds producing eggs for food purposes.	061623 061623

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(2) In feed for feedlot beef cattle at 37 milligrams per head per day as an aid in stimulating growth and improving feed efficiency.

[41 FR 10999, Mar. 15, 1976, as amended at 45 FR 56799, Aug. 26, 1980; 49 FR 31281, Aug. 6, 1984; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 54 FR 12189, Mar. 24, 1989; 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 79 FR 10982, Feb. 27, 2014]

§ 558.254 Famphur.

(a) *Approvals.* Type A medicated articles: 13.2 and 33.3 percent to 000061 in § 510.600(c) of this chapter.

(b) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Conditions of use.* It is used in the feed for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

[41 FR 11000, Mar. 15, 1976, as amended at 51 FR 7397, Mar. 3, 1986; 57 FR 7652, Mar. 4, 1992; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 558.258 Fenbendazole.

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

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

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

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use—(1) Turkeys.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million).	Growing turkeys: For the removal and control of gastrointestinal worms: roundworms, adult and larvae (<i>Ascaridia dissimilis</i>); cecal worms, adult and larvae (<i>Heterakis gallinarum</i>), an important vector of <i>Histomonas meleagridis</i> (Black-head).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	000061

(2) *Swine.*

Amount f mebendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period.	For the removal and control of: Adult stage lungworms (<i>Metastrongylus apri</i> and <i>M. pudendotectus</i>); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (<i>Ascaris suum</i>); adult stage nodular worms (<i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i>); adult stage small stomach worms (<i>Hyostrongylus rubidus</i>); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (<i>Trichuris suis</i>); adult and larvae kidney worms (<i>Stephanurus dentatus</i>).	Feed as sole ration	000061
(ii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 20	As in paragraph (e)(2)(i) of this section; for increased rate of gain in growing-finishing swine.	Feed as sole ration. Do not feed to swine that weigh more than 250 pounds (lbs); lincomycin as provided by 054771 in § 510.600(c) of this chapter.	000061
(iii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 40	As in paragraph (e)(2)(i) 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.	Feed as sole ration. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 054771 in § 510.600(c) of this chapter.	000061
(iv) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 100	As in paragraph (e)(2)(i) of this section; for the treatment of swine dysentery.	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 054771 in § 510.600(c) of this chapter.	000061
(v) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 200	As in paragraph (e)(2)(i) of this section; for reduction in the severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pound (lb); lincomycin as provided by 054771 in § 510.600(c) of this chapter.	000061
(vi) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylenedisalicylate 10 to 30.	Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.	054771
(vii) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylenedisalicylate 250.	1. Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.	054771

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Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. Pregnant sows: As in paragraph (e)(2)(i) of this section; for control of clostridial enteritis in suckling pigs caused by <i>Clostridium perfringens</i> .	2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.	

(3) *Cattle.*

Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) 5 mg/kg body weight (2.27 mg/lb)	Dairy and beef cattle: For the removal and control of: Lungworms (<i>Dictyocaulus viviparus</i>); Stomach worms: barberpole worms (<i>Haemonchus contortus</i>), brown stomach worms (<i>Ostertagia ostertagi</i>), small stomach worms (<i>Trichostrongylus axei</i>); Intestinal worms: hookworms (<i>Bunostomum phlebotomum</i>), thread-necked intestinal worms (<i>Nematodirus helvetianus</i>), small intestinal worms (<i>Cooperia oncophora</i> and <i>C. punctata</i>); Bankrupt worms (<i>Trichostrongylus colubriformis</i>); and Nodular worms (<i>Oesophagostomum radiatum</i>).	Feed as the sole ration or as a top dress for one day. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	000061
(ii) [Reserved]			

(iii) *Free-choice feeds*—(A) *Amount.* 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient ¹	Percent	International Feed No.
(1) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(2) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695

Ingredient ¹	Percent	International Feed No.
Potassium iodide	0.01	6-03-759
Fenbendazole 20% Type A article	2.10	n/a
(3) Free-choice, liquid Type C feed:		
Cane molasses ²	80.902	4-13-251
Water	9.36	n/a
Urea solution, 55%	7.05	5-05-707
Phosphoric acid 75% (feed grade)	2.00	6-03-707
Xantham gum	0.20	8-15-818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

¹The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (see 21 CFR 573.920).

²The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(B) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be

slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(4) *Horses.*

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (<i>Strongylus edentatus</i> , <i>S. equinus</i> , <i>S. vulgaris</i> , <i>Triodontophorus</i> spp.), small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocycclus</i> spp., <i>Cylicostephanus</i> spp.), and pinworms (<i>Oxyuris equi</i>); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (<i>Parascaris equorum</i>)..	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for human consumption..	000061
(ii) [Reserved]	

(5) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (<i>Sus scrofa</i>).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm (<i>Stephanurus dentatus</i>), roundworm (<i>Ascaris suum</i>), nodular worm (<i>Oesophagostomum dentatum</i>).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm (<i>Trichostrongylus</i> spp.), thread necked intestinal worm (<i>Nematodirus</i> spp.), barberpole worm (<i>Haemonchus</i> spp.), whipworm (<i>Trichuris</i> spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

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Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(iii) Rocky mountain bighorn sheep (<i>Ovis c. canadensis</i>).	10 mg/kg/day for 3 days..	For the removal and control of <i>Protostrongylus</i> spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003; 72 FR 66046, Nov. 27, 2007; 73 FR 58873, Oct. 8, 2008; 74 FR 61517, Nov. 25, 2009; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016]

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

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

(c) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

(i) For swine must not exceed 90 days from the date of issuance.

(ii) For fish must not exceed 6 months from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

(4) Type A medicated articles and medicated feeds intended for use in fish shall bear the following: “Not for use in animals intended for breeding purposes. The effects of florfenicol on reproductive performance have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy.”

(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use*—(1) *Swine*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
182	For the control of swine respiratory disease (SRD) associated with <i>Actinobacillus pleuropneumoniae</i> , <i>Pasteurella multocida</i> , <i>Streptococcus suis</i> , and <i>Bordetella bronchiseptica</i> in groups of swine in buildings experiencing an outbreak of SRD..	Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.

(2) *Fish*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 2,724	Catfish: For the control of mortality due to enteric septicemia of catfish associated with <i>Edwardsiella ictaluri</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> and furunculosis associated with <i>Aeromonas salmonicida</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iii) 182 to 2,724	Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iv) 273 to 2,724	Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicemia associated with <i>Streptococcus iniae</i> .	Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

[70 FR 70047, Nov. 21, 2005, as amended at 71 FR 70304, Dec. 4, 2006; 72 FR 19798, Apr. 20, 2007; 72 FR 65885, Nov. 26, 2007; 77 FR 32012, May 31, 2012; 79 FR 18159, Apr. 1, 2014; 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016]

§ 558.265 Halofuginone.

(a) *Specifications.* Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.308 of this chapter.

(d) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 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 virginiamycin 5 to 15 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mevati*, 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) [Reserved]

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mevati*, *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus linc-mycin 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 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(viii) [Reserved]

(2) It is used in feed for turkeys as follows:

(i) *Amount per ton.* 1.36 to 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*.

(B) *Limitations.* Feed continuously as sole ration; withdraw 7 days before slaughter; do not feed to layers or water fowl; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone hydrobromide 1.36 to 2.72 grams plus bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

(iii) *Amount per ton.* 1.36 to 2.72 grams of halofuginone hydrobromide plus 2 grams of bambermycins.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide is toxic to fish and other aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an eye and skin irritant. Avoid contact with skin, eyes, and clothing.

(3) It is used in feed for replacement cage laying chickens and replacement broiler breeder chickens as follows:

(i) *Amount per ton.* 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. mivati*/*E. mitis*, and *E. brunetti*.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Withdraw 4 days before slaughter. Do not feed to laying chickens or water fowl. Halofuginone

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hydrobromide is toxic to fish and aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an irritant to eyes and skin. Avoid contact with skin, eyes, and clothing.

(ii) [Reserved]

[50 FR 33719, Aug. 21, 1985, as amended at 50 FR 42518, Oct. 21, 1985; 51 FR 7397, Mar. 3, 1986; 51 FR 11439, Apr. 3, 1986; 51 FR 14989, Apr. 22, 1986; 51 FR 23737, July 1, 1986; 53 FR 1018, Jan. 15, 1988; 53 FR 11065, Apr. 5, 1988; 54 FR 11519, Mar. 21, 1989; 54 FR 28052, July 5, 1989; 59 FR 51498, Oct. 12, 1994; 61 FR 21076, May 9, 1996; 61 FR 24694, May 16, 1996; 64 FR 42597, Aug. 5, 1999; 65 FR 45712, July 25, 2000; 66 FR 47962, Sept. 17, 2001; 71 FR 27956, May 15, 2006; 79 FR 10982, Feb. 27, 2014; 81 FR 17609, Mar. 30, 2016]

§ 558.274 Hygromycin B.

(a) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for Type A medicated articles as follow:

(1) No. 000986: 2.4 and 8 grams per pound (g/lb).

(2) No. 054771: 0.6 and 1.6 g/lb.

(b) *Related tolerances.* See § 556.330 of this chapter.

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

(1) *Chickens—*

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12	Chickens: For control of infestation of large roundworms (<i>Ascaris galli</i>), cecal worms (<i>Heterakis gallinae</i>), and capillary worms (<i>Capillaria obsignata</i>).	Withdraw 3 days before slaughter	000986 054771
(ii) 8 to 12	Tylosin 4 to 50	Chickens: For control of infestations of large roundworms (<i>Ascaris galli</i>), cecal worms (<i>Heterakis gallinae</i>), and capillary worms (<i>Capillaria obsignata</i>); growth promotion and feed efficiency.	Withdraw 3 days before slaughter. Tylosin as tylosin phosphate as provided by No. 000986 in § 510.600 of this chapter.	000986

(2) *Swine—*

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 12	Swine: For control of infestation of large roundworms (<i>Ascaris suis</i>), nodular worms (<i>Oesophagostomum dentatum</i>), and whipworms (<i>Trichuris suis</i>).	Withdraw 15 days before slaughter.	000986 054771
(ii) 12	Tylosin 10 to 100 ...	Swine: For control of infestations of large roundworms (<i>Ascaris suis</i>), nodular worms (<i>Oesophagostomum dentatum</i>), and whipworms (<i>Trichuris suis</i>); growth promotion and feed efficiency.	Feed continuously as follows: Animal weight (lbs.): Up to 40 . . . 20 to 100 ¹ 41 to 100 . . . 20 to 40 ¹ 101 to market weight . . . 10 to 20 ¹ Withdraw 15 days before slaughter. Tylosin as tylosin phosphate as provided by No. 000986 in § 510.600 of this chapter.	000986

¹ Amount of Tylosin (g/t).

[79 FR 10982, Feb. 27, 2014, as amended at 79 FR 19815, Apr. 10, 2014]

§ 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

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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 1½ grams per 100 lb of body weight.

(ii) *Indications for use*. For increased milk production in dairy cows.

(iii) *Limitations*. This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration must be accompanied with increased

feed intake; administration may increase heat sensitivity of the animal.

[45 FR 41631, June 20, 1980]

§ 558.300 **Ivermectin.**

(a) *Specifications*. Type A medicated article containing 2.72 grams ivermectin per pound (g/lb).

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

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use in swine*. It is used in feed as follows:

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(1) 1.8 (to provide 0.1 milligram per kilogram (mg/kg) of body weight per day)		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(2) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 10 to 30	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for increased rate of weight gain and improved feed efficiency.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(3) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 250	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(4) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 20	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>); and for increased rate of weight gain.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(5) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 40	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter. Withdraw 5 days before slaughter. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment.	050604
(6) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 100	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for treatment of swine dysentery.	Feed as the only feed for 7 consecutive days followed by a separate feed containing 100 g/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 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(7) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 200	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for reduction in severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as the only feed for 7 consecutive days followed by a separate feed containing 200 g/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 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604

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Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(8) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylenedisalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by <i>Clostridium perfringens</i> in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylenedisalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

[72 FR 37437, July 10, 2007, as amended at 81 FR 17609, Mar. 30, 2016]

§ 558.305 Laidlomycin.

(a) *Specifications.* Type A medicated articles containing 50 grams laidlomycin propionate potassium per pound.

(b) *Approvals.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.346 of this chapter.

(d) *Special considerations.* (1) Laidlomycin liquid Type B feeds may be manufactured from dry laidlomycin Type A articles. The liquid Type B feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute

from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) The expiration date for the liquid Type B feed is 21 days after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 7 days after date of manufacture.

(3) Labeling for all Type B feeds (liquid and dry) and Type C feeds containing laidlomycin shall bear the following statements:

(i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.

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(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

(e) *Conditions of use.* It is used in cattle being fed in confinement for slaughter as follows:

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 5	For improved feed efficiency and increased rate of weight gain..	Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day..	054771
(2) 5	Chlortetracycline 10 mg/lb body weight.	For improved feed efficiency and increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	054771
(3) 5	Chlortetracycline 350 mg/head/day.	For improved feed efficiency and increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	054771
(4) 5 to 10	For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day..	054771
(5) 5 to 10	Chlortetracycline 10 mg/pound body weight.	For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	054771
(6) 5 to 10	Chlortetracycline 350 mg/head/day.	For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	054771

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004; 79 FR 13545, Mar. 11, 2014]

§ 558.311 Lasalocid.

(a) *Specifications.* A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals.* Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No.

054771 for use as in paragraphs (e)(1) (i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 066104 as provided by No. 054771 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 054771 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 054771 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(5) 15 and 20 percent activity to Nos. 012286 and 017800 for use in free-choice mineral feeds for cattle as in paragraph (e)(1)(xviii) of this section.

(6) 20 percent activity as a liquid Type A article to No. 054771 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 054771 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xvi).

(8) [Reserved]

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

(c) *Related tolerance.* See §556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable lasalocid liquid feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0

and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

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(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(iii) For Type A articles, Type B or Type C feeds (cattle): A withdrawal period has not been established for this product in preruminating calves. Do

not use in calves to be processed for veal.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(1)(xii) and (e)(1)(xviii) of this section must be the subject of an approved NADA or supplemental NADA as provided in §510.455 of this chapter.

(e)(1) *Conditions of use.* It is used as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	For broiler or fryer chickens only; feed continuously as the sole ration.	054771
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in §510.600(c) of this chapter..	016592
(iii) 68 (0.0075 pct).	Lincomycin 2 (0.00022 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ; for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	054771
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter.	054771
(v) 68 (0.0075 pct) to 113 (0.0125 pct).	Virginiamycin 20	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 054771 in §510.600(c) of this chapter.	054771
(vi) 10 (0.0011 pct) to 30 (0.0033 pct).	Cattle; for improved feed efficiency	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	054771
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses.	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 monoalkyl (C ₈ -C ₁₈) trimethyl ammonium oxytetracycline.	054771

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vii) 25 (0.0027 pct) to 30 (0.0033 pct).	Cattle; for improved feed efficiency and increased rate of weight gain.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	054771
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses.	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 monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline.	054771
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	Sheep; for the prevention of coccidiosis caused by <i>Eimeria ovina</i> , <i>E. crandallis</i> , <i>E. ovinoidalis</i> (<i>E. ninakohlyakimovae</i>), <i>E. parva</i> , and <i>E. intricata</i> .	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	054771
(ix)	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed..	054771
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter.	054771
(xi) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin zinc 4 to 50.	Broiler chickens. For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 054771 in §510.600(c) of this chapter..	054771
(xii)	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day..	054771
(xiii)	Cattle; for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> .	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.	054771
(xiv) 113 (0.0125 pct).	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria legionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	054771
(xv) 68 (0.0075 pct) to 113 (0.0125 pct).	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagris</i> , <i>E. gallopavonis</i> , and <i>E. adenoides</i> ..	Feed continuously as sole ration.	054771

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
.....	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoides</i> ; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration.	054771
.....	Bacitracin methylenedisalicylate 4 to 50.	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoides</i> ; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter..	054771
.....	Virginiamycin 10 to 20.	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoides</i> , and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 066104..	054771
(xvi)	Replacement calves; for control of coccidiosis caused by <i>E. bovis</i> and <i>E. zuernii</i> ..	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	054771
(xvii) 113 (0.0125 pct).	Rabbits; for prevention of coccidiosis caused by <i>Eimeria stiedae</i> .	Feed continuously as sole ration up to 6½ weeks of age.	054771
(xviii) 1440	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	021930 017800
(xix) 300	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	068287
(xx) 10 to 30	Chlortetracycline 25 to 100.	1. Cattle fed in confinement for slaughter: For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. 2. Cattle under 700 pounds fed in confinement for slaughter: For improved feed efficiency; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.. Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day..	054771 054771
(xxi) 10 to 30	Chlortetracycline 500 to 2000.	Cattle fed in confinement for slaughter: For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day..	054771
(xxii) 25 to 30	Chlortetracycline 25 to 42.2.	1. Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	054771

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xxiii) 25 to 30	Chlortetracycline 500 to 1200.	2. Cattle under 700 pounds fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	054771
(xxiv) 30 to 181.8	Chlortetracycline 25 to 2800.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	054771
(xxv) 30 to 181.8	Chlortetracycline 500 to 4000.	1. Beef cattle under 700 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.. 2. Beef cattle up to 800 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day..	054771
(xxvi) 30 to 600 ..	Chlortetracycline 25 to 700.	Cattle up to 800 pounds: For control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day..	054771
(xxvii) 30 to 600 ..	Chlortetracycline 25 to 1100.	1. Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.. 2. Pasture cattle under 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	054771
		Pasture cattle over 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain; and for control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline..	Hand feed continuously at a rate of 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	054771

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xxviii) 30 to 600.	Chlortetracycline 500 to 4000..	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	054771

(2) It is used as a free-choice mineral Type C feed as follows: (i) *Specifications.*

Ingredient	Percent	International feed No.
Defluorinated phosphate (20.5% Ca, 18.5% P)	35.9	6-01-080
Sodium chloride (salt)	20.0	6-04-152
Calcium carbonate (38% Ca)	18.0	6-01-069
Cottonseed meal	10.0	5-01-621
Potassium chloride	3.0	6-03-755
Selenium premix (0.02 percent Se) ¹	3.0	
Dried cane molasses (46% sugars)	2.5	4-04-695
Magnesium sulfate	1.7	6-02-758
Vitamin premix ¹	1.4	
Magnesium oxide (58% Mg)	1.2	6-02-756
Potassium sulfate	1.2	6-06-098
Trace mineral premix ¹	1.04	
Lasalocid Type A medicated article (68 g/lb) ²	1.06	

¹ Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

² To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

- (ii) *Amount.* 1,440 grams per ton.
- (iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.
- (iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.
- (v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (3) It is used as a ruminant free-choice liquid Type C feed as follows: (i) *Specifications.*

Ingredient	Percent	International feed No.
Cane molasses	55.167	4-13-241
Condensed molasses fermentation solubles	24.0	
50% Urea Solution (23% N)	12.0	
Ammonium polyphosphate solution	1.0	6-08-42
Phosphoric acid (54%)	3.0	6-03-707
Xanthan gum	0.05	8-15-818
Water	4.0	
Trace mineral premix ¹	0.5	
Vitamin premix ¹	0.2	
Lasalocid Type A medicated article (90.7 g/lb) ²	0.083	

¹ Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

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²To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

- (ii) *Amount.* 150 grams per ton.
- (iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.
- (iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and

- dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.
- (v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (4) It is used as a free-choice, loose mineral Type C feed as follows:
 - (i) *Specifications.*

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% P)	57.70	6-01-082
Salt	17.55	6-04-152
Distillers dried grains w/ solubles	5.40	5-28-236
Dried cane molasses (46% Sugars)	5.20	4-04-695
Potassium chloride	4.90	6-03-755
Trace mineral/vitamin premix ¹	3.35	
Calcium carbonate (38% Ca)	2.95	6-01-069
Mineral oil	1.05	8-03-123
Magnesium oxide (58% Mg)	1.00	6-02-756
Iron oxide (52% Fe)	0.10	6-02-431
Lasalocid Type A medicated article (68 g/lb) ²	0.80	

¹ Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

² To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

- (ii) *Amount.* 1,088 grams per ton.
- (iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.
- (iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.
- (v) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (5) Lasalocid may also be used in combination with:
 - (i) Melengestrol acetate alone or in combination with tylosin as in § 558.342.
 - (ii) [Reserved]

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

2. At 79 FR 13545, Mar. 11, 2014, § 558.311 was amended; however, the amendment could not be incorporated because of the inaccurate amendatory instruction.

§ 558.325 Lincomycin.

- (a) *Specifications.* Type A medicated articles containing 20 or 50 grams per pound lincomycin as lincomycin hydrochloride.
- (b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
- (c) *Related tolerances.* See § 556.360 of this chapter.
- (d) *Special considerations*—(1) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin shall bear the following directions: “CAUTION: Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.”
- (2) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions: “CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or

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swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.”

(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions:

(i) No. 054771: “CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed.”

(ii) No. 051311: “CAUTION: Not to be fed to swine that weigh more than 250 lb.”

(e) *Conditions of use*—(1) *Chickens*. It is used in feed as follows:

Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Broilers: For control of necrotic enteritis caused by <i>Clostridium</i> spp. or other susceptible organisms..	As lincomycin hydrochloride monohydrate.	054771
(ii) 2 to 4	Broilers: For increased rate of weight gain and improved feed efficiency..	As lincomycin hydrochloride monohydrate.	054771

(2) *Swine*. It is used in feed as follows:

Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 20	Growing-finishing swine: For increased rate of weight gain..	Feed as sole ration.	054771
(ii) 40	1. For control of swine dysentery.	Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for treatment of swine dysentery..	054771
	2. For control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as sole ration, or following use of lincomycin at 100 g/ton for control of porcine proliferative enteropathies (ileitis)..	054771
(iii) 100	1. For treatment of swine dysentery.	Feed as sole ration for 3 weeks or until signs of disease disappear..	054771
	2. For control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as sole ration for 3 weeks or until signs of disease disappear..	054771
(iv) 200	For reduction in the severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> ..	Feed as sole ration for 3 weeks.	054771

(3) Lincomycin may also be used in combination with:

- (i) Amprolium and ethopabate as in § 558.58.
- (ii) Clopidol as in § 558.175.
- (iii) Decoquinatate as in § 558.195.
- (iv) Fenbendazole as in § 588.258.
- (v) Halofuginone as in § 558.265.
- (vi) Ivermectin as in § 558.300.
- (vii) Lasalocid sodium as in § 558.311.
- (viii) Monensin as in § 588.355.
- (ix) Nicarbazine alone and with narasin as in § 558.366.
- (x) Pyrantel as in § 558.485.
- (xi) Robenidone as in § 558.515.
- (xii) Salinomycin as in § 558.550.

(xiii) Zoalene as in § 558.680.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.325, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.340 Maduramicin.

(a) *Approvals*. Type A medicated articles: 4.54 grams per pound to 054771 in § 510.600(c) of this chapter.

(b) *Tolerances*. See § 556.375 of this chapter.

(c) *Conditions of use*—(1) *Amount*. 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

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(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.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

(2) [Reserved]

[54 FR 5229, Feb. 2, 1989, as amended at 54 FR 26732, June 26, 1989; 54 FR 32635, Aug. 9, 1989; 54 FR 33885, Aug. 17, 1989; 55 FR 23, Jan. 2, 1990; 55 FR 8460, Mar. 8, 1990; 55 FR 49616, Nov. 30, 1990; 59 FR 8134, Feb. 18, 1994; 61 FR 18082, Apr. 24, 1996; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 79 FR 13545, Mar. 11, 2014]

§ 558.342 Melengestrol.

(a) *Specifications.* (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 054771 for use of products described in paragraph (a) of this section.

(2) No. 000986 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.380 of this chapter.

(d) *Special considerations.* (1) Type B or C medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B or C medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute

from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable melengestrol acetate liquid Type B or C feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) *Conditions of use—(1) Cattle.*

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)..	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day..	054771, 000986

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Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ii) 0.5	Heifers intended for breeding: For suppression of estrus (heat)..	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding..	054771, 000986
(iii) 0.25 to 0.5	Lasalocid 100 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 grams (g) of lasalocid per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to a ration of nonmedicated feed to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 mg lasalocid/head/day. . Lasalocid provided by No. 054771 in § 510.600(c) of this chapter..	054771, 000986
(iv) 0.25 to 0.5	Lasalocid 100 to 360 plus tylosin 90..	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Actinomyces</i> (<i>Corynebacterium</i>) <i>pyogenes</i> ..	To administer 0.25 to 0.5 mg melengestrol acetate plus 100 to 360 mg lasalocid plus 90 mg tylosin/head/day: 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 10 to 30 g lasalocid and 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a dry pelleted medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 50 to 720 mg lasalocid, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Lasalocid provided by No. 054771, and tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	054771, 000986, 016592
(v) [Reserved]. (vi)–(vii) [Reserved].				

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Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(viii) 0.25 to 0.5 ..	Oxytetracycline 75 ...	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduction of liver condemnation due to liver abscesses..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb per pound to a feed containing 6 to 10 g oxytetracycline per ton; or add at the rate of 0.5 to 2.0 lb/head/day a dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 37.5 to 150 mg oxytetracycline/lb to provide 0.25 to 0.5 mg melengestrol acetate and 75 mg oxytetracycline/head/day.. Oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter..	054771
(ix) 0.25 to 0.5	Tylosin 60 to 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by <i>F. necrophorum</i> and <i>Actinomyces (Corynebacterium) pyogenes</i> ..	To administer 0.25 to 0.5 mg melengestrol acetate with 60 to 90 mg tylosin/head/day:.. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article) plus 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	054771 000986 016592
(x) 0.25 to 0.5	Monensin 50 to 480.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day.. Monensin provided by No. 000986 in § 510.600(c) of this chapter..	054771 000986

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(xi) 0.25 to 0.5	Monensin 50 to 480, plus tylosin 60 to 90.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium pyogenes</i> ..	Feed continuously as sole ration (liquid or dry) at a rate of 0.5 to 2.0 lb/head/day to provide 0.25 to 0.5 mg/head/day melengestrol acetate; 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day; and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into a complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin in the amount of complete feed consumed by an animal per day.. Monensin provided by No. 000986 and tylosin provided by Nos. 000986 and 016592 in §510.600(c) of this chapter..	054771 016592

(2) Melengestrol may also be used with:

- (i) Ractopamine as in §558.500 of this chapter.
- (ii) Zilpaterol as in §558.665 of this chapter.

[42 FR 28535, June 3, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.342, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 054771 in §510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use—(1) Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation

of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982, as amended at 79 FR 13545, Mar. 11, 2014]

§ 558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing monensin, USP.

(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 No. 000986: 36.3 (for export only), 44, 45, 60, or 90.7 grams per pound for use as in paragraphs (f)(1)(i) and (f)(4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1) (i), (iii), (iv), (v), (ix), and (x).

(3) [Reserved]

(4) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(2) of this section.

(5) To 066104: 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 No. 000986: 45, 60, or 90.7 grams per pound for use as in 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 054771: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 054771: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 016592: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 054771: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiv), (xviii), (xix), (xxiii), (xxiv), (xxv), (xxvi), and (xxvii) of this section.

(12) To 066104: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.

(13) To No. 012286: 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)-(3) [Reserved]

(4) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(5) All Type A medicated articles containing monensin shall bear the following warning statement: When mixing and handling monensin Type A medicated articles, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs,

immediately rinse thoroughly with water.

(6) All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(7) Type A medicated articles containing monensin intended for use in cattle and goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following statements:

(i) Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) Do not feed to lactating goats.

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing (see paragraphs (d)(10)(i) and (d)(10)(ii) of this section).

(viii) A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(ix) You may notice the following: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding

calving intervals in dairy cows fed monensin. Have a comprehensive and ongoing nutritional, reproductive, and herd health program in place when feeding monensin to dairy cows.

(x) Inadequate mixing (recirculation or agitation) of monensin liquid Type B or Type C medicated feeds has resulted in increased monensin concentration which has been fatal to cattle and could be fatal to goats.

(8) Type A medicated articles containing monensin intended for use in chickens, turkeys, and quail shall bear the following statements:

(i) Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

(ii) Must be thoroughly mixed in feeds before use.

(iii) Do not feed undiluted.

(iv) Do not feed to laying chickens.

(v) Do not feed to chickens over 16 weeks of age.

(vi) For replacement chickens intended for use as cage layers only.

(vii) Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(viii) In the absence of coccidiosis in broiler chickens the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain.

(9) Type B feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(iv), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6) and (d)(7)(i) through (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i) through (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i), (d)(8)(ii), (d)(8)(iii), and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraphs (d)(8)(i), (d)(8)(ii), and (d)(8)(iii) of this section.

(10) Type C feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(iii) *Goats*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), and (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i), (d)(8)(iv), (d)(8)(v), (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i) and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraph (d)(8)(i) of this section.

(11) Type B and Type C liquid feeds requiring recirculation or agitation that contain monensin and are intended for use in cattle (including dairy cows) and goats shall bear the caution statement specified in paragraph (d)(7)(x) of this section.

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the

top. Agitate daily as described even when not used.

(e) *Related tolerances.* See § 556.420 of this chapter.

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

(1) *Broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Feed continuously as the sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens.

(ii) [Reserved]

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(a) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E.*

necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 054771 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 to 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.

(vii) [Reserved]

(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, 90–110 grams plus lincomycin, 2 grams.

(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 *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)–(xii) [Reserved]

(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 sole ration; as monensin sodium provided by No. 000986 in §510.600 of this chapter; virginiamycin provided by No. 066104 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 hydrochloride provided by Nos. 054771 and 069254 in §510.600(c) of this chapter.

(xv)–(xx) [Reserved]

(xxi) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams.

(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 sole ration; as monensin sodium provided by No. 000986 in §510.600 of this chapter; virginiamycin provided by No. 066104 in §510.600 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. brunetti*, *E. Mivati*, and *E.*

maxima; 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 sodium provided by No. 000986 in §510.600(c) of this chapter. As mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline provided by No. 066104 in §510.600(c) of this chapter.

(xxiii) [Reserved]

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylenedisalicylate, 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. 054771 in §510.600(c) of this chapter, as monensin sodium.

(xxvi)–(xxvii) [Reserved]

(xxviii) *Amount per ton.* Monensin, 90 to 110 grams, plus tylosin phosphate, 4 to 50 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*, for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* 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. Do not feed to laying chickens. As monensin sodium and tylosin phosphate provided by No. 000986 in §510.600(c) of this chapter.

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by

E. necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.

(xxx) *Amount per ton*. Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 100 to 200 grams.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylenedisalicylate as provided by 054771 in § 510.600(c) of this chapter.

(xxxi) *Amount per ton*. Monensin, 90 to 110 grams; plus virginiamycin, 20 grams.

(a) *Indications for use*. Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to laying chickens. See paragraph (d) of this section. As monensin provided by No. 000986; virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

(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. adenoides*, *E. meleagritidis*, and *E. gallopavonis*.

(b) *Limitations*. For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton*. Monensin, 54 to 90 grams, and bacitracin methylenedisalicylate, 4 to 50 grams.

(a) *Indications for use*. For prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency.

(b) *Limitations*. For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iii) *Amount per ton*. Monensin, 54 to 90 grams, and bacitracin methylenedisalicylate, 200 grams.

(a) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.

(b) *Limitations*. For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with

development of immunity to turkey coccidiosis.

Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, 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. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–40 grams.

(a) *Indications for use.* Improved feed efficiency.

(b) *Limitations.* (1) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased monensin concentration which has been fatal to cattle.

(2) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(i) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(iii) Requesting No. 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 feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable

monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) *Amount per ton.* Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in 558.625(c) of this chapter. Tylosin provided by Nos. 000986 and 016592 in §510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 15 to 400 grams.

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.

(iv) *Amount.* Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and con-

trol of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

(v) [Reserved]

(vi) *Amount per ton.* Monensin, 25 to 400 grams.

(a) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) *Amount per ton.* Monensin, 10 to 40 grams.

(a) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

(viii)–(ix) [Reserved]

(x) *Amount per ton.* 1,620 grams monensin, USP.

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate

of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.37	6-04-152
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632
Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix ¹	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

¹ Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(c) *Limitations.* Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed-and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows and bulls has not been established.

(xi) *Amount per ton.* Monensin, 10 to 200 grams.

(a) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

(xii) *Amount per ton.* Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body

weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day. Tylosin provided by Nos. 000986 and 016592 in §510.600(c) of this chapter.

(xiii) *Amount per ton.* Monensin, 11 to 22 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a total mixed ration ("complete feed"). See special labeling considerations in paragraph (d) of this section.

(xiv) *Amount per ton.* Monensin, 11 to 400 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.

(4) *Replacement chickens intended for use as cage layers—(i) Amount per ton.* Monensin, 90 to 110 grams.

(i)(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

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(ii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 4 to 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylenedisalicylate as provided by 054771 in §510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylenedisalicylate as provided by 054771 in §510.600(c) of this chapter.

(iv) *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.

(v) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylenedisalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce

bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylenedisalicylate as provided by 054771 in §510.600(c) of this chapter.

(vi)-(vii) [Reserved]

(5) *Bobwhite quail*—(i) *Amount per ton.* Monensin, 73 grams.

(ii) *Indications for use.* For the prevention of coccidiosis in growing bobwhite quail caused by *Eimeria dispersa* and *E. Lettyae*.

(iii) *Limitations.* Feed continuously as the sole ration; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

(6) *Goats*—(i) *Amount per ton.* Monensin, 20 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria crandallis*, *E. christenseni*, and *E. ninakohlyakimovae*.

(b) *Limitations*—(1) *Feed continuously.* Feed only to goats being fed in confinement. Do not feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. See special labeling considerations in paragraph (d) of this section.

(2) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(i) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(iii) Requesting No. 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 feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file,

the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) [Reserved]

(7) *Free-choice feeds*—(i) *Amount*. 150 milligrams per pound of protein-mineral block (0.033 percent).

(a) [Reserved]

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) which may require supplemental feed.

(2) *Limitations*. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(ii) *Amount*. 400 milligrams per pound of protein-mineral block (0.088 percent).

(a) *Sponsor*. See No. 067949 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) *Limitations*. Provide 80 to 200 milligrams of monensin (0.2 to 0.5 pounds of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iii) *Amount*. 175 milligrams per pound of protein-mineral block (0.038 percent).

(a) *Sponsor*. See No. 017800 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder).

(2) *Limitations*. Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iv) *Amount*. 400 milligrams per pound of block (0.088 percent).

(a) *Sponsor*. See No. 051267 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) *Limitations*. Provide 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(8) Monensin may also be used in combination with:

(i) Decoquinatone alone or with tylosin as in § 558.195.

(ii) Melengestrol acetate alone or with tylosin as in § 558.342.

(iii) Ractopamine alone or in combination as in § 558.500.

(iv) Tilmicosin alone or in combination as in § 558.618.

(v) Zilpaterol alone or in combination as in § 558.665.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

2. At 79 FR 13545, Mar. 11, 2014, § 558.355 was amended; however, the amendments to

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(f)(1)(vii)(b) and (f)(4)(iv)(b) could not be incorporated because those paragraphs did not exist.

§ 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.425 of this chapter.

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Conditions of use—(1) Amount.* 0.44 to 4.4 grams of morantel tartrate per pound of feed.

(2) *Indications for use—(i) Cattle.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(ii) *Goats.* For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus*, *Ostertagia (Teladorsagia) circumcincta*, and *Trichostrongylus axei*.

(3) *Limitations.* Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter; do not treat goats within 30 days of slaughter.

[46 FR 50950, Oct. 16, 1981, as amended at 47 FR 53352, Nov. 26, 1982; 51 FR 7399, Mar. 3, 1986; 51 FR 9005, Mar. 17, 1986; 52 FR 11642, Apr. 10, 1987; 59 FR 17922, Apr. 15, 1994; 66 FR 47963, Sept. 17, 2001]

§ 558.363 Narasin.

(a) *Approvals.* Type A medicated articles containing specified levels of narasin approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:

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(1) To 000986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) [Reserved]

(3) To 000986: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.

(4) To 016592: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambarmycins, paragraph (d)(1)(iv) of this section.

(5)–(6) [Reserved]

(7) To 054771: 36, 45, 54, 72, or 90 grams per pound, with 10, 25, 40, or 50 grams per pound bacitracin zinc, paragraph (d)(1)(x) of this section.

(8) To 000986: 45.4 grams per pound for use as in paragraph (d)(2) of this section.

(b) *Tolerances.* See § 556.428 of this chapter.

(c) *Special considerations.* An expiration date of 2 months (8 weeks) is required for narasin Type C medicated swine feeds.

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

(1) *Broiler chickens—(i) Amount per ton.* Narasin, 54 to 90 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.

(ii) *Amount per ton.* Narasin, 27 to 45 grams, plus nicarbazin, 27 to 45 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Withdraw 5 days before slaughter. The 2 drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 000986 in § 510.600(c) of this chapter may be used in the combination.

(iii) *Amount per ton.* Narasin, 54 to 72 grams, plus bambermycins, 1 to 2 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. May be fatal if fed to adult turkeys, horses, or other equines. Narasin as provided by No. 000986; bambermycins by No. 016592 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Narasin 54 to 72 grams, and bacitracin methylenedisalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*, *E. necatrix*, and *E. tenella*, for increased rate of weight gain, and for improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin methylenedisalicylate by 046573 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Narasin, 54 to 72 grams and bacitracin zinc, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin zinc by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Narasin, 54 to 72 grams, plus tylosin, 4 to 50 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, for increased rate of weight gain, and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and tylosin as provided by 000986 in § 510.600(c) of this chapter.

(2) *Growing-finishing swine*—(i) *Amount per ton.* Narasin, 13.6 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(ii) *Amount per ton.* Narasin, 18.1 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds

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containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(3) Narasin may also be used for broilers in combination with:

(i) Nicarbazin with lincomycin as in § 558.366.

(ii) Nicarbazin and bacitracin methylenedisalicylate as in § 558.366.

[51 FR 29098, Aug. 14, 1986]

EDITORIAL NOTES: 1. For FEDERAL REGISTER citations affecting § 558.363, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at www.fdsys.gov.

2. At 79 FR 13545, Mar. 11, 2014, § 558.363 was amended; however, the amendment could not be incorporated because of an inaccurate amendatory instruction.

§ 558.364 Neomycin sulfate.

(a) *Approvals.* Type A medicated article: 325 grams per pound to 054771 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.430 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* Neomycin sulfate is used as follows:

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(1) 250 to 2,250 grams per ton (g/t) of dry type C feed..	Cattle, swine, sheep, and goats. For treatment and control of colibacillosis (bacterial enteritis) caused by <i>Escherichia coli</i> susceptible to neomycin..	To provide 10 milligrams (mg) of neomycin sulfate per pound of body weight per day for a maximum of 14 days. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in dry feeds only. Not for use in liquid feed supplements..	054771

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(2) 400 to 2,000 g/t of type C milk replacer..	Do.	To provide 10 mg of neomycin sulfate per pound of body weight per day for a maximum of 14 days. Amount consumed will vary depending on animal's consumption and weight. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in milk replacers only..	054771

[64 FR 70576, Dec. 17, 1999, as amended at 65 FR 45881, July 26, 2000; 79 FR 13545, Mar. 11, 2014]

§ 558.365 Nequinatate.

(a) *Approvals.* Type A medicated articles: 4 percent to No. 051311 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.440 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

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

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinatate, 18.16 grams.

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinatate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2685, Jan. 26, 1987; 66 FR 45167, Aug. 28, 2001; 70 FR 32489, June 3, 2005]

§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Approvals.* See Nos. 000986, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) *Conditions of use.* It is used in chicken feed as follows:

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Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ..	Sec. 558.363(d)(1)(iii)	000986
	Narasin 27 to 45 and bacitracin methylenedisalicylate 4 to 50.	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 000986, bacitracin methylenedisalicylate by 054771.	000986
	Narasin 27 to 45 and bacitracin methylenedisalicylate 50..	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylenedisalicylate by No. 054771 in § 510.600(c) of this chapter..	054771
	Narasin 27 to 45 and bacitracin methylenedisalicylate 100 to 200..	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin..	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylenedisalicylate by No. 054771 in § 510.600(c) of this chapter..	054771
	Narasin 27 to 45, and bambermycins 1 to 2.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter. Bambermycins provided by No. 016592; nicarbazin and narasin by No. 066104 in § 510.600(c) of this chapter.	000986

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
90.8 to 181.6 (0.01 to 0.02 pct).	Narasin 27 to 45 and Lincomycin 2 to 4.	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. 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. Narasin and nicarbazin as provided by 000986, lincomycin by 054771.	000986
	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Bacitracin methylenedisalicylate 4 to 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	054771
	Bacitracin methylenedisalicylate 30.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	066104

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Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
113.5 (0.0125 pct).	Bacitracin methylenedisalicylate 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
	Chickens; aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	000986 060728
	Bacitracin methylenedisalicylate 30.	Broiler chickens; aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; for increased rate of weight gain and improved feed efficiency.do	060728
	Bacitracin zinc 4 to 50..	Broiler chickens; aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis, and for increased rate of weight gain and improved feed efficiency..	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Discontinue medication 4 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by 066104, bacitracin zinc by 054771..	066104 054771
	Bambermycins 1 to 2	Broiler chickens; aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis, for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter. Nicarbazin as provided by 066104..	057926
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Lincomycin 2 (0.00044 pct).	Broiler chickens; aid in preventing outbreaks of secal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; for increased rate of weight gain..	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..	060728 066104

[42 FR 56729, Oct. 28, 1977; 43 FR 1942, Jan. 13, 1978, as amended at 44 FR 40887, July 13, 1979; 50 FR 13562, Apr. 5, 1985; 51 FR 7399, Mar. 3, 1986; 54 FR 1928, Jan. 18, 1989; 60 FR 29483, June 5, 1995; 61 FR 1832, Jan. 24, 1996; 61 FR 14021, Mar. 29, 1996; 61 FR 14483, Apr. 2, 1996; 62 FR 29011, May 29, 1997; 63 FR 13124, Mar. 18, 1998; 63 FR 57248, Oct. 27, 1998; 64 FR 4966, Feb. 2, 1999; 64 FR 18574, Apr. 15, 1999; 64 FR 20164, Apr. 26, 1999; 64 FR 49384, Sept. 13, 1999; 65 FR 11889, Mar. 7, 2000; 66 FR 46706, Sept. 7, 2001; 66 FR 47962, Sept. 17, 2001; 66 FR 63500, Dec. 7, 2001; 67 FR 30327, May 6, 2002; 71 FR 16224, Mar. 31, 2006; 71 FR 27957, May 15, 2006; 73 FR 15884, Mar. 26, 2008; 75 FR 7555, Feb. 22, 2010; 78 FR 23, Jan. 2, 2013; 78 FR 42007, July 15, 2013; 78 FR 52429, Aug. 23, 2013; 79 FR 10983, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016]

§ 558.415 Novobiocin.

(a) *Specifications.* Type A medicated article containing 25 grams of novobiocin activity per pound.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.460 of this chapter.

(d) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount.* Novobiocin, 4–5 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per

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ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount*. 20 mgs. per lb. body weight per day.

(ii) *Indications for use*. For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations*. Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

(4) *Ducks*—(i) *Amount*. Novobiocin, 350 grams per ton.

(ii) *Indications for use*. Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida*, susceptible to novobiocin.

(iii) *Limitations*. Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary, repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

[40 FR 13959, Mar. 27, 1975, as amended at 45 FR 42263, June 24, 1980; 51 FR 7399, Mar. 3, 1986; 52 FR 36402, Sept. 29, 1987; 79 FR 13545, Mar. 11, 2014]

§ 558.430 Nystatin.

(a) *Specifications*. Type A medicated article containing 20 grams of nystatin activity per pound.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.470 of this chapter.

(d) *Conditions of use*. It is used for chickens and turkeys as follows:

(1) *Amount*. 50 grams per ton.

(i) *Indications for use*. Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations*. Growing and laying chickens; growing turkeys.

(2) *Amount*. 100 grams per ton.

(i) *Indications for use*. Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

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(ii) *Limitations*. Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 79 FR 13545, Mar. 11, 2014]

§ 558.435 Oleandomycin.

(a) *Approvals*. Type A medicated articles: 5 grams of activity per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances*. See § 556.480 of this chapter.

(c) *Special considerations*. Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin. Oleandomycin refers to oleandomycin or feed-grade oleandomycin.

(d) *Conditions of use*. It is used in animal feed as follows:

(1) *Chickens and turkeys*—(i) *Amount per ton*. Oleandomycin, 1 to 2 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton*. Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 66 FR 47963, Sept. 17, 2001]

§ 558.450 Oxytetracycline.

(a) *Approvals*. Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to No. 066104 in § 510.600(c) of this chapter.

(2) 50, 100, and 200 grams per pound to No. 069254 in § 510.600(c) of this chapter.

(b) *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-alkyl (C₈–C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in

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terms of an equivalent amount of oxytetracycline hydrochloride.

(3) 50-, 100-, and 200-gram per pound articles in paragraph (a)(2) of this section contain oxytetracycline dihydrate expressed in terms of an equivalent amount of oxytetracycline hydro-

chloride. Another 100-gram per pound article in paragraph (a)(2) of this section contains oxytetracycline hydrochloride.

(c) *Related tolerances.* See §556.500 of this chapter.

(d) *Conditions of use—(1) Chickens—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 grams per ton (g/ton).	Chickens: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to chickens producing eggs for human consumption..	066104, 069254
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> and control of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 069254
(iii) 400 g/ton	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 069254
(iv) 500 g/ton	Chickens: For reduction of mortality due to air sacculitis (air sac infection) caused by <i>E. coli</i> susceptible to oxytetracycline..	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds, withdraw 3 d before slaughter..	066104, 069254

(2) Turkeys—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to turkeys producing eggs for human consumption..	066104, 069254
(ii) 100 g/ton	Turkeys: For control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	066104, 069254
(iii) 200 g/ton	Turkeys: For control of infectious synovitis caused by <i>M. synoviae</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 069254 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 069254
(iv) 25 milligrams/pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 069254 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 069254

(3) Swine—

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Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Swine: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 069254
(ii) 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> susceptible to oxytetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.. 2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d.	066104, 069254
		Feed continuously for 14 d.	066104, 069254

(4) Cattle—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously in milk replacer or starter feed..	066104, 069254
(ii) 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline.. 2. Calves: For treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 069254, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 069254
		Feed continuously for 7 to 14 d in milk replacer or starter feed; for No. 069254, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 069254
(iii) 25 mg/head/day.	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 069254
(iv) 75 mg/head/day.	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	Feed continuously.	066104, 069254

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Oxytetracycline amount	Indications for use	Limitations	Sponsor
(v) 0.5 to 2.0 g/head/day.	Cattle: For prevention and treatment of the early stages of shipping fever complex..	Feed 3 to 5 d before and after arrival in feedlots..	066104, 069254

(5) *Minor species*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 g/ton ...	Sheep: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 069254
(ii) 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter..	066104, 069254
(iii) 200 mg/colony	Honey bees: For control of American foulbrood caused by <i>Paenibacillus larvae</i> and European foulbrood caused by <i>Streptococcus pluton</i> susceptible to oxytetracycline..	Remove at least 6 weeks prior to main honey flow..	066104, 069254
(iv) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day).	Pacific salmon: For marking of skeletal tissue..	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 d following the last administration of medicated feed..	066104
(v) 2.5 to 3.75 g/100 lb of fish/day.	1. Salmonids: For control of ulcer disease caused by <i>Haemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> , and pseudomonas disease.. 2. Catfish: For control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and pseudomonas disease..	Administer 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.. Administer 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 16.7 °C (62 °F)..	066104 066104
(vi) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> ..	Administer 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..	066104