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Title 21: Food and Drugs

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Contents

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

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§558.3 Definitions and general considerations applicable to this part.

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

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

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

(i) Category I—These drugs require no withdrawal period at the lowest use level in each major species for which they are approved or are approved for use only in minor species.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one major species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of carcinogenic concern regardless of whether a withdrawal period is required in any species.

(2) A “Type A medicated article” is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under §514.105 of this chapter or an index listing granted under §516.151 of this chapter.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) “Major species” means cattle, horses, swine, chickens, turkeys, dogs, and cats.

(14) “Minor species” means animals, other than humans, that are not major species.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007; 80 FR 31733, June 3, 2015; 81 FR 57800, Aug. 24, 2016]

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§558.4 Requirement of a medicated feed mill license.

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

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

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

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

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part.

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

Category I

Drug	Assay limits percent[1] Type A	Type B maximum (200x)	Assay limits percent[1] Type B/C[2]
Amprolium with Ethopabate	94-114	22.75 g/lb (5.0%)	80-120.
Avilamycin	90-110	7.3 g/lb (1.6%)	80-110.
Bacitracin methylenedisalicylate	85-115	25.0 g/lb (5.5%)	70-130.
Bacitracin zinc	84-115	5.0 g/lb (1.1%)	70-130.
Bambermycins	90-110	800 g/ton (0.09%)	80-120/70-130.
Chlortetracycline	85-115	40.0 g/lb (8.8%)	80-115/70-130.
Coumaphos	95-115	6.0 g/lb (1.3%)	80-120.
Decoquinate	90-105	2.72 g/lb (0.6%)	80-120.
Dichlorvos	100-115	33.0 g/lb (7.3%)	90-120/80-130.
Diclazuril	90-110	182 g/t (0.02%)	85-115/70-120.
Efrotomycin	94-113	1.45 g/lb (0.32%)	80-120.
Iodinated casein	85-115	20.0 g/lb (4.4%)	75-125.
Laidlomycin propionate potassium	90-110	1 g/lb (0.22%)	90-115/85-115.
Lasalocid	95-115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80-120; Type C (all): 75-125.
Lincomycin	90-115	20.0 g/lb (4.4%)	80-130.
Lubabegron	87-107	908 g/ton	85-115/80-120.
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	9.0 g/lb (1.98%)	85-115/75-125.
Nicarbazin (granular)	90-110	9.0 g/lb (1.98%)	85-115/75-125.
Narasin	90-110	9.0 g/lb (1.98%)	85-115/75-125.
Nystatin	85-125	5.0 g/lb (1.1%)	75-125.
Oxytetracycline	90-120	20.0 g/lb (4.4%)	75-125/65-135.
Poloxalene	90-110	54.48 g/lb (12.0%)	Liq. feed: 85-115.
Ractopamine	85-105	2.46 g/lb (0.54%)	80-110/75-125.
Salinomycin	90-110	6.0 g/lb (1.3%)	80-120.
Semduramicin (as semduramicin sodium)	90-110	2.27 g/lb (0.50%)	80-110
Semduramicin (as semduramicin sodium biomass)	90-110	2.27 g/lb (0.50%)	80-120
Tylosin	80-120	10.0 g/lb (2.2%)	75-125.
Tylvalosin	90-110	3.86 g/lb	85-115.
Virginiamycin	85-115	10.0 g/lb (2.2%)	70-130.
Zoalene	92-104	11.35 g/lb (2.5%)	85-115.

[1]Percent of labeled amount.

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

Category II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
Amprolium	94-114	11.35 g/lb (2.5%)	80-120.
Apramycin	88-112	7.5 g/lb (1.65%)	80-120.
Carbadox	90-110	2.5 g/lb (0.55%)	75-125.
Clopidol	94-106	11.4 g/lb (2.5%)	90-115/80-120.
Erythromycin	85-115	4.625 g/lb (1.02%)	75-125.
Famphur	100-110	5.5 g/lb (1.21%)	90-115/80-120.
Fenbendazole	93-113	8.87 g/lb (1.96%)	75-125.
Florfenicol	90-110	9.1 g/lb (2.0%)	Swine feed: 85-115 Catfish feed: 80-110. Salmonid feed: 80-110.
Halofuginone hydrobromide	90-115	272.0 g/ton (.03%)	75-125.

Hygromycin B	90-110	1,200 g/ton (0.13%)	75-125.
Ivermectin	95-105	1,180 g/ton (0.13%)	80-110.
Maduramicin ammonium	90-110	545 g/ton (.06%)	80-120.
Morantel tartrate	90-110	66.0 g/lb (14.52%)	85-115.
Neomycin	80-120	20 g/lb (4.4%)	70-125.
Oxytetracycline	80-120	20 g/lb (4.4%)	65-135.
Neomycin sulfate	80-120	100 g/lb (22.0%)	70-125.
Nicarbazin (granular)	90-110	5.675 g/lb (1.25%)	85-115/75-125.
Nicarbazin (powder)	96-104	9.08 g/lb (2.00%)	85-115/75-125.
Novobiocin	85-115	17.5 g/lb (3.85%)	80-120.
Pyrantel tartrate	90-110	36 g/lb (7.9%)	75-125.
Robenidine	95-115	1.5 g/lb (0.33%)	80-120.
Sulfadimethoxine	90-110	Poultry: 5.675 g/lb Fish: 85.1 g/lb	80-115/75-125.
Ormetoprim	90-110	Poultry: 3.405 g/lb Fish: 17.0 g/lb	80-115.
Sulfamerazine	85-115	18.6 g/lb (4.0%)	85-115.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	10.0 g/lb (2.2%)	85-125/70-130.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Tylosin	80-120	10.0 g/lb (2.2%)	75-125.
Sulfaquinoxaline	98-106	11.2 g/lb (2.5%)	85-115.
Thiabendazole	94-106	45.4 g/lb (10.0%)	>7% 85-115; <7% 90-110.
Tiamulin hydrogen fumarate	90-115	10 g/lb	90-115/70-130.
Tilmicosin	90-110	37.9 g/lb (8.35%)	Swine Type B/C feed: 85-115. Cattle Type B feed: 85-115. Cattle Type C feed: 80-110.
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.govinfo.gov.*

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§558.5 Requirements for liquid medicated feed.

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

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

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

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

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

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

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

(1) An original NADA,

(2) A supplemental NADA, or

(3) An abbreviated NADA.

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

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

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

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

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

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

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

(1) Directly in the NADA,

(2) By a sponsor, or

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

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

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

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

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

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

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

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

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

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

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

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section?* The labeling provisions of paragraph (h) of this section may be implemented without prior approval as provided for in §514.8(c)(3) of this chapter.

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

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§558.6 Veterinary feed directive drugs.

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

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

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

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

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

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

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

(i) Be licensed to practice veterinary medicine; and

(ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in §530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in §530.3(i) of this chapter.

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

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

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

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

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

(iv) The date of VFD issuance;

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

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

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

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

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

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

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

the approval;

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

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

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

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

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

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

(ii) The approximate age range of the animals;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The distributor's complete name and business address;

(ii) The distributor's signature or the signature of the distributor's authorized agent; and

(iii) The date the notification was signed.

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

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

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

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

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

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§558.55 Amprolium.

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

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

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

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

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

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

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

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

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

(iv) 72.6 to 113.5	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella* only; and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592
(v) 113.5		1. Laying chickens: For prevention of coccidiosis	Feed continuously as the sole ration; as the sole source of amprolium	016592
		2. Laying chickens: For treatment of coccidiosis in moderate outbreaks	Feed for 2 weeks	
(vi) 113.5 to 227		1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired	Feed continuously from day-old until onset of production; as the sole source of amprolium	016592
		2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired	Feed continuously as the sole ration; as sole source of amprolium	
(vii) 113.5 to 227	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592
(viii) 227		Laying chickens: For treatment of coccidiosis in severe outbreaks.	Feed for 2 weeks	016592

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

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

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

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

(5) *Permitted combinations.* Amprolium may also be used in combination with:

(i) Virginiamycin as in §558.635.

(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.govinfo.gov.*

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§558.58 Amprolium and ethopabate.

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

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

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

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

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

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

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

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6		Broiler chickens: As an aid in the prevention of coccidiosis	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens	016592

(2) Amprolium 113.5 and ethopabate 36.3		Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur	Feed continuously as sole ration; as sole source of amprolium. Not for chickens over 16 weeks of age	016592
(3) Amprolium 113.5 and ethopabate 36.3	Bacitracin 4 to 50	1. Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens	Feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis. Bacitracin as bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	016592
(4) Amprolium 113.5 and ethopabate 36.3	Bacitracin 4 to 50	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for improved feed efficiency	Feed as the sole ration from the time chickens are placed on litter until market weight. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter	054771
(5) Amprolium 113.5 and ethopabate 36.6	Bambermycins 1 to 3	Broiler chickens: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain, improved feed efficiency	Feed continuously as the sole ration; as sole source of amprolium Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592
(6) Amprolium 227 and ethopabate 3.6		For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis	Not for laying chickens	016592

(f) Amprolium and ethopabate may also be used in combination with:

(1)-(2) [Reserved]

(3) Chlortetracycline as in §558.128.

[41 FR 10990, Mar. 15, 1976]

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

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§558.59 Apramycin.

(a) *Specifications.* Type A articles containing 75 grams apramycin (as apramycin sulfate) per pound.

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

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

(d) *Conditions of use in swine*—

Apramycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 150		For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli*	Feed as the sole ration for 14 consecutive days. Withdraw 28 days before slaughter	058198
(2) [Reserved]				

[81 FR 94995, Dec. 27, 2016]

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§558.68 Avilamycin.

(a) Each pound of Type A medicated article contains 45.4 or 90.7 grams of avilamycin.

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

(c) *Related tolerances.* See §556.60 of this chapter.

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

(2) The expiration date of VFDs for avilamycin medicated feeds must not exceed 90 days from the date of issuance. VFDs for avilamycin shall not be refilled.

(e) *Conditions of use.* Administer in feed as follows:

(1) *Chickens—*

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.6 to 40.9		Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age	058198
(ii) 13.6 to 40.9		Monensin, 90 to 110	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens* in broiler chickens. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. Do not feed to chickens over 16 weeks of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow horses or other equines access to feed containing avilamycin and monensin. Ingestion of monensin by horses has been fatal. Do not feed to chickens producing eggs for human consumption. Monensin as provided by No. 058198 in §510.600(c) of this chapter	058198
(iii) 13.6 to 40.9		Narasin, 54 to 90	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to chickens producing eggs for human consumption. Narasin as provided by No. 058198 in §510.600(c) of this chapter	058198
(iv) 13.6 to 40.9	Narasin 27 to 45; nicarbazin 27 to 45	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed as the sole ration for 21 consecutive days to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Withdraw 5 days before slaughter. Narasin and nicarbazin as provided by No. 058198 in §510.600(c) of this chapter	058198
(v) 13.6 to 40.9		Salinomycin sodium, 40 to 60	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. May be fatal if fed to adult turkeys or to horses. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. Salinomycin as provided by No. 016592 in §510.600(c) of this chapter	058198

(2) *Swine—*

Avilamycin in grams/ton	Combinationin grams/ton	Indications for use	Limitations	Sponsor
(i) 73		Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in pigs, do not administer to pigs 14 weeks of age or older	058198
(ii) [Reserved]				

[80 FR 61297, Oct. 13, 2015, as amended at 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 48703, July 26, 2016; 81 FR 59134, Aug. 29, 2016; 81 FR 67152, Sept. 30, 2016; 82 FR 11509, Feb. 24, 2017; 83 FR 14587, Apr. 5, 2018; 83 FR 64741, Dec. 18, 2018; 84 FR 8974, Mar. 13, 2019; 84 FR 33001, July 11, 2019; 85 FR 4209, Jan. 24, 2020]

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§558.76 Bacitracin methylenedisalicylate.

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

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

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

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

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

(c) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

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

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

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
(i) 4 to 50 g/ton		Chickens, turkeys, and pheasants: For increased rate of weight gain and improved feed efficiency		054771
(ii) 4 to 50 g/ton		Broiler and replacement chickens, growing turkeys, and growing pheasants: For increased rate of weight gain and improved feed efficiency		069254
(iii) 5 to 20 g/ton		Quail not over 5 weeks of age: For increased rate of weight gain and improved feed efficiency		054771
(iv) 5 to 20 g/ton		Growing quail: For increased rate of weight gain and improved feed efficiency	For use in quail not over 5 weeks of age	069254
(v) 10 to 25 g/ton		Chickens: For increased egg production and improved feed efficiency for egg production	For first 7 months of production	054771
(vi) 10 to 30 g/ton		Swine: For increased rate of weight gain and improved feed efficiency	For growing and finishing swine	054771
(vii) 50 g/ton		Broiler chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration	054771
(viii) 100 to 200 g/ton		Broiler chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/ton)	054771
(ix) 200 g/ton		Turkeys: As an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylenedisalicylate. Quail: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate	Feed continuously as the sole ration	054771
(x) 250 g/ton		1. Growing/finishing swine: For control of swine dysentery *Treponema hyodysenteriae* on premises with history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition	As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian a when results are not satisfactory	054771
		2. Pregnant sows: For control of clostridial enteritis caused by *C. perfringens* in suckling piglets	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by veterinarian when results are not satisfactory	
(xi) 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
(xii) 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
(xiii) 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
(xiv) To provide 250 mg per head per day		Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period	069254

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

(i) Amprolium as in §558.55.

(ii) Amprolium and ethopabate as in §558.58.

(iii) Chlortetracycline as in §558.128.

(iv) Clopidol as in §558.175.

(v) Decoquinate as in §558.195.

(vi) Diclazuril as in §558.198.

(vii) Fenbendazole as in §558.258.

(viii) Halofuginone as in §558.265.

(ix) Ivermectin as in §558.300.

(x) Lasalocid as in §558.311.

(xi) Monensin as in §558.355.

(xii) Narasin as in §558.363.

(xiii) Narasin and nicarbazin as in §558.364.

(xiv) Nicarbazin as in §558.366.

(xv) Robenidine as in §558.515.

(xvi) Salinomycin as in §558.550.

(xvii) Semduramicin as in §558.555.

(xviii) 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.govinfo.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) Decoquinate as in §558.195.

(iv) Lasalocid as in §558.311.

(v) Monensin as in §558.355.

(vi) Naracin as in §558.363.

(vii) Nicarbazin as in §558.366.

(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.govinfo.gov.*

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§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) *Related tolerances.* See §556.75 of this chapter.

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

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

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

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

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

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

(4) *Cattle.*

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

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

(*a*) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.24
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix *	.....	3.72
Mineral oil	.....	1.00
Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)	.....	0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Selenium premix (270 mg/lb) *	.....	0.21
Copper sulfate	6-01-720	0.18
Potassium sulfate (0.33%)	6-06-098	0.16

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

(*b*) *Amount per ton.* 120 grams.

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

(*d*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

(*a*) *Amount.* Feed continuously to provide 10 to 40 milligrams of bambermycins per head per day.

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

(*c*) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

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

(A) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6-01-080	42.50
Sodium chloride (salt)	6-04-152	20.10
Calcium carbonate (38% calcium)	6-01-069	15.45
Corn distillers dried grains w/solubles	5-28-236	9.57
Magnesium oxide	6-02-756	5.15
Vitamin and trace mineral premix*		3.72
Mineral oil		1.00

Yeast (primary dehydrated yeast)	7-05-533	0.75
Bambermycins Type A article (10 g/lb)		0.60
Iron oxide	6-02-431	0.50
Magnesium sulfate (67%)	6-02-758	0.32
Copper sulfate	6-01-720	0.18
Potassium sulfate (0.33%)	6-06-098	0.16

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

(B) *Amount per ton.* 120 grams.

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

(D) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers). Feed a non-medicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(5) Bambermycins may also be used in combination with:

(i) Amprolium as in §558.55.

(ii) Amprolium and ethopabate as in §558.58.

(iii) Clopidal as in §558.175.

(iv) Diclazuril as in §558.198.

(v) Halofuginone as in §558.265.

(vi) Lasalocid as in §558.311.

(vii) Monensin as in §558.355.

(viii) Narasin as in §558.363.

(ix) Narasin and nicarbazin as in §558.364.

(x) Nicarbazin as in §558.366.

(xi) Salinomycin as in §558.550.

(xii) 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.govinfo.gov.*

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§558.115 Carbadox.

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) Carbadox may also be used in combination with oxytetracycline as in §558.450.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004; 82 FR 21691, May 10, 2017]

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§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) *No. 054771:* 50, 70, 80, 90, or 100 grams per pound (g/lb) Type A medicated article.

(2) *No. 066104:* 10, 20, 30, 50, 70, or 100 g/lb of Type A medicated article.

(3) *No. 069254:* 50, 90, or 100 g/lb of Type A medicated article.

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

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

(2) The expiration date of VFDs for chlortetracycline medicated feeds must not exceed 6 months from the date of issuance. VFDs for chlortetracycline shall not be refilled.

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

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

(5) When manufactured for use as in paragraph (e)(5)(iii) of this section, include on labeling the warning: “Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.”

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 100 to 200 g/ton		Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline	Feed continuously for 7 to 14 days. For No. 066104: Do not feed to chickens producing eggs for human consumption	054771 066104 069254
(ii) 100 to 200 g/ton	Clopidol, 113.5	Broiler and replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E.*	Feed continuously as the sole ration from the time chicks are placed in floor pens for 7 to 14 days. Do not feed to chickens over 16 weeks of age. Do not feed to chickens producing	016592

		brunetti; and for control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline	eggs for human consumption. Chlortetracycline as provided by No. 054771; clopidol as provided by No. 016592 in §510.600(c) of this chapter	
(iii) 100 to 200 g/ton	Decoquinate, 27.2	Chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* and for control of infectious synovitis caused by *M, synoviae* susceptible to chlortetracycline	Feed continuously for 7 to 14 days. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption Chlortetracycline and decoquinate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 100 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline	Feed continuously as sole ration. Do not use this product in feeds conta Chlortetracycline and robenidine as provided by No.054771 in §510.600(c) of this chapter	054771
(v) 200 to 400 g/ton		Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline	Feed continuously for 7 to 14 days. For No. 066104: Do not feed to chickens producing eggs for human consumption	054771 066104 069254
(vi) 200 g/ton	Amprolium, 227 and ethopabate, 3.6	For chickens where immunity to coccidiosis is not desired: For prevention of coccidiosis; and for treatment of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline	Use in low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption. Chlortetracycline as provided by No.054771; amprolium and ethopabate as provided by No. 016592 in §510.600(c) of this chapter	054771
(vii) 200 g/ton	Decoquinate, 27.2	Broilers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* and for the treatment of chronic respiratory disease (air sac infection) and the prevention of synovitis	Feed continuously as the sole ration for no more than 8 weeks. Use in low calcium feed containing 0.8% dietary calcium. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption Chlortetracycline and decoquinate as provided by No. 054771 in §510.600(c) of this chapter	054771
(viii) 200 g/ton	Robenidine 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline	Feed continuously as sole ration. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter Chlortetracycline and robenidine as provided by No. 054771 in §510.600(c) of this chapter	054771
(ix) 500 g/ton		Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline	1. Feed for 5 days. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: zero withdrawal time	054771 069254
			2. Feed for 5 days; withdraw 24 hours prior to slaughter. Do not feed to chickens producing eggs for human consumption	054771 066104 069254
(x) 500 g/ton	Monensin, 90 to 110	Chickens: As an aid in the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline; and as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed for 5 days as the sole ration. Do not feed to laying chickens. Not to be fed continuously for more than 5 days. Do not feed to chickens over 16 weeks of age. Withdraw 24 hours before slaughter. See §558.355(d) of this chapter. Chlortetracycline as provided by No. 054771; monensin as provided by No. 058198 in §510.600(c) of this chapter	054771 069254
(xi) 500 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline	Feed continuously as sole ration for up to 5 days. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter Chlortetracycline and robenidine as provided by No. 054771 in §510.600(c) of this chapter	054771
(xii) 500 g/ton	Salinomycin, 40 to 60	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline	For use in low calcium feeds containing 0.8% calcium. Not approved for use with pellet binders. Not to be fed continuously for more than 5 days. Do not feed to laying chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by Nos. 054771 or 069254; salinomycin as provided by Nos. 054771 or 016592 in §510.600(c) of this chapter	016592 054771 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 200 g/ton		Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption	054771 066104 069254
(ii) 400 g/ton		1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption	054771 066104 069254
		2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline		054771 066104 069254

(iii) 25 mg/lb of body weight		Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption	054771 066104 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 50 to 100 g/ton		Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline		054771 066104 069254
(ii) 400 g/ton		Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline	Feed continuously for not more than 14 days	054771 066104 069254
(iii) 10 mg/lb of body weight		Swine: For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254 in §510.600(c) of this chapter	054771 066104 069254
(iv) 10 mg/lb of body weight	Bacitracin methylenedisalicylate, 10 to 30	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days. Chlortetracycline and bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 10 mg/lb of body weight	Bacitracin methylenedisalicylate, 10 to 30	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide 10 mg/lb of body weight. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254. Bacitracin methylenedisalicylate provided by No. 054771; chlortetracycline provided by Nos. 054771 and 069254 in §510.600(c) of this chapter	054771 069254
(vi) 10 mg/lb of body weight	Tiamulin hydrogen fumarate, 35	For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin and for treatment of swine bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* sensitive to chlortetracycline and treatment of bacterial pneumonia caused by *P. multocida* sensitive to chlortetracycline	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide 10 mg/lb of body weight. Feed continuously as the sole ration for 14 days. Withdraw medicated feed 2 days before slaughter. Tiamulin as provided by Nos. 058198 or 069254 in §510.600(c) of this chapter	058198 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.5 mg/lb of body weight daily		Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time	054771 066104 069254
(ii) 25 to 1,100 to provide 0.5 mg/lb of body weight daily	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) over 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis 0.5 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 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 *A. marginale* susceptible to chlortetracycline	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section	054771 069254
(iv) 10 mg/lb of body weight daily		1. Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor Nos. 054771 and 069254: zero withdrawal time. See paragraph (d)(3) of this section	054771 066104 069254
		2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline	See paragraph (d)(3) of this section	054771 066104 069254
(v) 10 mg/lb of body weight daily	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and	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	054771

		bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency	be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in §510.600(c) of this chapter	
(vi) 10 mg/lb of body weight daily	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in §510.600(c) of this chapter	054771
(vii) 500 to 2,000 to provide 10 mg/lb of body weight daily	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(viii) 500 to 1,200 to provide 10 mg/lb of body weight daily	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(ix) 500 to 4,000 to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(x) 500 to 4,000 g/ton		Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046-699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: Zero withdrawal period	054771 069254
(xi) 500 to 4,000	Decoquinate, 12.9 to 90.8	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xii) 4,000 to 20,000 g/ton		Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(3) of this section	054771 069254
(xiii) 4,000 to 20,000 g/ton	Decoquinate, 90.8 to 535.7	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *E. bovis* and *E. zuernii*	Administer as a top dress supplement or mix into the daily ration to provide 22.7 mg decoquinate per 100 lb of body weight per day and 1 g chlortetracycline per 100 lb body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in §510.600(c) of this chapter	054771
(xiv) 70 mg/head/day		Growing cattle (over 400 lb): For reduction of incidence of liver abscesses	See paragraph (d)(3) of this section	054771 066104 069254
(xv) 350 mg/head/day		1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline	To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 hours prior to slaughter. To sponsor No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal period	*
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline	To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 048-761 and No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal time	*
(xvi) 20 to 350 g/ton		Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline	Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to	054771

			be processed for veal. To sponsor No. 054771 under NADA 048-761: Zero withdrawal period	
(xvii) 350 mg/head/day	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in §510.600(c) of this chapter	054771
(xviii) 350 mg/head/day	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in §510.600(c) of this chapter	054771
(xix) 25 to 42.2 g/ton to provide 350 mg/head/day	Lasalocid, 25 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xx) 25 to 42.2 g/ton to provide 350 mg/head/day	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxi) 25 to 100 g/ton to provide 350 mg/head/day	Lasalocid, 10 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxii) 25 to 100 g/ton to provide 350 mg/head/day	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxiii) 25 to 700 to provide 350 mg/head/day	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxiv) 25 to 700 to provide 350 mg/head/day	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) under 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxv) 25 to 2,800 to provide 350 mg/head/day	Lasalocid, 30 to 181.8	Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Chlortetracycline and lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxvi) 25 to 2,800 to provide 350 mg/head/day	Lasalocid, 30 to 181.8	Beef cattle weighing up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for the control of coccidiosis caused by *E. bovis* and *E. zuernii*	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771 069254
(xxvii) 500 to 4,000 to provide 10 mg/head/day	Lasalocid, 30 to 181.8	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the control of coccidiosis caused	Hand feed continuously for not more than 5 days at a rate of 10 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for	054771 069254

		by *Eimeria bovis* and *E. zuernii*	veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	

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

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline		054771 066104 069254
(ii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day, depending upon age and severity of disease, for not more than 21 days. Do not feed to ducks producing eggs for human consumption	054771 069254
(iii) 10 mg/g of finished feed daily	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline	Feed continuously for 45 days. Each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. See paragraph (d)(5) of this section	054771 069254

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

(i) *Specifications.*

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

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

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

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

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

(v) *Sponsors.* See Nos. 054771 and 069254 in §510.600(c) of this chapter.

[81 FR 94995, Dec. 27, 2016, as amended at 82 FR 21691, May 10, 2017; 82 FR 43485, Sept. 18, 2017; 83 FR 13636, Mar. 30, 2018; 83 FR 14588, Apr. 5, 2018; 83 FR 48947, Sept. 28, 2018; 83 FR 64741, Dec. 18, 2018; 84 FR 8975, Mar. 13, 2019; 84 FR 39185, Aug. 9, 2019]

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§558.140 Chlortetracycline and sulfamethazine.

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

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

(2) 40 g/lb each, chlortetracycline and sulfamethazine.

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

(1) Nos. 054771 and 069254 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 054771 and 069254 for use of product described in paragraph (a)(2) as in paragraph (e)(2) of this section.

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

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

(2) The expiration date of VFDs for chlortetracycline and sulfamethazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for chlortetracycline and sulfamethazine shall not be refilled.

(e) *Conditions of use—*

(1) *Cattle—*

Chlortetracycline and sulfamethazine amount	Indications for use	Limitations	Sponsors
(i) To provide 350 milligrams per head per day each, chlortetracycline and sulfamethazine	Beef cattle: For aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever	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	054771 069254
(ii) [Reserved]			

(2) *Swine—*

Chlortetracycline and sulfamethazine amount	Indications for use	Limitations	Sponsors
(i) 100 g/ton of feed each, chlortetracycline and sulfamethazine	Swine: For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis	Feed as the sole ration. Withdraw 15 days prior to slaughter	054771 069254
(ii) [Reserved]			

[79 FR 37622, July 2, 2014, as amended at 80 FR 13231, Mar. 13, 2015; 81 FR 63054, Sept. 14, 2016; 81 FR 95004, Dec. 27, 2016; 82 FR 21691, May 10, 2017; 84 FR 12495, Apr. 2, 2019]

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§558.175 Clopidol.

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

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

(c) *Related tolerances.* See §556.160 of this chapter.

(d) *Conditions of use*—(1) *Chickens—*

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 113.5		Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Do not feed to chickens over 16 weeks of age	016592
(ii) 113.5	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and 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
(iii) 113.5	Bacitracin zinc, 5 to 25	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and 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
(iv) 113.5	Bambermycins, 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age	016592
(v) 227		Broiler and replacement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed continuously as the sole ration; 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
(vi) 227	Bambermycins, 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;*	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	016592

		and for increased rate of weight gain and improved feed efficiency.	slaughter. Do not feed to chickens over 16 weeks of age	

(2) *Turkeys*—

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 113.5 or 227		Turkeys: As an aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi.*	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter	016592
(ii) [Reserved]				

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

(i)-(ii) [Reserved]

(iii) Chlortetracycline as in §558.128.

(iv) Lincomycin as in §558.325.

(e) Clopidol may also be used in combination with:

(1)-(2) [Reserved]

(3) Chlortetracycline as in §558.128.

(4) Lincomycin as in §558.325.

[68 FR 17882, Apr. 14, 2003, as amended at 72 FR 60551, Oct. 25, 2007; 74 FR 61028, Nov. 23, 2009; 79 FR 10965, 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95004, Dec. 27, 2016; 84 FR 12495, Apr. 2, 2019]

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§558.195 Decoquinate.

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

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

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

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

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

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

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

(1) *Chickens*—

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2		Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*	Do not feed to laying hens producing eggs for human consumption	054771
(ii) 27.2	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* 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: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*	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

(2) *Cattle*—

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for human consumption. See paragraph (d)(3) of this section	054771
(ii) 12.9 to 90.8	Monensin, 5 to 30	Cattle fed in confinement for slaughter: For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for improved feed efficiency	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb of 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)(9)(i). Monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592, 054771
(iii) 90.9 to 535.7		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	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

(3) *Minor species—*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		1. Young sheep: For the prevention of coccidiosis caused by *Eimeria ovinoidalis, E. crandallis, E. parva,* and *E. bakuensis*	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption	054771
		2. Young goats: For the prevention of coccidiosis caused by *Eimeria christenseni* and *E. ninakohlyakimovae*	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption	
(ii) 90.9 to 535.7		1. Young sheep: For the prevention of coccidiosis caused by *Eimeria ovinoidalis, E. crandallis, E. parva,* and *E. bakuensis*	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 per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption	054771
		2. Young goats: For the prevention of coccidiosis caused by *Eimeria christenseni* and *E. ninakohlyakimovae*	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 per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption	

(4) Decoquinate may also be used in combination with:

(i)-(ii) [Reserved]

(iii) Chlortetracycline as in §558.128.

(iv) Lincomycin as in §558.325.

[67 FR 72370, Dec. 5, 2002; 68 FR 15372, Mar. 31, 2003; 69 FR 26499, May 13, 2004; 69 FR 52816, Aug. 30, 2004; 69 FR 62407, Oct. 26, 2004; 69 FR 67264, Nov. 17, 2004; 70 FR 2567, Jan. 14, 2005; 78 FR 25183, Apr. 30, 2013; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 79 FR 17860, Mar. 31, 2014; 80 FR 13231, Mar. 13, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 22525, Apr. 18, 2016; 81 FR 67152, Sept. 30, 2016; 81 FR 95004, Dec. 27, 2016; 83 FR 48947, Sept. 28, 2018; 84 FR 12496, Apr. 2, 2019; 85 FR 18121, Apr. 1, 2020]

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§558.198 Dichlorvos.

(a) *Specifications.* Each pound of Type A medicated article containing 3.1 or 9.6 percent dichlorvos.

(b) *Sponsor.* See No. 054628 in §510.600(c) of this chapter.

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

(d) *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.

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

Dichlorvos grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 348		Swine up to 70 pounds body weight: 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.	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.	054628
(ii) 479		Boars, open or bred gilts, and sows: 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.	Feed as sole ration at the rate of 6 pounds per head for one feeding.	054628
(iii) 334 to 500		Pregnant swine: 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 spp.*) large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.	Mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.	054628

[84 FR 12497, Apr. 2, 2019]

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§558.205 Diclazuril.

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

(b) *Sponsor.* See No. 058198 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 in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati*), and *E. maxima*	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*	058198
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati*), and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima.* Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	058198
(iii) 0.91	Bambermycins, 1 to 2	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati*), and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima.* Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	058198

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

Diclazuril grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91		Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis.*	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption.	058198
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis,* and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	058198

(iii) 0.91	Bambermycins, 1 to 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis,* and for improved feed efficiency	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	058198
(iv) 0.91	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis,* and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	058198

(3) Diclazuril may also be used in combination with virginiamycin as in §558.635.

[64 FR 35923, July 2, 1999, as amended at 65 FR 50134, Aug. 17, 2000; 66 FR 47962, 47963, Sept. 17, 2001; 66 FR 62917, Dec. 4, 2001; 67 FR 34830, May 16, 2002; 67 FR 47257, July 18, 2002; 67 FR 48549, July 25, 2002; 69 FR 9947, Mar. 3, 2004; 72 FR 60552, Oct. 25, 2007; 79 FR 10982, Feb. 27, 2014; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95004, Dec. 27, 2016. Redesignated and amended at 84 FR 12497, 12498, Apr. 2, 2019]

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§558.235 Efrotomycin.

(a) *Specifications.* Type A medicated articles containing 14.5 grams efrotomycin per pound.

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

(c) *Related tolerances.* See §556.224 of this chapter.

(d) *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; 84 FR 33001, July 11, 2019; 84 FR 39185, Aug. 9, 2019]

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§558.248 Erythromycin.

(a) *Specifications.* Type A medicated articles containing 92.5 grams per pound erythromycin (as the thiocyanate salt).

(b) *Sponsor.* See No. 061133 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.230 of this chapter.

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

(2) The expiration date of VFDs for erythromycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for erythromycin shall not be refilled.

(e) *Conditions of use*—(1) *Chickens*—

Erythromycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 92.5		Chickens: As an aid in the prevention of chronic respiratory disease during periods of stress	Feed for 2 days before stress and 3 to 6 days after stress. Withdraw 24 hours before slaughter	061623
(ii) 92.5		Chickens: As an aid in the prevention of infectious coryza	Feed for 7 to 14 days. Withdraw 24 hours before slaughter	061623
(iii) 185		Chickens: As an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease (CRD)	Feed for 5 to 8 days. Withdraw 48 hours before slaughter. Do not use in birds producing eggs for food	061623

(2) *Turkeys*—

Erythromycin thiocyanate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 92.5		Turkeys: As an aid in the prevention of chronic respiratory disease during periods of stress	Feed for 2 days before stress and 3 to 6 days after stress	061623
(ii) 185		Turkeys: As an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease (CRD)	Feed for 5 to 8 days. Do not use in birds producing eggs for food	061623

[41 FR 10999, Mar. 15, 1976, as amended at 45 FR 56799, Aug. 26, 1980; 49 FR 31281, Aug. 6, 1984; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 54 FR 12189, Mar. 24, 1989; 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 79 FR 10982, Feb. 27, 2014; 81 FR 36790, June 8, 2016; 81 FR 95004, Dec. 27, 2016; 84 FR 8975, Mar. 13, 2019]

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§558.254 Famphur.

(a) *Specifications.* Type A medicated articles containing 13.2 or 33.3 percent famphur.

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

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

(d) *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.

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

TABLE 2—SIZE PROXIES FOR SRCS IN 2016

Famphur in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.1 milligrams per pound (mg/lb) body weight per day	Beef cattle and nonlactating dairy cows: For control of grubs and as an aid in control of sucking lice	Feed for 30 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter	000061
(ii) 2.3 mg/lb body weight per day	Beef cattle and nonlactating dairy cows: For control of grubs	Feed for 10 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter	000061

[84 FR 39185, Aug. 9, 2019]

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§558.258 Fenbendazole.

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

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

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

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

(e) *Conditions of use*—(1) *Turkeys.*

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

(2) *Swine.*

Fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period		For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*)	Feed as the sole ration	000061

(ii) 10 to 300 (to provide 9 mg/kg of body weight)	Bacitracin methylenedisalicylate, 10 to 30	Growing/finishing swine: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); and for increased rate of weight gain and improved feed efficiency	Feed as the sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iii) 10 to 300 (to provide 9 mg/kg of body weight)	Bacitracin methylenedisalicylate, 250	1. Growing/finishing swine: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition	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 No. 054771 in §510.600(c) of this chapter	054771
		2. Pregnant sows: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*	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 No. 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 (*Dictyocaulus viviparus*); Stomach worms: barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*); Intestinal worms: hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia oncophora* and *C. punctata*); Bankrupt worms (*Trichostrongylus colubriformis*); and Nodular worms (*Oesophagostomum radiatum*).	Feed as the sole ration or as a top dress for one day. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	000061
(ii) [Reserved]			

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

Ingredient[1]	Percent	International Feed No.
(*1*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6-04-152
Monosodium phosphate	31.16	6-04-288
Dried cane molasses	3.12	4-04-695
Zinc sulfate	0.76	6-05-556
Copper sulfate	0.45	6-01-720
Fenbendazole 20% Type A article	5.51	n/a
(*2*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6-04-152
Dicalcium phosphate (18.5% P)	32.44	6-00-080
Calcium carbonate (38% Ca)	15.93	6-01-069
Magnesium oxide (56% Mg)	10.14	6-02-756
Zinc sulfate	1.47	6-05-556
Mineral oil	1.00	8-03-123
Dried cane molasses (46% sugars)	0.98	4-04-695
Potassium iodide	0.01	6-03-759
Fenbendazole 20% Type A article	2.10	n/a
(*3*) Free-choice, liquid Type C feed:		
Cane molasses[2]	80.902	4-13-251
Water	9.36	n/a
Urea solution, 55%	7.05	5-05-707
Phosphoric acid 75% (feed grade)	2.00	6-03-707
Xantham gum	0.20	8-15-818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

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

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

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

(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(4) *Horses.*

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

(5) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (*Sus scrofa*)	3 mg/kg/day for 3 days.	For the removal and control of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*)	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae)	2.5 mg/kg/day for 3 days.	For the removal and control of small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.)	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season	000061
(iii) Rocky mountain bighorn sheep (*Ovis c. canadensis*)	10 mg/kg/day for 3 days.	For the removal and control of *Protostrongylus* spp	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season	000061

(6) Fenbendazole may also be used in combination with:

(i) [Reserved]

(ii) Lincomycin as in §558.325.

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003; 72 FR 66046, Nov. 27, 2007; 73 FR 58873, Oct. 8, 2008; 74 FR 61517, Nov. 25, 2009; 79 FR 13545, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95005, Dec. 27, 2016; 84 FR 12499, Apr. 2, 2019]

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§558.261 Florfenicol.

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

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

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

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

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

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

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

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

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

(3) VFDs for florfenicol shall not be refilled.

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

(e) *Conditions of use*—(1) *Swine*—

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

(2) *Fish*—

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

[70 FR 70047, Nov. 21, 2005, as amended at 71 FR 70304, Dec. 4, 2006; 72 FR 19798, Apr. 20, 2007; 72 FR 65885, Nov. 26, 2007; 77 FR 32012, May 31, 2012; 79 FR 18159, Apr. 1, 2014; 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016; 81 FR 67152, Sept. 30, 2016]

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§558.265 Halofuginone.

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

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

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

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

(1) *Chickens*—

Halofuginone in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor

(i) 2.72		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed continuously as sole ration. Do not feed to layers. Withdraw 4 days before slaughter	016592
(ii) 2.72	Bacitracin methylenedisalicylate, 10 to 50	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* for improved feed efficiency	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days before slaughter	016592
(iii) 2.72	Bambermycins, 1 to 2	Broiler chickens: 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	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days before slaughter	016592
(iv) 2.72		Replacement broiler breeder chickens and replacement cage laying chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati/E. mitis,* and *E. brunetti*	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. Do not feed to laying chickens or water fowl. Withdraw 4 days before slaughter	016592

(2) *Turkeys*—

Halofuginone in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.36 to 2.72		Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis*	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to layers or water fowl	016592
(ii) 1.36 to 2.72	Bacitracin methylenedisalicylate, 10 to 50	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl	016592
(iii) 1.36 to 2.72	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl	016592

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

(i) Lincomycin as in §558.325.

(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; 84 FR 8975, Mar. 13, 2019]

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§558.274 Hygromycin B.

(a) *Specifications.* Type A medicated articles containing 2.4 or 8 grams hygromycin B per pound (g/lb).

(b) *Sponsor.* See No. 058198 in §510.600(c) of this chapter for as follows:

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

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

(2) The expiration date of VFDs for hygromycin B medicated feeds must not exceed 6 months from the date of issuance. VFDs for hygromycin B shall not be refilled.

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

(1) *Chickens*—

Hygromycin B grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8 to 12		Chickens: For control of infections of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*)	Use in complete feed. Withdraw 3 days before slaughter	058198
(ii) [Reserved]				

(2) Swine—

Hygromycin B grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor

(i) 12		Swine: For control of infections of large roundworms (*A. suis*), nodular worms (*O. dentatum*), and whipworms (*Trichuris suis*)	In market hogs, use in complete feed for 8 weeks during the growing period. Withdraw 15 days before slaughter	058198
(ii) [Reserved]				

[81 FR 95005, Dec. 27, 2016]

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§558.295 Iodinated casein.

(a) *Approvals.* See 017762 in §510.600(c) of this chapter.

(b) [Reserved]

(c) *Conditions of use*—(1) *Ducks*—(i) *Amount per ton.* 100 to 200 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feathering in growing ducks.

(2) *Dairy cows*—(i) *Amount per pound.* ½ to 1½ grams per 100 lb of body weight.

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

(iii) *Limitations.* This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration must be accompanied with increased feed intake; administration may increase heat sensitivity of the animal.

[45 FR 41631, June 20, 1980, as amended at 81 FR 67152, Sept. 30, 2016]

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§558.300 Ivermectin.

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

(b) *Sponsor.* See No. 000010 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 grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 1.8		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*)	Feed as the only feed for 7 consecutive days to provide 0.1 milligrams per kilograms (mg/kg) of body weight per day. Withdraw 5 days before slaughter	000010
(2) 1.8	Bacitracin methylenedisalicylate, 10 to 30	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei*var. *suis*); and for increased rate of weight gain and improved feed efficiency	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter	000010
(3) 1.8	Bacitracin methylenedisalicylate, 250	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter	000010

(4) 1.8 to 11.8		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*)	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter	000010
(5) 1.8 to 11.8	Bacitracin methylenedisalicylate, 250	Pregnant sows: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. 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	000010
(6) 18.2 to 120		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*)	Top dress on daily ration for individual treatment for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter	000010

[72 FR 37437, July 10, 2007, as amended at 81 FR 17609, Mar. 30, 2016; 81 FR 95005, Dec. 27, 2016; 84 FR 12499, Apr. 2, 2019; 84 FR 39185, Aug. 9, 2019]

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§558.305 Laidlomycin.

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

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

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

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

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

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

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

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

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

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

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

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

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 5		For improved feed efficiency and increased rate of weight gain.	Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day.	054771
(2) 5 to 10		For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day.	054771

(f) Laidlomycin may also be used in combination with chlortetracycline as in §558.128.

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004; 79 FR 13545, Mar. 11, 2014; 81 FR 95005, Dec. 27, 2016]

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§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. 067949 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

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

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

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

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

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

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

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

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

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

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

(5) Required label statements:

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

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

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

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

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

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

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct)		For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	For broiler or fryer chickens only; feed continuously as the sole ration	054771
(ii) 68 (0.0075 pct) to 113 (0.0125 pct)	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bambermycins provided by No. 016592 in §510.600(c) of this chapter.	016592
(iii) [Reserved]				
(iv) 68 (0.0075 percent)	Bacitracin 10 to 50	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	054771
(v) [Reserved]				
(vi) 10 (0.0011 pct) to 30 (0.0033 pct)		Cattle; for improved feed efficiency	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day	054771
(vii) 25 (0.0027 pct) to 30 (0.0033 pct)		Cattle; for improved feed efficiency and increased rate of weight gain	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day	054771
(viii) 20 (0.0022 pct) to 30 (0.0033 pct)		Sheep; for the prevention of coccidiosis caused by *Eimeria ovina, E. crandallis, E. ovinoidalis* (*E. ninakohlyakimovae*), *E. parva,* and *E. intricata*	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight	054771
(ix)		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed.	054771

(x) 68 (0.0075 pct) to 113 (0.0125 pct)	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for improved feed efficiency	For broiler chickens only; feed continuously as the sole ration; bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	054771
(xi) 68 (0.0075 pct) to 113 (0.0125 pct)	Bacitracin zinc 4 to 50	Broiler chickens. For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 054771 in §510.600(c) of this chapter.	054771
(xii)		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day.	054771
(xiii)		Cattle; for control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day	054771
(xiv) 113 (0.0125 pct)		Chukar partridges; for prevention of coccidiosis caused by *Eimeria legionensis*	Feed continuously as sole ration up to 8 weeks of age	054771
(xv) 68 (0.0075 pct) to 113 (0.0125 pct)		Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides.*	Feed continuously as sole ration	054771
	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration	054771
	Bacitracin methylenedisalicylate 4 to 50	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	054771
(xvi)		Replacement calves; for control of coccidiosis caused by *E. bovis* and *E. zuernii.*	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: “A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal”	054771
(xvii) 113 (0.0125 pct)		Rabbits; for prevention of coccidiosis caused by *Eimeria stiedae*	Feed continuously as sole ration up to 6½ weeks of age	054771
(xviii) 1440		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	021930 017800
(xix) 300		Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	067949
(xx)-(xxviii) [Reserved]				

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

(i) *Specifications.*

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

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

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

(ii) *Amount.* 1,440 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

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

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

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

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

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

(ii) *Amount.* 150 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

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

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

(i) *Specifications.*

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

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

(CPG 7125.18).

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

(ii) *Amount.* 1,088 grams per ton.

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

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

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

(5) Lasalocid may also be used in combination with:

(i) Chlortetracycline as in §558.128.

(ii) Lincomycin as in §558.325.

(iii) Melengestrol as in §558.342.

(iv) Oxytetracycline as in §558.450.

(v) Tylosin alone or in combination with melengestrol acetate as in §558.625.

(vi) Virginiamycin as in §558.635.

[41 FR 44382, Oct. 8, 1976]

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

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§558.325 Lincomycin.

(a) *Specifications.* Type A medicated articles containing 20 or 50 grams of lincomycin (as lincomycin hydrochloride) per pound.

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

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

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

(2) The expiration date of VFDs for lincomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for lincomycin shall not be refilled.

(3) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin shall bear the following:

(i) “CAUTION: Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.”

(ii) [Reserved]

(4) Labeling of medicated feeds containing lincomycin intended for use in swine shall bear the following:

(i) “CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.”

(ii) “CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been

determined."

(e) *Conditions of use*—(1) *Chickens*—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 2		Broilers: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin	Feed as the sole ration. Not for use in layers, breeders, or turkeys	054771
(ii) [Reserved]				
(iii) 2	Clopidol, 113.5	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid in the prevention of cecal and intestinal coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed as the sole ration to broiler chickens. Do not feed to chickens over 16 weeks of age. Not for use in laying hens, breeding chickens, or turkeys. 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. Clopidol as provided by No. 016592 in §510.600 of this chapter	054771
(iv) 2	Decoquinate, 27.2	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed as the sole ration. Do not use in feeds containing bentonite. Not for use in laying hens, breeding chickens, or turkeys. 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. Decoquinate as provided by No. 054771 in §510.600 of this chapter	054771
(v) 2	Halofuginone 2.72	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed continuously as sole ration. Withdraw 4 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide as provided by No. 016592 in §510.600 of this chapter	016592
(vi) 2	Lasalocid, 68 to 113	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E maxima*	Feed as the sole ration. Type C feed must be used within 4 weeks of manufacture. Not for use in laying hens, breeding chickens, or turkeys. 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. Lasalocid as provided by No. 054771 in §510.600 of this chapter	054771
(vii) 2	Monensin, 90 to 110	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed as the sole ration. Must be thoroughly mixed in feeds before use. Do not feed undiluted. Not for use in laying hens, breeding chickens, or turkeys. Do not allow horses, or other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. 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. Monensin as provided by No. 058198 in §510.600 of this chapter	054771
(viii) 2	Robenidine hydrochloride, 30	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*	Feed as the sole ration. Do not use in feeds containing bentonite. Do not feed to laying hens producing eggs for human consumption. Not for use in laying hens, breeding chickens, or turkeys. 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. Withdraw 5 days prior to slaughter. Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Robenidine hydrochloride as provided by No. 054771 in §510.600 of this chapter	054771
(ix) 2	Salinomycin sodium, 40 to 60	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E maxima, E. brunetti,* and *E. mivati*	Feed as the sole ration to broiler chickens. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Not for use in laying hens, breeding chickens, or turkeys. 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. Salinomycin sodium as provided by No. 054771 in §510.600 of this chapter	054771
(x) 2	Zoalene, 113.5	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and for the prevention and control of coccidiosis	Feed as the sole ration from the time chicks are placed in floor pens until slaughtered for meat. Not for use in laying hens, breeding chickens, or turkeys. 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. Zoalene as provided by No. 054771 in §510.600 of this chapter	054771

(2) *Swine*—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 40		For control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*	Feed as sole ration. For use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis)	054771

(ii) 40	Fenbendazole, 10 to 80	For control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages —intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*)	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in §510.600(c) of this chapter	000061
(iii) 40	Pyrantel, 96	For control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(iv) 40	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(v) 40 or 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	For treatment of swine dysentery, feed 100 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed for 3 weeks or until clinical signs of the disease disappear, following with 40 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(vi) 40	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections	Feed as a single therapeutic treatment at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb and 5 lb of feed per head for animals over 200 lb. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. See paragraph (d) of this section. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(vii) 100		For treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear	054771
(viii) 100	Fenbendazole, 10 to 80	For the treatment of swine dysentery; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*)	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in §510.600(c) of this chapter	000061
(ix) 100	Pyrantel, 96	For the treatment of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(x) 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(xi) 100	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections	Feed as a single therapeutic treatment. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(xii) 100 to 200		For reduction in the severity of the effects of respiratory disease associated with *Mycoplasma hyopneumoniae*	Feed as sole ration for 21 days	054771
(xiii) 200	Fenbendazole, 10 to 80	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages —intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*)	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in §510.600(c) of this chapter	000061
(xiv) 200	Pyrantel, 96	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed as the sole ration for 21 days. Not for use in swine that weigh more than 250 pounds. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in §510.600(c) of this chapter	054771

[81 FR 95005, Dec. 27, 2016, as amended at 82 FR 12170, Mar. 1, 2017; 82 FR 21691, May 10, 2017; 83 FR 13637, Mar. 30, 2018; 83 FR 14588, Apr. 5, 2018; 83 FR 48947, Sept. 28, 2018; 83 FR 64741, Dec. 18, 2018; 84 FR 8976, Mar. 13, 2019; 84 FR 12501, Apr. 2, 2019; 84 FR 39185, Aug. 9, 2019]

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§558.330 Lubabegron.

(a) *Specifications.* Each pound of Type A medicated article contains 4.54 grams (10 grams per kilogram) of lubabegron as lubabegron fumarate.

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

(c) *Related tolerances.* See §556.370 of this chapter.

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

Lubabegron fumarate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.25 to 4.54		Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron	058198
(ii) 1.25 to 4.54	Monensin, 5 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. 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. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal	058198
(iii) 1.25 to 4.54	Monensin, 10 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. 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. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal	058198

(2) Lubabegron may also be used in combination with:

(i) Tylosin as in §558.625.

(ii) [Reserved]

[84 FR 12501, Apr. 2, 2019, as amended at 84 FR 53311, Oct. 7, 2019]

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§558.340 Maduramicin.

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

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

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

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

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

[54 FR 5229, Feb. 2, 1989, as amended at 54 FR 26732, June 26, 1989; 54 FR 32635, Aug. 9, 1989; 54 FR 33885, Aug. 17, 1989; 55 FR 23, Jan. 2, 1990; 55 FR 8460, Mar. 8, 1990; 55 FR 49616, Nov. 30, 1990; 59 FR 8134, Feb. 18, 1994; 61 FR 18082, Apr. 24, 1996; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 79 FR 13545, Mar. 11, 2014; 81 FR 22525, Apr. 18, 2016]

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§558.342 Melengestrol.

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

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

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

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

(2) No. 058198 for use of product described in paragraph (a)(2) of this section.

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

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

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

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

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

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

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

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

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

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

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

(e) *Conditions of use*—(1) *Cattle.*

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor

(i) 0.25 to 0.5		Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day.	054771, 058198
(ii) 0.5		Heifers intended for breeding: For suppression of estrus (heat).	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding.	054771, 058198
(iii) 0.25 to 0.5	Lasalocid, 10 to 30	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 g of lasalocid per ton to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 milligrams of lasalocid per head/day. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771, 058198
(iv) 0.25 to 0.5	Monensin, 10 to 40	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Add at the rate of 0.5 to 2 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1 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. See §558.355(d). Monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592, 054771, 058198

(2) Melengestrol may also be used in combination with:

(i) Oxytetracycline as in §558.450.

(ii) Ractopamine as in §558.500.

(iii) Tylosin as in §558.625.

(iv) Zilpaterol as in §558.665.

[42 FR 28535, June 3, 1977]

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

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§558.348 Mibolerone.

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

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

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

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

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§558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing 45, 60, 90.7, or 110 grams monensin, USP, per pound.

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

(1) No. 058198 for use as in paragraph (f) of this section.

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams monensin, USP, per pound as in paragraphs (f)(3), (f)(4)(vi), and (f)(6) of this section.

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

(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) [Reserved]

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

(1) *Chickens*—

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 90 to 110		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*	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	058198
(ii) 90 to 110		Replacement chickens intended for use as cage layers: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens	058198

		E. maxima		
(iii) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50	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 improved feed efficiency	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. Bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50	Replacement chickens intended for use as cage layers: 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 increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 90 to 110	Bacitracin methylenedisalicylate, 5 to 25	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 increased rate of weight gain and improved feed efficiency	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. Bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	058198
(vi) 90 to 110	Bacitracin methylenedisalicylate, 50	Broiler and replacement chickens intended for use as cage layers: 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 improved feed efficiency, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in §510.600(c) of this chapter	054771
(vii) 90 to 110	Bacitracin zinc, 4 to 50	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 increased rate of weight gain and improved feed efficiency	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. Bacitracin zinc provided by No. 054771 in §510.600(c) of this chapter	054771
(viii) 90 to 110	Bacitracin zinc, 10	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 increased rate of weight gain and improved feed efficiency	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. Bacitracin zinc provided by No. 054771 in §510.600(c) of this chapter	058198
(ix) 90 to 110	Bacitracin zinc, 10 to 30	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 improved feed efficiency	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. Bacitracin zinc provided by No. 054771 in §510.600(c) of this chapter	058198
(x) 90 to 110	Bambermycins, 1 to 2	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 increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Do not feed to laying chickens. Bambermycins provided by No. 016592 in §510.600(c) of this chapter	016592, 058198

(2) *Turkeys*—

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 54 to 90		Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis*	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. 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	058198
(ii) 54 to 90	Bacitracin methylenedisalicylate, 4 to 50	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency	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. 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. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	058198
(iii) 54 to 90	Bacitracin methylenedisalicylate, 200	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate	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. 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. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	058198
(iv) 54 to 90	Bambermycins, 1 to 2	Growing turkeys: For the prevention of coccidiosis in turkeys caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for improved feed efficiency	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	058198
(v) 54 to 90	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency	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	058198

(3) *Cattle—*

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency	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)	058198
(ii) 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	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	058198
(iii) 10 to 200	Calves excluding veal calves: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	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	058198
(iv) 11 to 22	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)	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	058198
(v) 11 to 400	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)	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	058198
(vi) 15 to 400	Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	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	058198
(vii) 25 to 400	For improved feed efficiency, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	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	058198

(4) *Free-choice cattle feeds—*

Monensin amount	Indications for use	Limitations	Sponsor
(i) 150 milligrams per pound of protein-mineral block (0.033%)	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis caused by *E. bovis* and *E. zuernii* in pasture cattle which may require supplemental feed	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	058198
(ii) 175 milligrams per pound of protein-mineral block (0.038%)	Pasture cattle (slaughter, stocker, and feeder): For increased rate of weight gain	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	017800
(iii) 400 milligrams per pound of protein-mineral block (0.088%)	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain	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	067949
(iv) 400 mg per pound of block (0.088%)	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain	Provide 50 to 200 mg 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 mg 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	086113
(v) In free-choice Type C medicated feeds to provide 50 to 200 mg per head per day	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 *E. bovis* and *E. zuernii*	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	058198
(vi) 1,620 grams per ton of mineral granules as specified in paragraph (f)(4)(vi)(A) of this section	Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	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	058198

(A) *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 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).

(B) [Reserved]

(5) *Bobwhite quail—*

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 73	Growing bobwhite quail: For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*	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)	058198
(ii) [Reserved]			

(6) *Goats—*

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 20	For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae*	Feed only to goats being fed in confinement. Do not feed to lactating goats. See paragraph (d)(11) of this section for provisions for monensin liquid Type C goat feeds	058198
(ii) [Reserved]			

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

(i) Avilamycin as in §558.68.

(ii) Chlortetracycline as in §558.128.

(iii) Decoquinate as in §558.195.

(iv) Lubabegron as in §558.330.

(v) Lincomycin as in §558.325.

(vi) Melengestrol acetate as in §558.342.

(vii) Oxytetracycline as in §558.450.

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

(ix) Tilmicosin as in §558.618.

(x) Tylosin as in §558.625.

(xi) Virginiamycin as in §558.635.

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

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: 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.govinfo.gov.*

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§558.360 Morantel.

(a) *Specifications.* Each pound of Type A medicated article contains 88 grams morantel tartrate.

(b) *Sponsor.* See No. 066104 in §510.600(c) of this chapter.

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

(d) *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.

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

Morantel tartrate in grams/ton	Indications for use	Limitations	Sponsor
(1) 0.44 to 4.4 grams of morantel tartrate per pound of feed	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*)	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	066104
(2) 0.44 to 4.4 grams of morantel tartrate per pound of feed	Goats: For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus, Ostertagia (Teladorsagia) circumcincta,* and *Trichostrongylus axei*	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 goats within 30 days of slaughter	066104

[84 FR 39185, Aug. 9, 2019]

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§558.363 Narasin.

(a) *Specifications.* Type A medicated articles containing 36, 45, 54, 72, and 90 grams narasin per pound.

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

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

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

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

(1) *Chickens*—

Narasin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 54 to 90		Broiler chickens: For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	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	058198
(ii) 54 to 72	Bacitracin methylenedisalicylate, 10 to 50	Broiler chickens: 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	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. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iii) 54 to 72	Bacitracin zinc, 4 to 50	Broiler chickens: 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	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. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 54 to 72	Bambermycins, 1 to 2	Broiler chickens: 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	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. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592

(2) *Swine*—

Narasin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor

(i) 13.6 to 27.2		Growing-finishing swine: For increased rate of weight gain when fed for at least 4 weeks	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	058198
(ii) 18.1 to 27.2		Growing-finishing swine: For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks	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	058198

(3) Narasin single-ingredient Type A medicated articles may also be used in combination with:

(i) Avilamycin as in §558.68.

(ii) [Reserved]

[83 FR 64741, Dec. 18, 2018]

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§558.364 Narasin and nicarbazin.

(a) *Specifications.* A fixed-ratio, combination drug Type A medicated article containing 36 grams narasin and 36 grams nicarbazin per pound.

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

(c) *Tolerances.* See §§556.428 and 556.445 of this chapter.

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

(1) *Chickens—*

Narasin and nicarbazin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27 to 45 of each drug		Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. The two drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 058198 in §510.600(c) of this chapter may be used in the combination	058198
(ii) 27 to 45 of each drug	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. 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. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	058198
(iii) 27 to 45 of each drug	Bacitracin methylenedisalicylate, 50	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 27 to 45 of each drug	Bacitracin methylenedisalicylate, 100 to 200	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 27 to 45 of each drug	Bambermycins, 1 to 2	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed	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 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. Bambermycins as provided by No. 016592 in §510.600(c) of this	058198

		efficiency	chapter	

(2) Narasin and nicarbazin fixed-ratio, combination drug Type A medicated articles may also be used in combination with:

(i) Avilamycin as in §558.68.

(ii) [Reserved]

[83 FR 64742, Dec. 18, 2018, as amended at 84 FR 8981, Mar. 13, 2019]

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§558.365 Neomycin sulfate.

(a) *Specifications.* Type A medicated article containing 325 grams neomycin sulfate per pound.

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

(c) *Related tolerances.* See §556.430 of this chapter.

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

(2) The expiration date of VFDs for neomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for neomycin shall not be refilled.

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

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(1) 250 to 2,250 grams per ton (g/t) of dry type C feed.		Cattle, swine, sheep, and goats. For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin.	To provide 10 milligrams (mg) of neomycin sulfate per pound of body weight per day for a maximum of 14 days. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in dry feeds only. Not for use in liquid feed supplements.	054771
(2) 400 to 2,000 g/t of type C milk replacer.		Do.	To provide 10 mg of neomycin sulfate per pound of body weight per day for a maximum of 14 days. Amount consumed will vary depending on animal's consumption and weight. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in milk replacers only.	054771

[64 FR 70576, Dec. 17, 1999, as amended at 65 FR 45881, July 26, 2000; 79 FR 13545, Mar. 11, 2014; 81 FR 95009, Dec. 27, 2016. Redesignated at 83 FR 64742, Dec. 18, 2018]

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§558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Sponsors.* See Nos. 058198, 060728, and 066104 in §510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances.* See §556.445 of this chapter.

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

(1) *Chickens*—

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor

(i) 90.8 to 181.6		Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. 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
(ii) 90.8 to 181.6	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, 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 outbreaks of coccidiosis. Do not use in flushing mashes. 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. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iii) 90.8 to 181.6	Bacitracin methylenedisalicylate, 30	Broiler chickens; As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	066104
(iv) 90.8 to 181.6	Bacitracin methylenedisalicylate 50	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. 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. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 113.5		Chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter	058198 060728
(vi) 113.5	Bacitracin methylenedisalicylate, 30	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	060728
(vii) 113.5	Bacitracin zinc, 4 to 50	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104, bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter	054771 066104
(viii) 113.5	Bambermycins, 1 to 2	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104; bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592

(2) [Reserved]

[83 FR 64743, Dec. 18, 2018]

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§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*—

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) To provide 6 to 7 milligrams per pound (mg/lb) of body weight per day.	Chickens: As an aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying chickens. Withdraw 4 days before slaughter.	054771
(ii) To provide 10 to 14 mg/lb of body weight per day.	Chickens: For the treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 350 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying chickens. Withdraw 4 days before slaughter.	054771

(2) *Turkeys—*

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) To provide 4 to 5 mg/lb of body weight per day.	Turkeys: As an aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771
(ii) To provide 5 to 8 mg/lb of body weight per day.	Turkeys: As an aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7 to 8 mg/lb of body weight per day.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771
(iii) To provide 7 to 8 mg/lb of body weight per day.	Turkeys: For the treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin; and treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.	Administer feed which contains not less than 350 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771

(3) *Minor species—*

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) 350 grams per ton.	Ducks: For the control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida,* susceptible to novobiocin.	Administer as the 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.	054771
(ii) To provide 20 mg/lb of body weight per day.	Mink: For the treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 7 days.	054771

[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; 84 FR 12501, Apr. 2, 2019]

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§558.430 Nystatin.

(a) *Specifications.* Type A medicated article containing 20 grams of nystatin activity per pound.

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

(c) *Related tolerances.* See §556.470 of this chapter.

(d) *Conditions of use.* It is used for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 79 FR 13545, Mar. 11, 2014]

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§558.450 Oxytetracycline.

(a) *Specifications.* Each pound of Type A medicated article contains:

(1) Oxytetracycline (from oxytetracycline quaternary salt) equivalent to 50 or 100 grams oxytetracycline hydrochloride; or oxytetracycline (from oxytetracycline dihydrate base) equivalent to 10, 30, 50, 100, or 200 grams oxytetracycline hydrochloride.

(2) Oxytetracycline (from oxytetracycline dihydrate base) equivalent to 50, 100, or 200 grams oxytetracycline hydrochloride; or 100 grams oxytetracycline hydrochloride.

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

(1) No. 066104: Type A medicated articles as in paragraph (a)(1) of this section.

(2) No. 069254: Type A medicated articles as in paragraph (a)(2) of this section.

(c) *Related tolerances.* See §556.500 of this chapter.

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

(2) The expiration date of VFDs for oxytetracycline medicated feeds must not exceed 6 months from the date of issuance. VFDs for oxytetracycline shall not be refilled.

(3) In accordance with §558.5, labeling shall bear the statement: “For use in dry animal feed only. Not for use in liquid feed supplements.”

(e) *Conditions of use*—(1) *Chickens*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 100 to 200 g/ton		Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* and control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Zero-day withdrawal period	066104 069254
(ii) 200 g/ton	Monensin, 90 to 110	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for the control of complicated chronic respiratory disease (CRD or air sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*	Feed continuously as the sole ration. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 72 hours before slaughter. See §558.355(d) of this chapter Oxytetracycline as provided by No. 066104; monensin as provided by No. 058198 in §510.600(c) of this chapter	066104
(iii) 400 g/ton		Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Zero-day withdrawal period	066104 069254
(iv) 400 g/ton	Robenidine, 30	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for the control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 5 days before slaughter. Oxytetracycline as provided by No. 066104; robenidine as provided by No. 054771 in §510.600(c) of this chapter	066104
(v) 500 g/ton		Chickens: For reduction of mortality due to air saccultis (air sac infection) caused by *E. coli* susceptible to oxytetracycline	Feed continuously for 5 days. Do not feed to chickens producing eggs for human consumption. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 24 hours before slaughter	066104 069254
(vi) 500 g/ton	Monensin, 90 to 100	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and as an aid in the reduction of mortality due to air-sacculitis (air sac infection) caused by *Escherichia coli* sensitive to oxytetracycline	Feed for 5 days as the sole ration. Treat at first clinical signs of the disease. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 72 hours before slaughter. See §558.355(d) of this chapter. Oxytetracycline as provided by No. 066104; monensin as provided by No. 058198 in §510.600(c) of this chapter	066104
(vii) 500 g/ton	Salinomycin, 40 to 60	Chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and as an aid in the reduction of mortality due to air-sacculitis (air sac infection) caused by *E. coli* sensitive to oxytetracycline	Feed for 5 days as the sole ration. Treat at first clinical signs of the disease. Do not feed to laying chickens. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 24 hours before slaughter. Oxytetracycline as provided by No. 066104; salinomycin as provided by No. 016592 in §510.600(c) of this chapter	066104 016592

(2) *Turkeys*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 100 g/ton	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period	066104 069254
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. For No. 066104, withdraw 5 days before slaughter. For No. 069254, zero-day withdrawal period	066104 069254
(iii) 25 mg/lb of body weight daily	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. For No. 066104, withdraw 5 days before slaughter. For No. 069254, zero-day withdrawal period	066104 069254

(3) *Swine*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor

(i) 10 mg/lb of body weight daily		1. Swine: For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	Feed continuously for 7 to 14 days	066104 069254
		2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	Feed continuously for 14 days	066104 069254
(ii) 10 mg/lb of body weight daily	Carbadox, 10 to 25	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not mix in feeds containing bentonite. Do not feed to swine within 42 days of slaughter. Oxytetracycline and carbadox as provided by No. 066104 in §510.600(c) of this chapter	066104

(4) *Cattle—*

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily		1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	Feed continuously for 7 to 14 days. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period	066104 069254
		2. Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline	Feed continuously for 7 to 14 days in milk replacer or starter feed. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period	066104 069254
(ii) 75 mg/head/day		Growing cattle (over 400 lb): For reduction of incidence of liver abscesses	Feed continuously	066104 069254
(iii) 75 mg/head/day	Lasalocid 25 to 30	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain and improved feed efficiency	Feed continuously to provide 250 to 360 mg lasalocid and 75 mg of oxytetracycline per head per day. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 75 mg/head/day	Melengestrol acetate, 0.25 to 2.0	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Feed continuously to provide 0.25 to 0.5 mg of melengestrol acetate and 75 mg of oxytetracycline per head per day. Melengestrol as provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 0.5 to 2.0 g/head/day		Cattle: For prevention and treatment of the early stages of shipping fever complex	Feed 3 to 5 days before and after arrival in feedlots	066104 069254

(5) *Minor species—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter	066104 069254
(ii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline	Remove at least 6 weeks prior to main honey flow	066104 069254
(iii) 2.5 to 3.75 g/100 lb of fish/day	1. Salmonids: For control of ulcer disease caused by *Haemophilus piscium,* furunculosis caused by *Aeromonas salmonicida,* bacterial hemorrhagic septicemia caused by *A. hydrophila,* and pseudomonas disease	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed	066104
	2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. hydrophila* and pseudomonas disease	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F)	066104
(iv) 3.75 g/100 lb of fish/day.	3. Freshwater-reared salmonids weighing up to 55 grams: For marking the skeletal tissue	Feed for 10 days. Immediate release is permitted following the last feeding of medicated feed	066104
(v) 11.35 g/100 lb of fish/day.	Pacific salmon not over 30 grams body weight: For marking of skeletal tissue	Administer medicated feed as the sole ration for 4 consecutive days. Do not liberate for at least 7 days following last feeding of medicated feed	066104
(vi) 1 g/lb of medicated feed	Lobsters: For control of gaffkemia caused by *Aerococcus viridans*	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 days before harvesting lobsters	066104

[81 FR 95009, Dec. 27, 2016, as amended at 82 FR 11512, Feb. 24, 2017; 83 FR 48948, Sept. 28, 2018; 84 FR 12502, Apr. 2, 2019]

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§558.455 Oxytetracycline and neomycin.

(a) *Specifications.* Type A medicated articles containing oxytetracycline equivalent to 50 grams per pound (g/lb)

oxytetracycline hydrochloride and 50 g/lb neomycin sulfate or oxytetracycline equivalent to 100 g/lb oxytetracycline hydrochloride and 100 g/lb neomycin sulfate.

(b) *Sponsors.* See Nos. 066104 and 069254 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §§556.430 and 556.500 of this chapter.

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

(2) The expiration date of VFDs for oxytetracycline and neomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for oxytetracycline and neomycin shall not be refilled.

(3) Cattle feeds shall bear the following warning statement: “Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.”

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

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) [Reserved]			
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.	066104 069254
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	066104 069254
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac- infection) caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.	066104 069254

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

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) [Reserved]			
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	066104 069254
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	066104 069254
(iv) To provide 25 milligrams per pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	066104 069254

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

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) [Reserved]			
(ii) To provide 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	066104 069254
	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	066104 069254

(4) *Cattle and sheep.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i)-(ii) [Reserved]			
(iii) To provide 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	066104 069254

	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	066104 069254
	3. Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.	066104 069254
(iv) [Reserved]			
(v) To provide 75 mg/head/day	Growing cattle (over 400 lb): For reduction of liver condemnation due to liver abscesses.	Feed continuously.	066104 069254
(vi) To provide 0.5 to 2.0 g/head/ day	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.	066104 069254

[71 FR 16225, Mar. 31, 2006, as amended at 74 FR 40724, Aug. 13, 2009; 80 FR 13232, Mar. 13, 2015; 81 FR 95012, Dec. 27, 2016]

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§558.464 Poloxalene.

(a) *Specifications.* Dry Type A medicated articles containing 53 percent poloxalene or liquid Type A medicated articles containing 99.5 percent poloxalene.

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

(c) *Related tolerances.* See §556.517 of this chapter.

(d) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A article and liquid Type A article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by adding the Type A article to a small quantity of feed, mixing thoroughly, then adding this mixture to the remaining feed and again mixing thoroughly. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

[40 FR 39857, Aug. 29, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 79 FR 13545, Mar. 11, 2014; 84 FR 33001, July 11, 2019]

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§558.465 Poloxalene free-choice liquid Type C feed.

(a) *Specifications.* Type A medicated articles containing 99.5 percent poloxalene.

(b) *Sponsor.* See No. 066104 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.517 of this chapter.

(d) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid Type C feed (1.65 percent weight/weight). Each animal must consume 0.2 pound of Type C feed per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene per pound of liquid Type C feed (2.2 percent weight/weight). Each animal must consume 0.15 pound of Type C feed per 100 pounds of body weight daily for adequate protection. If consumption exceeds 0.2 pound of Type C feed per 100 pounds of body weight daily, cattle should be changed to a Type C feed containing 7.5 grams of poloxalene per pound.

(3) Poloxalene liquid Type A article must be thoroughly blended and evenly distributed into a liquid Type C feed and offered to cattle in a covered liquid Type C feed feeder with lick wheels. The formula for the liquid Type C feed, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.66 percent, phosphoric acid (75 percent) 3.37 percent, sulfuric acid 1.00 percent, water 10.00 percent, and molasses sufficient to make 100.00 percent, vitamins A and D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C feed must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C feed and to lick wheel feedings. If the medicated liquid wheel Type C feed feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 21281, Apr. 26, 1977; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001; 84 FR 33001, July 11, 2019]

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§558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 48 or 80 grams per pound pyrantel tartrate.

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

(1) No. 066104: 48 and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2) Nos. 017135 and 054771: 48 grams per pound for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §556.560 of this chapter.

(d) *Special considerations.* (1) See §500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

(e) *Conditions of use*—(1) *Swine*—

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
(i) 96	Swine: As an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections	Feed continuously as the sole ration in a Type C feed. Withdraw 24 hours prior to slaughter	066104
(ii) 96	Swine: For the removal and control of large roundworm (*Ascaris suum*) infections	Feed for 3 days as the sole ration in a Type C feed. Withdraw 24 hours prior to slaughter	066104
(iii) 800	Swine: For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections	Feed as the sole ration for a single therapeutic treatment in Type C feed at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over. Withdraw 24 hours prior to slaughter	066104

(2) *Horses*—

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
To provide 1.2 mg/lb body weight	Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris,* and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*)	Feed continuously. Administer either as a top-dress (not to exceed 20,000 g/ton) or mixed in the horse's daily grain ration (not to exceed 1,200 g/ton) during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism	017135 054771

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

(i) Carbadox as in §558.115.

(ii) Lincomycin as in §558.325.

(iii) Tylosin as in §558.625.

[83 FR 48948, Sept. 28, 2018, as amended at 83 FR 64744, Dec. 18, 2018]

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§558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45.4 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See Nos. 054771 and 058198 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.570 of this chapter.

(d) *Special considerations.* (1) Labeling of Type B and Type C feeds shall bear the following: “Not for animals intended for breeding.”

(2) Labeling of Type B and Type C swine feeds shall bear the following:

(i) “No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton.”

(ii) “Ractopamine may increase the number of injured and/or fatigued pigs during marketing.”

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: “No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton.”

(4) Tylosin in combinations as tylosin phosphate.

(5) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5 or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(e) *Conditions of use*—(1) *Swine*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9.0		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter	Feed continuously as sole ration	058198, 054771
(ii)-(iv) [Reserved]				

(2) *Cattle.*

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed	054771 058198
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed continuously as sole ration during the last 28 to 42 days on feed. See paragraph §558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 054771 058198
(iii) 9.8 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding	054771 058198
(iv) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See paragraph §558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 054771 058198
(v) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii,* and for suppression of estrus (heat)	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See §§558.342(d) and 558.355(d). Melengestrol acetate as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 054771 058198
(vi) Not to exceed 800; to provide 70 to 400 mg/head/day		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed	Top dress in a minimum of 1 lb of medicated feed	054771 058198
(vii) Not to exceed 800; to provide 70 to 400 mg/head/day	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Top dress ractopamine in a minimum of 1 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See §558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 054771 058198

(3) *Turkeys*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 11.8 (5 to 13 ppm)		Finishing hen turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 7 to 14 days prior to slaughter.	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter.	058198
(ii) 4.6 to 11.8 (5 to 13 ppm)		Finishing tom turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 14 days prior to slaughter.	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality.	058198
(iii) 4.6 to 11.8 (5 to 13 ppm)	Monensin 54 to 90	Finishing hen turkeys: As in paragraph (e)(3)(i) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis.*	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter. See §558.355(d).	058198
(iv) 4.6 to 11.8 (5 to 13 ppm)	Monensin 54 to 90	Finishing tom turkeys: As in paragraph (e)(3)(ii) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis.*	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality. See §558.355(d).	058198

(4) Ractopamine may also be used in combination with tylosin in as in §558.625.

[67 FR 71820, Dec. 3, 2002, as amended at 68 FR 54659, Sept. 18, 2003; 69 FR 12068, Mar. 15, 2004; 69 FR 51174, Aug. 18, 2004; 71 FR 31074, June 1, 2006; 71 FR 67301, Nov. 21, 2006; 72 FR 10358, Mar. 8, 2007; 72 FR 41619, July 31, 2007; 72 FR 56897, Oct. 5, 2007; 72 FR 62571, Nov. 6, 2007; 72 FR 65667, Nov. 23, 2007; 72 FR 70777, Dec. 13, 2007; 73 FR 72715, Dec. 1, 2008; 73 FR 75323, Dec. 11, 2008; 74 FR 66914, Dec. 17, 2009; 75 FR 1276, Jan. 11, 2010; 75 FR 5888, Feb. 5, 2010; 75 FR 20917, Apr. 22, 2010; 75 FR 54018, Sept. 3, 2010; 77 FR 31724, May 30, 2012; 78 FR 63872, Oct. 25, 2013; 79 FR 13546, Mar. 11, 2014; 79 FR 37621, July 2, 2014; 79 FR 44278, July 31, 2014; 79 FR 53136, Sept. 8, 2014; 80 FR 61298, Oct. 13, 2015; 81 FR 48703, July 26, 2016; 81 FR 95013, Dec. 27, 2016; 85 FR 18122, Apr. 1, 2020]

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§558.515 Robenidine.

(a) *Approvals.* Type A medicated articles: 30 grams per pound to 054771 in §510.600(c) of this chapter.

(b) *Special considerations.* Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See §556.580 of this chapter.

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

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
30 (0.0033 pct)		Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*	Feed continuously as sole ration. Do not feed to chickens producing eggs for food. Withdraw 5 days prior to slaughter.	054771
	Bacitracin (as bacitracin methylenedisalicylate) 4 to 30	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	054771
	Bacitracin (as bacitracin methylenedisalicylate) 27 to 50	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	054771
	Bacitracin (as bacitracin methylenedisalicylate) 50	For broiler and fryer chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.	054771
	Bacitracin (as bacitracin methylenedisalicylate) 100 to 200	For broiler and fryer chickens: As an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin.	To control a necrotic enteritis outbreak, start medication at first clinical signs of disease; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin methylenedisalicylate to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter.	054771
	Bacitracin (as bacitracin zinc) 4 to 30	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	054771 054771
	Bacitracin (as bacitracin zinc) 27 to 50	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	054771 054771

		For improved feed efficiency.		

(e) Robenidine may also be used in combination with:

(1) Chlortetracycline as in §558.128.

(2) Lincomycin as in §558.325.

(3) Oxytetracycline as in §558.450.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.515, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

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§558.550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass).

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

(c) *Related tolerances.* See §556.592 of this chapter.

(d) *Special considerations.* Not approved for use with pellet binders.

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

(1) *Chickens—*

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40 to 60		Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses	016592
(ii) 40 to 60	Bacitracin methylenedisalicylate, 4 to 50	Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	016592 054771
(iii) 40 to 60	Bacitracin methylenedisalicylate, 50	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) in this chapter	054771
(iv) 40 to 60	Bacitracin methylenedisalicylate, 100 to 200	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) in this chapter	054771
(v) 40 to 60	Bacitracin zinc, 10 to 50	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter	016592 054771
(vi) 40 to 60	Bambermycins, 1 to 3	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for improved feed efficiency	Feed continuously as sole ration. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin and bambermycins as provided by No. 016592 in §510.600(c) in this chapter	016592

(2) *Game birds—*

Salinomycin in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50		Quail: For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses	
(ii) [Reserved]				

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

(i) Chlortetracycline as in §558.128.

(ii) Lincomycin as in §558.325.

(iii) Oxytetracycline as in §558.450.

(iv) Virginiamycin as in §558.635.

[48 FR 30616, July 5, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.550, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

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§558.555 Semduramicin.

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

(1) 22.7 grams (g) per pound (lb) (50 g/kilogram (kg)) semduramicin (as semduramicin sodium).

(2) 22.7 g/lb (50 g/kg) semduramicin (as semduramicin sodium biomass).

(b) *Approvals.* See No. 066104 in §510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d) of this section; for use of product described in paragraph (a)(2) as in paragraph (e) of this section.

(c) *Related tolerances.* See §556.597 of this chapter.

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

Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/E. mitis, E. necatrix*, and *E. tenella.*	Do not feed to laying hens.	066104
(2) 22.7	Bacitracin methylenedisalicylate 10 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	066104

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

Semduramicin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix, and E. mitis.*	Do not feed to laying hens.	066104
(2) [Reserved]				

(f) Semduramycin may also be used in combination with virginiamycin as in §558.635.

[59 FR 17477, Apr. 13, 1994, as amended at 60 FR 57928, Nov. 24, 1995; 61 FR 29481, June 11, 1996; 61 FR 43451, Aug. 23, 1996; 61 FR 66584, Dec. 18, 1996; 62 FR 66985, Dec. 23, 1997; 64 FR 48296, Sept. 3, 1999; 66 FR 47964, Sept. 17, 2001; 69 FR 13221, Mar. 22, 2004; 70 FR 41961, July 21, 2005; 73 FR 812, Jan. 4, 2008; 74 FR 41631, Aug. 18, 2009; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 17609, Mar. 30, 2016; 81 FR 95013, Dec. 27, 2016]

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§558.575 Sulfadimethoxine and ormetoprim.

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

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim; or

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim.

(b) *Sponsors.* See sponsors in §510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraphs (e)(1), (e)(2)(i), and (e)(3)(i) through (iii) of this section.

(2) No. 015331 for use of the product described in paragraph (a)(2) as in paragraphs (e)(3)(iv) and (v) of this section.

(c) *Related tolerances.* See §§556.490 and 556.640 of this chapter.

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

(2) The expiration date of VFDs for sulfadimethoxine and ormetoprim medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfadimethoxine and ormetoprim shall not be refilled.

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

(1) *Chickens*—

Sulfadimethoxine and ormetoprim grams/ton	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 113.5; ormetoprim, 68.1.	Broiler chickens: As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *Heterakis gallinarum* (infectious coryza), *Escherichia coli* (colibacillosis) and *Pasteurella multocida* (fowl cholera).	Feed as sole ration. Withdraw 5 days before slaughter.	054771
(ii) Sulfadimethoxine, 113.5; ormetoprim, 68.1.	Replacement chickens: As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *Heterakis gallinarum* (infectious coryza), *Escherichia coli* (colibacillosis) and *Pasteurella multocida* (fowl cholera).	Feed as sole ration. Do not feed to chickens over 16 weeks (112 days) of age. Withdraw 5 days before slaughter.	054771

(2) *Turkeys*—

Sulfadimethoxine and ormetoprim grams/ton	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 56.75; ormetoprim, 34.05.	Turkeys: As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis* and bacterial infection due to *Pasteurella multocida* (fowl cholera).	Do not feed to turkeys producing eggs for food. Withdraw 5 days before slaughter.	054771
(ii) [Reserved]			

(3) *Minor species*—

Sulfadimethoxine and ormetoprim amount	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 227; ormetoprim, 136.2 grams/ton of feed.	Ducks, including breeding ducks: As an aid in the control of bacterial infections due to *Pasteurella multocida* (fowl cholera).	Feed as sole ration for 7 days. Medication should be started at the first signs of infection. Do not feed to ducks producing eggs for food. Withdraw 5 days before slaughter.	054771
(ii) Sulfadimethoxine, 454; ormetoprim, 272.4 grams/ton of feed.	Ducks: As an aid in the control of bacterial infections due to *Escherichia coli, Riemerella anatipestifer,* and severe challenge of *Pasteurella multocida* (fowl cholera).	Feed as a sole ration for 7 days. Medication should be started at the first signs of infection. Not for breeding ducks. Do not feed to ducks producing eggs for food. Withdraw 5 days before slaughter.	
(iii) Sulfadimethoxine, 113.5; ormetoprim, 68.1 grams/ton of feed.	Chukar partridges: For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis.*	Feed continuously to young birds up to 8 weeks of age as sole ration.	054771
(iv) 50 milligrams (mg) of active ingredients per kilogram of body weight per day.	Salmonids: For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 42 days before release as stocker fish or slaughter.	015331
(v) 50 mg of active ingredients per kilogram of body weight per day.	Catfish: For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 3 days before slaughter or release as stocker fish.	015331

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 13550, Mar. 11, 1977; 49 FR 33442, Aug. 23, 1984; 49 FR 46371, Nov. 26, 1984; 51 FR 7400, Mar. 3, 1986; 51 FR 18884, May 23, 1986; 52 FR 2686, Jan. 26, 1987; 54 FR 1686, Jan. 17, 1989; 63 FR 27846, May 21, 1998; 64 FR 26672, May 17, 1999; 64 FR 43910, Aug. 12, 1999; 66 FR 46707, Sept. 7, 2001; 70 FR 52292, Sept. 2, 2005; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 95013, Dec. 27, 2016; 83 FR 13637, Mar. 30, 2018; 84 FR 12502, Apr. 2, 2019]

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§558.582 Sulfamerazine.

(a) *Specifications.* Type A medicated articles containing 99 percent sulfamerazine.

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

(c) *Related tolerances.* See §556.660 of this chapter.

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

(2) The expiration date of VFDs for sulfamerazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfamerazine shall not be refilled.

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

Sulfamerazine grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) To deliver 10 grams of sulfamerazine per 100 pounds of fish per day		Rainbow trout, brook trout, and brown trout: For control of furunculosis	Formulate to deliver 10 grams of sulfamerazine per 100 pounds of fish per day. Treat for not more than 14 days. Do not treat within 3 weeks of marketing or stocking in stream open to fishing	054771
(2) [Reserved]				

[81 FR 95013, Dec. 27, 2016]

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§558.586 Sulfaquinoxaline.

(a) *Specifications.* Type A medicated articles containing 40 percent sulfaquinoxaline.

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

(c) *Related tolerances.* See §556.685 of this chapter.

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

(2) The expiration date of VFDs for sulfaquinoxaline medicated feeds must not exceed 6 months from the date of issuance. VFDs for sulfaquinoxaline shall not be refilled.

(e) *Conditions of use*—(1) *Chickens*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.015 percent		As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti* under average conditions of exposure	Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption	016592
(ii) 0.0175 percent		As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti* where excessive exposure to coccidia is increased due to overcrowding or other management factors	Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption	016592
(iii) 0.1 to 0.05 percent		As an aid in controlling outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti*	Feed at 0.1 percent level for first 48 to 72 hours. Skip 3 days; 0.05 percent for 2 days, skip 3 days; 0.05 percent for 2 days. If bloody droppings recur, give 0.05 percent for another 2 days. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption	016592
(iv) 0.05 or 0.1 percent		As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline	Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption	016592

(2) *Turkeys*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.0175 percent		As an aid in preventing outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides*	Feed continuously during time birds are closely confined. May be continued for a week to 10 days after flock is transferred to range to reduce danger of an outbreak following moving of the flock. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption	016592
(ii) 0.05 percent		As an aid in controlling outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides*	Feed for 2 days. Follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Again follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Continue this schedule if necessary until all signs of the outbreaks have subsided. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption	016592
(iii) 0.05 or 0.1 percent		As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline	Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption	016592

(3) *Rabbits*—

Sulfaquinoxaline in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.025 percent		As an aid in preventing coccidiosis caused by *Eimeria stiedae*	Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2 days out of every week until marketing. Do not treat within 10 days of slaughter	016592
(ii) 0.1 percent		As an aid in controlling outbreaks of coccidiosis caused by *Eimeria stiedae*	Feed for 2 weeks. Do not treat within 10 days of slaughter	016592

[81 FR 95013, Dec. 27, 2016]

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§558.600 Thiabendazole.

(a) *Specifications.* Dry Type A medicated articles containing 22, 44.1, 66.1, or 88.2 percent thiabendazole. The 66.1 percent Type A medicated article is solely for the manufacture of cane molasses liquid Type B feed, which is mixed in dry feeds. The 88.2 percent Type A medicated article is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

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

(c) *Related tolerances.* See §556.730 of this chapter.

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

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

(1) *Swine*—

Thiabendazole in grams/ton	Indications for use	Limitations	Sponsor
(i) 45.4 to 908 (0.005 to 0.1 percent)	Swine: As an aid in the prevention of infections of large roundworms (genus *Ascaris*)	Administer continuously in feed containing 0.05 to 0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005 to 0.02 percent thiabendazole per ton for 8 to 14 weeks. Do not treat animals within 30 days of slaughter	000010
(ii) [Reserved]			

(2) *Cattle*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 3 grams per 100 lb. body weight	For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*)	Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food	000010
(ii) 5 grams per 100 lb. body weight	For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp*	Use 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food	000010

(3) *Minor species—*

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 2 grams per 100 lb. body weight	Sheep and goats: For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*)	Use 2 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food	050604
(ii) 3 grams per 100 lb. body weight	Goats: For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*)	Use 3 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food	050604
(iii) 454 grams per ton of feed	Pheasants: For the treatment of gapeworms (*Syngamus trachea*)	Feed continuously for 2 weeks (14 days). Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals	050604

[84 FR 39186, Aug. 9, 2019]

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§558.612 Tiamulin.

(a) *Specifications.* Type A article containing 363.2 grams of tiamulin hydrogen fumarate per pound.

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

(c) *Related tolerances.* See §556.732 of this chapter.

(d) *Special considerations.* (1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

(3) Use as sole source of tiamulin.

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

Tiamulin hydrogen fumarate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 35		1. For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin	Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter	058198
		2. For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*	Feed continuously as the sole ration for not less than 10 days. Withdraw 2 days before slaughter	058198
(ii) 200		For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin	Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter	058198

(2) Tiamulin may also be used in combination with chlortetracycline as in §558.128.

[67 FR 7268, Feb. 19, 2002, as amended at 69 FR 62407, Oct. 26, 2004; 70 FR 75018, Dec. 19, 2005; 74 FR 6, Jan. 2, 2009; 77 FR 24139, Apr. 23, 2012; 79 FR 13546, Mar. 11, 2014. Redesignated and amended at 80 FR 13232, Mar. 13, 2015; 81 FR 95015, Dec. 27, 2016]

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§558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).

(b) *Approvals. See* Nos. 016592 and 058198 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.735 of this chapter.

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

(2) VFDs for tilmicosin phosphate shall not be refilled.

(3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:

(i) Do not allow horses or other equines access to feeds containing tilmicosin.

(ii) [Reserved]

(4) Special considerations for use of tilmicosin medicated swine feeds include the following:

(i) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for swine must bear the following warning: “Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.”

(iii) Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial.

(5) Special consideration for use of tilmicosin medicated cattle feeds include the following:

(i) The expiration date of VFDs for cattle must not exceed 45 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for cattle must bear the following warning: “Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.”

(iii) To assure both food safety and responsible use in cattle, administration of feed containing tilmicosin to cattle experiencing an outbreak of BRD must be initiated during the first 45 days of the production period, shall not exceed a single 14-consecutive-day treatment, should not occur concurrent with or following administration of an injectable macrolide, and should not occur within 3 days following administration of a nonmacrolide injectable BRD therapy. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.

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

(1) *Swine*—

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 181 to 363		Swine: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*	Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an anticipated disease outbreak. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product	058198, 016592
(ii) [Reserved]				

(2) *Cattle*—

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 568 to 757		Beef and nonlactating dairy cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product	058198, 016592

(ii) 568 to 757	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency; and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See §558.355(d). Tilmicosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 058198
(iii) 568 to 757	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for the control of BRD associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See §558.355(d). Tilmicosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198 in §510.600(c) of this chapter	016592 058198

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000; 67 FR 21997, May 2, 2002; 69 FR 78306, Dec. 30, 2004; 76 FR 76894, Dec. 9, 2011; 77 FR 60623, Oct. 4, 2012; 78 FR 19987, Apr. 3, 2013; 80 FR 61298, Oct. 13, 2015; 80 FR 76387, Dec. 9, 2015; 81 FR 48703, July 26, 2016; 81 FR 59135, Aug. 29, 2016; 81 FR 67153, Sept. 30, 2016; 85 FR 18123, Apr. 1, 2020]

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§558.625 Tylosin.

(a) *Specifications.* Type A medicated articles containing tylosin phosphate.

(b) *Sponsors.* See sponsor numbers in §510.600(c) of this chapter.

(1) No. 016592: Type A medicated articles containing 40 or 100 grams per pound (g/lb).

(2) No. 054771: Type A medicated article containing 40 g/lb.

(3) No. 058198: Type A medicated articles containing 10, 40, or 100 g/lb.

(4) No. 066104: Type A medicated articles containing 20 or 40 g/lb.

(c) *Related tolerances.* See §556.746 of this chapter.

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

(2) The expiration date of VFDs for tylosin medicated feeds must not exceed 6 months from the date of issuance. VFDs for tylosin shall not be refilled.

(3) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

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

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

(4) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.

(5) Do not use tylosin liquid Type B medicated feeds in any liquid feed containing sodium metabisulfite or in any finished feed (supplement, concentrate, or complete feed) containing in excess of 2 percent bentonite.

(e) *Conditions of use*—(1) *Swine*—

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors

(i) 40 or 100		For control of swine dysentery associated with *Brachyspira hyodysenteriae*	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight	016592 054771 058198 066104
(ii) 40 or 100	Pyrantel, 96	For control of swine dysentery associated with *Brachyspira hyodysenteriae;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(iii) 40 or 100		For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight	016592 054771 058198 066104
(iv) 40 or 100	Pyrantel, 96	For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed as the sole ration 100 g of tylosin per ton of complete feed for at least 3 weeks. Follow with 40 grams per ton of complete feed until market weight. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(v) 40 or 100	Ractopamine, 4.5 to 9.0	Finishing swine: For the control of swine dysentery associated with *Brachyspira hyodysenteriae;* for control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 100 g/ton of tylosin for at least 3 weeks, followed by 40 g/ton until market weight. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in §510.600(c) of this chapter	016592 054771 058198
(vi) 40 to 100		For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin in drinking water	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in §520.2640(d)(3) of this chapter	016592 054771 058198 066104
(vii) 40 or 100	Pyrantel, 96	For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin in drinking water; and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in §520.2640(d)(3) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(viii) 40 to 100		For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with tylosin in drinking water	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in §520.2640(d)(3) of this chapter	016592 054771 058198 066104
(ix) 40 or 100	Pyrantel, 96	For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with tylosin in drinking water; and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Administer as tylosin phosphate in feed continuously as the sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in §520.2640(d)(3) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(x) 40 to 100	Ractopamine, 4.5 to 9.0	Finishing swine: For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae,* for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 40 to 100 grams of tylosin phosphate per ton of complete feed for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water for 3 to 10 days as in §520.2640(d)(3) of this chapter. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in §510.600(c) of this chapter	016592 054771 058198
(xi) 100		For reduction in severity of effects of atrophic rhinitis	Feed continuously as the sole ration	016592 054771 058198 066104
(xii) 100	Pyrantel, 96	For reduction in severity of effects of atrophic rhinitis; aid as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections	Feed continuously as the sole ration. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter. Tylosin phosphate and pyrantel as provided by No. 066104 in §510.600(c) of this chapter	066104
(xiii) 100	Ractopamine, 4.5 to 9.0	For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis;* and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter	Feed continuously as the sole ration to finishing swine weighing not less than 150 lbs for the last 45 to 90 lbs (group average) of weight gain prior to slaughter. Include 100 g/ton of tylosin for 3 weeks. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine as provided by Nos. 058198 and 054771 in §510.600(c) of this chapter	016592 054771 058198

(2) Cattle—

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 8 to 10		Beef cattle: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces)*	Feed continuously as the sole ration to provide 60 to 90 mg/head/day tylosin	016592 054771 058198 066104

		pyogenes		
(ii) 8 to 10	Lasalocid, 100 to 1440; plus melengestrol, 0.25 to 2.0	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Feed continuously as sole ration. Feed to heifers at the rate of 0.5 to 2.0 pound(s) per head per day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate per head per day (specify one level), 100 to 360 mg lasalocid per head per day (specify one level), and 90 mg tylosin per head per day. This Type C product may be top dressed onto or mixed into a complete feed prior to feeding. Tylosin as provided by Nos. 016592 and 058198; lasalocid as provided by No. 054771; melengestrol as provided by Nos. 054771 and 058198 in §510.600(c) of this chapter. See §§558.311(d) and 558.342(d) in this chapter	016592 054771 058198
(iii) 8 to 10	Melengestrol, 0.25 to 2.0	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Feed continuously as sole ration. Each pound contains 0.125 to 1.0 mg melengestrol acetate and 45 to 180 mg of tylosin. Feed to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg melengestrol acetate and 60 to 90 mg tylosin per head per day. Prior to feeding, this Type C product must be top-dressed onto a complete feed or mixed into the amount of complete feed consumed by an animal per day. Tylosin provided by Nos. 016592 and 058198; melengestrol provided by Nos. 054771 and 058198 in §510.600(c) of this chapter. See §558.342(d) in this chapter	016592 054771 058198
(iv) 8 to 10	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for improved feed efficiency	Feed continuously as sole ration to provide 50 to 480 monensin mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198 in §510.600(c) of this chapter. See §558.355(d) in this chapter	016592 058198
(v) 8 to 10	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for prevention of coccidiosis caused by *Eimeria bovis* and *E zuernii*	Feed continuously as sole ration to provide 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198 in §510.600(c) of this chapter. See §558.355(d) in this chapter	016592 058198
(vi) 8 to 10	Monensin, 5 to 30 plus decoquinate, 13.6 to 22.7	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for improved feed efficiency	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin/head/day, and 60 to 90 mg of tylosin/head/day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; decoquinate as provided by No. 058198 in §510.600(c) of this chapter. See §§558.311(d) and 558.355(d)	016592 054771
(vii) 8 to 10	Monensin, 5 to 40 plus lubabegron fumarate, 1.25 to 4.54	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for improved feed efficiency during the last 14 to 91 days on feed	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. 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. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal	058198
(viii) 8 to 10	Monensin, 10 to 40 plus lubabegron fumarate, 1.25 to 4.54	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, up to 480 mg/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. 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. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal	058198
(ix) 8 to 10	Monensin, 10 to 40 plus melengestrol, 0.25 to 2.0	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria*	Feed continuously as sole ration to heifers at a rate of 0.5 to 2 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been	016592 054771 058198

		bovis and *E. zuernii*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; melengestrol provided by No. 054771 or 058198 in §510.600(c) of this chapter. See §§558.342(d) and 558.355(d)	
(x) 8 to 10	Monensin, 10 to 40 plus ractopamine, 8.2 to 24.6	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed continuously as sole ration to provide 70 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198; ractopamine provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.355(d) and 558.500(d) in this chapter	016592 054771 058198
(xi) 8 to 10	Monensin, 10 to 40 plus ractopamine, not to exceed 800	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed a minimum of 1.0 lb/head/day ractopamine Type C top dress feed continuously to cattle fed in confinement for slaughter, to provide 70 to 400 mg/head/day ractopamine for the last 28 to 42 days on feed. Feed on top of a ration containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin phosphate, to provide 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198; ractopamine provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.355(d) and 558.500(d) in this chapter	016592 054771 058198
(xii) 8 to 10	Monensin 10 to 40 plus ractopamine 9.8 to 24.6	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198; ractopamine as provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.355(d) and 558.500(d) in this chapter	016592 054771 058198
(xiii) 8 to 10	Monensin, 10 to 40 plus ractopamine, 9.8 to 24.6 plus melengestrol, 0.125 to 1 mg/lb	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and suppression of estrus (heat)	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by Nos. 016592 or 058198; ractopamine as provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.342(d), 558.355(d), and 558.500(d) in this chapter	016592 054771 058198
(xiv) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed	Feed continuously as the sole ration to cattle during the last 20 to 40 days on feed to provide 60 to 90 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Do not use in veal calves. Withdrawal period 3 days. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061 in §510.600(c) of this chapter. See §§558.355(d) and 558.665(d) in this chapter	000061 016592
(xv) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 to 24	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed	Feed this component feed continuously to cattle during the last 20 to 40 days on feed to provide 60 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Do not use in veal calves. Withdrawal period 3 days. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061 in §510.600(c) of this chapter. See §§558.355(d) and 558.665(d) in this chapter	000061 016592
(xvi) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 plus melengestrol,	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*)	Feed continuously as the sole ration to cattle during the last 20 to 40 days on feed to provide 60 to 90 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one	000061 016592 058198

	0.125 to 1 mg/lb	*pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed; and for suppression of estrus (heat)	level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). Do not use in veal calves. Withdrawal period 3 days. Tylosin as provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061; melengestrol provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.342(d), 558.355(d) and 558.665(d) in this chapter	
(xvii) 8 to 10	Monensin, 10 to 40 plus zilpaterol, 6.8 to 24 plus melengestrol, 0.125 to 1 mg/lb	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 20 to 40 days on feed; and for suppression of estrus (heat)	Feed this component feed continuously to cattle during the last 20 to 40 days on feed to provide 60 mg/head/day zilpaterol, 0.14 to 0.42 mg/lb body weight/day monensin, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin, and 60 to 90 mg/head/day tylosin. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). Do not use in veal calves. Withdrawal period 3 days. Tylosin as provided by Nos. 016592 or 058198; monensin as provided by No. 058198; zilpaterol as provided by No. 000061; melengestrol provided by Nos. 054771 or 058198 in §510.600(c) of this chapter. See §§558.342(d), 558.355(d) and 558.665(d) in this chapter	000061 016592 058198

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.625, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

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§558.630 Tylosin and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing equal amounts of tylosin phosphate and sulfamethazine, available in concentrations of 5, 10, 20, or 40 grams each, per pound.

(b) *Sponsors.* See sponsor numbers in §510.600(c) of this chapter.

(1) No. 058198 for use as in paragraph (e)(1) of this section.

(2) No. 054771: 10 or 40 grams per pound each for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §§556.670 and 556.746 of this chapter.

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

(2) The expiration date of VFDs for tylosin and sulfamethazine medicated feeds must not exceed 6 months from the date of issuance. VFDs for tylosin and sulfamethazine shall not be refilled.

(3) Labeling shall bear the statement: “Do not use in medicated feeds containing in excess of 2% bentonite.”

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

Tylosin phosphate and sulfamethazine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(1) 100 each		For reduction in the severity of effects of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae;* control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*); reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci.* Only the sulfamethazine portion of this combination is active in controlling jowl abscesses	Withdraw 15 days before swine are slaughtered	058198
(2) 100 each		For reduction in the severity of effects of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae;* and control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*)	Withdraw 15 days before swine are slaughtered	054771

[81 FR 95021, Dec. 27, 2016, as amended at 84 FR 33002, July 11, 2019]

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§558.633 Tylvalosin.

(a) *Specifications.* Type A medicated articles containing 77.12 grams tylvalosin per pound as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.748 of this chapter.

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

(2) VFDs for tylvalosin shall not be refilled.

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form.

(e) *Conditions of use.*

Tylvalosin in grams/ton	Indications for use	Limitations	Sponsor
(i) 38.6	Swine: For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.	Feed continuously as the sole ration for 14 consecutive days.	066916
(ii) [Reserved]			

[81 FR 36790, June 8, 2016, as amended at 81 FR 67153, Sept. 30, 2016; 84 FR 12504, Apr. 2, 2019]

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§558.635 Virginiamycin.

(a) *Specifications.* Type A medicated articles containing 10, 20, 50, or 227 grams virginiamycin per pound.

(b) *Sponsors.* See No. 066104 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.750 of this chapter.

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

(2) The expiration date of VFDs for virginiamycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for virginiamycin shall not be refilled.

(3) Not for use in breeding swine over 120 pounds.

(4) Dilute Type A article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of Type C feed.

(e) *Conditions of use*—(1) *Chickens*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 20		Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin	Not for use in layers	066104
(ii) 20	Amprolium 72.6 to 113.5	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella*	For field conditions where only *E. tenella* is the major problem, feed continuously as the sole ration. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in §510.600(c) of this chapter	066104
(iii) 20	Amprolium 113.5 to 227	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis where immunity to coccidiosis is not desired	For most field conditions as they exist under modern management practices, feed 113.5 g/ton amprolium continuously. Where severe coccidiosis conditions exist, feed 227 g/ton. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in §510.600(c) of this chapter	066104
(iv) 20	Diclazuril, 0.91	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati),* and *E. maxima*. Because diclazuril is effective against *E. maxima* late in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima*	Feed continuously as the sole ration. Do not use in hens producing eggs for human food. Diclazuril as provided by No. 058198 in §510.600(c) of this chapter	058198

(v) 20	Lasalocid 68 to 113	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed continuously as the sole ration. Do not feed to laying chickens. For broiler or fryer chickens only. Lasalocid as provided by No. 054771 in §510.600(c) of this chapter	066104
(vi) 20	Monensin 90 to 110	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati*	Feed continuously as the sole ration. Do not feed to laying chickens. See §558.355(d) in this chapter. Monensin as provided by No. 058198 in §510.600(c) of this chapter	066104
(vii) 20	Salinomycin 40 to 60	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by No. 016592 in §510.600(c) of this chapter	
(viii) 20	Semduramicin 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in §510.600(c) of this chapter	066104
(ix) 20	Semduramicin (biomass) 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Semduramicin as provided by No. 066104 in §510.600(c) of this chapter	066104

(2) *Swine*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 25		Growing-finishing swine: As an aid in control of dysentery in swine up to 120 pounds in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred		066104
(ii) 50 or 100		Growing-finishing swine: For treatment and control of swine dysentery in swine up to 120 pounds	Feed 100 grams per ton for 2 weeks, 50 grams per ton thereafter	066104
(iii) 100		Growing-finishing swine: For treatment of swine dysentery in nonbreeding swine over 120 pounds	Feed for 2 weeks	066104

(3) *Cattle*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.5 to 16.0		Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses	Feed continuously as the sole ration to provide 85 to 240 milligrams per head per day. Not for use in animals intended for breeding	066104
(ii) [Reserved]				

[81 FR 95022, Dec. 27, 2016, as amended at 82 FR 11512, Feb. 24, 2017; 82 FR 21692, May 10, 2017; 85 FR 18125, Apr. 1, 2020]

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§558.665 Zilpaterol.

(a) *Specifications.* Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

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

(c) *Tolerances.* See §556.765 of this chapter.

(d) *Special considerations.* (1) Labeling shall bear the following caution statements: “Zilpaterol hydrochloride is not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.”

(2) Labeling of Type A medicated articles and Type B medicated feeds used to manufacture complete Type C medicated feeds shall bear the caution statement in paragraph (d)(3) of this section.

(3) Labeling of complete Type C medicated feeds shall bear the following caution statements: “Not to be fed to cattle in excess of 90 mg zilpaterol/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed.”

(4) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Conditions of use in cattle.* It is administered in feed as follows:

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section	000061
(2) 6.8	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph §558.355(d) of this chapter Monensin as provided by No. 058198 in §510.600(c) of this chapter	000061 058198
(3) 6.8	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat)	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section Melengestrol acetate as provided by Nos. 058198 or 054771 in §510.600(c) of this chapter	000061 058198
(4) 6.8	Monensin 10 to 40 plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for suppression of estrus (heat)	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d) and 558.355(d) of this chapter Monensin as provided by No. 058198; melengestrol acetate as provided by Nos. 058198 or 054771 in §510.600(c) of this chapter	000061 058198
(5)-(6) [Reserved]				
(7) 6.8 to 24		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section	000061
(8) 6.8 to 24	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph §558.355(d) of this chapter Monensin as provided by No. 058198 in §510.600(c) of this chapter	000061
(9) 6.8 to 24	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat)	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph §558.342(d) of this part Melengestrol acetate as provided by No. 054771 in §510.600(c) of this chapter	000061
(10) 6.8 to 24	Monensin 10 to 40, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for suppression of estrus (heat)	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d) and 558.355(d) of this chapter Monensin as provided by No. 058198; melengestrol acetate as provided by No. 054771 in §510.600(c) of this chapter	000061

(f) Zilpaterol may also be used in combination with tylosin as in §558.625.

[71 FR 53006, Sept. 8, 2006, as amended at 72 FR 9245, Mar. 1, 2007; 72 FR 6019, Feb. 1, 2008; 73 FR 14385, Mar. 18, 2008; 73 FR 16755, Mar. 31, 2008; 73 FR 18959, Apr. 8, 2008; 73 FR 19432, Apr. 10, 2008; 74 FR 61517, Nov. 25, 2009; 75 FR 11451, Mar. 11, 2010; 77 FR 31724, May 30, 2012; 78 FR 42008, July 15, 2013; 78 FR 52852, Aug. 27, 2013; 80 FR 13232, Mar. 13, 2015; 80 FR 53460, Sept. 4, 2015; 81 FR 48703, July 26, 2016; 81 FR 95025, Dec. 27, 2016]

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§558.680 Zoalene.

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

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

(c) *Related tolerances.* See §556.770 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5		Replacement chickens: For development of active immunity to coccidiosis	Grower ration not to be fed to birds over 14 weeks of age; as follows:	054771

Growing conditions	Starter ration Grams per ton	Grower ration Grams per ton
Severe exposure	113.5 (0.0125%)	75.4-113.5 (0.0083%-0.0125%)
Light to moderate exposure	75.4-113.5 (0.0083%-0.0125%)	36.3-75.4 (0.004%-0.0083%)

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3-113.5	Bacitracin methylenedisalicylate 4 to 50	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iii) 36.3-113.5	Bacitracin methylenedisalicylate 50	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(iv) 36.3-113.5	Bacitracin methylenedisalicylate 100 to 200	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration as in subtable in item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(v) 113.5		Broiler chickens: For prevention and control of coccidiosis	Feed continuously as sole ration	054771
(vi) 113.5	Bacitracin methylenedisalicylate 4 to 50	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(vii) 113.5	Bacitracin methylenedisalicylate 50	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(viii) 113.5	Bacitracin methylenedisalicylate 100 to 200	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton) Bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter	054771
(ix) 113.5	Bambermycins 1	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter	016592

(2) *Turkeys*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3		Growing turkeys: For prevention and control of coccidiosis	Feed continuously as sole ration. For turkeys grown for meat purposes only. Do not feed to laying birds	054771
(ii) 113.5 to 170.3	Bacitracin methylenedisalicylate 4 to 50	Growing turkeys: For prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration until 14 to 16 weeks of age. For turkeys grown for meat purposes only. Do not feed to laying birds	054771

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

(i)-(ii) [Reserved]

(iii) Lincomycin as in §558.325.

[41 FR 11005, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 20817, Apr. 22, 1977; 42 FR 36995, July 19, 1977; 51 FR 7401, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8461, Mar. 8, 1990; 57 FR 8403, Mar. 10, 1992; 57 FR 8578, Mar. 11, 1992; 61 FR 35957, July 9, 1996; 63 FR 38750, July 20, 1998; 67 FR 6868, Feb. 14, 2002; 71 FR 16223, Mar. 31, 2006; 71 FR 27958, May 15, 2006; 76 FR 17027, Mar. 28, 2011; 79 FR 10983, Feb. 27, 2014; 79 FR 13546, Mar. 11, 2014; 81 FR 17610, Mar. 30, 2016; 81 FR 95025, Dec.

27, 2016; 82 FR 21693, May 10, 2017]

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