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wet beef liver and muscle necessitating a correction factor.

$$\text{Zeranol, parts per billion} = \frac{\text{Micrograms of zeranol found A1,000}}{W A0.7}$$

Where:

0.7=Correction factor for 70 percent recovery.

W=Grams of tissue examined.

VII. RECOVERY STUDY

A. Fortification of reagent blank.

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with zeranol should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of the standard zeranol. Level of recovery should be in the same range as the samples.

2. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate.

3. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2N HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate. Spike the concentrate with 1.0 milliliter of stock solution D.

4. Assay both samples as described in the procedure beginning extraction step V-E1.

B. Fortification of samples.

1. Transfer 100-gram portions of partially thawed tissues into 250-milliliter homogenizing flasks and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution D to serve as fortified samples to which 20 parts per billion zearalanol have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with V-C1.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989]

§ 556.770 Zoalene.

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

(a) In edible tissues of chickens:

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

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

(3) 2 parts per million in uncooked fat.

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Subpart A—General Provisions

Sec.

558.3 Definitions and general considerations applicable to this part.

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558.15 Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals.

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

- 558.35 Aklomide.
- 558.55 Amprolium.
- 558.58 Amprolium and ethopabate.
- 558.59 Apramycin.
- 558.60 Arsanilate sodium.
- 558.62 Arsanilic acid.
- 558.76 Bacitracin methylene disalicylate.
- 558.78 Bacitracin zinc.
- 558.95 Bambermycins.
- 558.105 [Reserved]
- 558.115 Carbadox.
- 558.120 Carbarosone (not U.S.P.).
- 558.128 Chlortetracycline.
- 558.140 Chlortetracycline and sulfamethazine.
- 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.
- 558.155 Chlortetracycline, sulfathiazole, penicillin.
- 558.175 Clopidol.
- 558.185 Coumaphos.
- 558.195 Decoquinat.
- 558.205 Dichlorvos.
- 558.235 Efrogomycin.
- 558.248 Erythromycin thiocyanate.
- 558.254 Famphur.
- 558.258 Fenbendazole.
- 558.265 Halofuginone hydrobromide.
- 558.274 Hygromycin B.
- 558.295 Iodinated casein.
- 558.300 Ivermectin.
- 558.305 Laidlomycin propionate potassium.
- 558.311 Lasalocid.
- 558.315 Levamisole hydrochloride (equivalent).
- 558.325 Lincomycin.
- 558.340 Maduramicin ammonium.
- 558.342 Melengestrol acetate.
- 558.348 Mibolerone.
- 558.355 Monensin.
- 558.360 Morantel tartrate.
- 558.363 Narasin.
- 558.365 Nequinat.
- 558.366 Nicarbazin.
- 558.369 Nitarosone.

558.376	Nitromide and sulfanitran.
558.415	Novobiocin.
558.430	Nystatin.
558.435	Oleandomycin.
558.450	Oxytetracycline.
558.460	Penicillin.
558.464	Poloxalene.
558.465	Poloxalene free-choice liquid Type C feed.
558.485	Pyrantel tartrate.
558.515	Robenidine hydrochloride.
558.530	Roxarsone.
558.550	Salinomycin.
558.555	Semduramicin.
558.575	Sulfadimethoxine, ormetoprim.
558.579	Sulfaethoxyypyridazine.
558.582	Sulfamerazine.
558.586	Sulfaquinoxoline.
558.600	Tiamulin.
558.615	Thiabendazole.
558.618	Tilmicosin.
558.625	Tylosin.
558.630	Tylosin and sulfamethazine.
558.635	Virginiamycin.
558.680	Zoalene.

AUTHORITY: 21 U.S.C. 360b, 371.

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

### Subpart A—General Provisions

#### § 558.3 Definitions and general considerations applicable to this part.

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

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

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

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

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

(2) A “Type A medicated article” is intended solely for use in the manufac-

ture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105(a) of this chapter.

(3) A “Type B medicated feed” is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term “highest continuous use level” means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires an application approved under § 514.105(b) of this chapter.

(4) A “Type C medicated feed” is intended as the complete feed for the animal or may be fed “top dressed” (added on top of usual ration) on or offered “free-choice” (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires an application approved under § 514.105(b) of this chapter.

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

[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]

**§ 558.4 Medicated feed applications.**

(a) The manufacture of a Type B or Type C medicated feed from a Category I, Type A medicated article is exempt from the requirement of an approved medicated feed application.

(b) The manufacture of a Type B or Type C medicated feed from a Category II, Type A medicated article requires an approved medicated feed application.

(c) The use of Type B and Type C medicated feeds shall conform to the conditions of use provided for in subpart B of this part and in §§510.515 and 558.15.

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

CATEGORY I

Drug	Assay limits percent <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
Aklomide .....	90–110	22.75 g/lb (5.0%) .....	85–120.
Amprolium with Ethopabate .....	94–114	22.75 g/lb (5.0%) .....	80–120.
Bacitracin methylene disalicylate .....	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.
Buquinolate .....	90–110	9.8 g/lb (2.2%) .....	80–120.
Chlortetracycline .....	85–115	40.0 g/lb (8.8%) .....	80–115/70–130.
Coumaphos .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Decoquinatate .....	90–105	2.72 g/lb (0.6%) .....	80–120.
Dichlorvos .....	100–115	33.0 g/lb (7.3%) .....	90–120/80–130.
Efrotomycin .....	94–113	1.45 g/lb (0.32%) .....	80–120
Erythromycin (thiocyanate salt) .....	85–115	9.25 g/lb (2.04%) .....	<20g/ton 70–115/150–50;>20g/ton 75–125.
Iodinated casein .....	85–115	20.0 g/lb (4.4%) .....	75–125.
Laidlomycin propionate potassium .....	90–110	1 g/lb (0.22%) .....	90–115/85–115.
Lasalocid .....	95–115	40.0 g/lb (8.8%) .....	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin .....	90–115	20.0 g/lb (4.4%) .....	80–130.
Melengestrol acetate .....	90–110	10.0 g/ton (0.0011%) .....	70–120
Monensin .....	90–110	40.0 g/lb (8.8%) .....	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin .....	90–110	7.2 g/lb (1.6%) .....	85–115/75–125.
Nequinatate .....	95–112	1.83 g/lb (0.4%) .....	80–120.
Niclosamide .....	85–120	225g/lb (49.5%) .....	80–120.
Nystatin .....	85–125	5.0 g/lb (1.1%) .....	75–125.
Oleandomycin .....	85–120	1.125 g/lb (0.25%) .....	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline .....	90–120	20.0 g/lb (4.4%) .....	75–125/65–135.
Penicillin .....	80–120	10.0 g/lb (2.2%) .....	65–135.
Poloxalene .....	90–110	54.48 g/lb (12.0%) .....	Liq. feed: 85–115.
Salinomycin .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Semduramicin .....	90–110	2.25 g/lb (0.50%) .....	80–110.
Tiamulin .....	113.4 g/lb, 100–108	3.5 g/lb (0.8%) .....	90–115.
	5 and 10 g/1b, 90–115	.....	70–130.
Tylosin .....	80–120	10.0 g/lb (2.2%) .....	75–125.
Virginiamycin .....	85–115	10.0 g/lb (2.2%) .....	70–130.
Zoalene .....	92–104	11.35 g/lb (2.5%) .....	85–115.

<sup>1</sup> Percent of labeled amount.

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<sup>2</sup>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 <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Amprolium	94-114	11.35 g/lb (2.5%)	80-120.
Apramycin	88-112	7.5 g/lb (1.65%)	80-120.
Arsanilate sodium	90-110	4.5 g/lb (1.0%)	85-115/75-125.
Arsanilic acid	90-110	4.5 g/lb (1.0%)	85-115/75-125.
Carbadox	90-110	2.5 g/lb (0.55%)	75-125.
Carbarson	93-102	17.0 g/lb (3.74%)	85-115.
Clopidol	94-106	11.4 g/lb (2.5%)	90-115/80-120.
Famphur	100-110	5.5 g/lb (1.21%)	90-115/80-120.
Fenbendazole	93-113	8.87 g/lb (1.96%)	75-125
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.
Levamisole	85-120	113.5 g/lb (25%)	85-125.
Maduramicin ammonium	90-110	545 g/ton (.06%)	80-120.
Morantel tartrate	90-110	66.0 g/lb (14.52%)	85-115.
Neomycin	80-120	7.0 g/lb (1.54%)	70-125.
Oxytetracycline	80-120	10.0 g/lb (2.2%)	65-135.
Nicarbazin (granular)	90-110	5.675 g/lb (1.25%)	85-115/75-125
Narasin	90-110	5.675 g/lb (1.25%)	85-115/75-125
Nicarbazin (powder)	98-106	5.675 g/lb (1.25%)	85-115/80-120
Nitarson	90-110	8.5 g/lb (1.87%)	85-120.
Nitromide	90-110	11.35 g/lb (2.5%)	80-120.
Sulfantran	85-115	13.6 g/lb (3.0%)	75-125.
Nitromide	90-110	11.35 g/lb (2.5%)	85-115.
Sulfantran	85-115	5.65 g/lb (1.24%)	75-125.
Roxarsone	90-110	2.275 g/lb (0.5%)	85-120.
Novobiocin	85-115	17.5 g/lb (3.85%)	80-120.
Pyrantel tartrate	90-110	36 g/lb (7.9%)	75-125.
Robenidine	95-115	1.5 g/lb (0.33%)	80-120.
Ronnel	85-115	27.2 g/lb (6.0%)	80-120.
Roxarsone	90-110	2.275 g/lb (0.5%)	85-120.
Roxarsone	90-110	2.275 g/lb (0.5%)	85-120.
Aklomide	90-110	11.35 g/lb (2.5%)	85-120.
Roxarsone	90-110	2.275 g/lb (0.5%)	85-120.
Clopidol	94-106	11.35 g/lb (2.5%)	80-120.
Bacitracin methylene disalicylate	85-115	5.0 g/lb (1.1%)	70-130.
Roxarsone	90-110	2.275 g/lb (0.5%)	85-120.
Monensin	90-110	5.5 g/lb (1.2%)	75-125.
Sulfadimethoxine	95-115	5.675 g/lb (1.25%)	85-115/75-125.
Ormetoprim (5/3)	95-115	3.405 g/lb (0.75%)	85-115.
Sulfadimethoxine	95-115	85.1 g/lb (18.75%)	85-115/75-125.
Ormetoprim (5/1)	95-115	17.0 g/lb (3.75%)	85-115.
Sulfaethoxypyridazine	95-105	50.0 g/lb (11.0%)	85-115.
Sulfamerazine	85-115	18.6 g/lb (4.0%)	85-115.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	10.0 g/lb (2.2%)	85-125/70-130.
Penicillin	85-115	5.0 g/lb (1.1%)	85-125/70-130.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	10.0 g/lb (2.2%)	85-125/70-130.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Tylosin	80-120	10.0 g/lb (2.2%)	75-125.
Sulfantran	85-115	13.6 g/lb (3.0%)	75-125.
Aklomide	90-110	11.2 g/lb (2.5%)	85-120.
Sulfantran	85-115	13.6 g/lb (3.0%)	75-125.
Aklomide	90-110	11.2 g/lb (2.5%)	85-120.
Roxarsone	90-110	2.715 g/lb (0.60%)	85-120.
Sulfantran	85-115	13.6 g/lb (3.0%)	75-125.
Aklomide	90-110	11.2 g/lb (2.5%)	85-120.
Roxarsone	90-110	2.27 g/lb (0.5%)	85-120.
Sulfaquinoxaline	98-106	11.2 g/lb (2.5%)	85-115.
Sulfathiazole	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-125	10.0g/lb (2.2%)	70-130.
Penicillin	80-120	5.0 g/lb (1.1%)	70-130.
Thiabendazole	94-106	45.4 g/lb (10.0%)	>7% 85-115; <7% 90-110.

CATEGORY II—Continued

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Tilmicosin .....	90-110	18.2 g/lb (4.0%) .....	85-115.

<sup>1</sup> Percent of labeled amount.  
<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.5 New animal drug requirements for liquid Type B feeds.**

(a) Information available to the Commissioner of Food and Drugs shows that certain drugs are unstable when added to some liquid Type B medicated feeds. The demonstrated instability of these drugs gives rise to the question of the stability of other drugs when added to liquid Type B medicated feeds, except where specific approval has been granted for such use. Therefore, the labeling of a drug to provide for its use in a liquid Type B medicated feed causes the drug to be a new animal drug for such use for which an approved new animal drug application is required pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act.

(b) The addition of a drug to a liquid Type B medicated feed causes such Type B feed to become an animal feed bearing or containing a new animal drug for which an approved application is required pursuant to section 512(m) of the act.

(c) Each drug product, intended for oral administration to animals, which contains any of the drugs listed in paragraph (d) of this section and which bears labeling for its use in animal feed and/or drinking water shall also include in such labeling the following statement: "FOR USE IN \_\_\_\_\_ ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS," the

blank being filled in with the words "DRY FEEDS," "DRINKING WATER," "DRY FEEDS AND DRINKING WATER" as applicable, unless:

(1) Such drug product is the subject of an approved new animal drug application providing for its use in liquid Type B medicated feeds, or;

(2) The labeling provisions of this paragraph have been waived on the basis of approval of a petition which includes a copy of the product label; a description of the formulation; and information which establishes that the physical, chemical, or other properties of the particular drug product are such that it cannot reasonably be expected to be diverted for use in liquid Type B medicated feeds. Such petitions shall be submitted to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(d) The labeling provisions of paragraph (c) of this section apply to all forms of bacitracin, oxytetracycline, and chlortetracycline.

(e) For any drug which is the subject of an approved new animal drug application, the labeling provisions of paragraph (c) of this section may be implemented without prior approval as provided for in § 514.8(d) and (e) of this chapter.

[40 FR 13959, Mar. 27, 1975, as amended at 52 FR 2684, Jan. 26, 1987; 57 FR 6475, Feb. 25, 1992]

**§ 558.15 Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals.**

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by

approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofurans by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofurans not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofurans, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofurans, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofurans by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs

by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofurans, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofurans, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofurans, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and

only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements

of this section: *Provided*, That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Pitman-Moore, Inc. ....	Bacitracin zinc ....	Chickens, turkeys, swine, pheasants, quail, and cattle.	Sec. 558.78 .....	Sec. 558.78.
A. L. Laboratories, Inc. ....	.....do .....	Chickens, turkeys, pheasants, and quail.	.....do .....	Do.
A.L. Laboratories, Inc., Fermenta Animal Health Co..	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76 .....	Sec. 558.76.
Elanco Products Co .....	Hygromycin B .....	Chickens and swine.	Sec. 558.274 .....	Sec. 558.274.
Do .....	Tylosin .....	Chickens, swine, and beef cattle.	Sec. 558.625 .....	Sec. 558.625.
Sanofi Animal Health, Inc. ....	Erythromycin .....	Chickens, turkeys, and swine.	Sec. 558.248 .....	Sec. 558.248.
The Upjohn Co .....	Lincomycin .....	Chickens .....	Sec. 558.325 .....	Sec. 558.325.
Pfizer, Inc. ....	Oleandomycin .....	Chickens, turkeys, and swine.	Sec. 558.435 .....	Sec. 558.435.
Hoechst-Roussel Agri-Vet, Inc ..	Bambermycins ....	Chickens .....	Sec. 558.95 .....	Sec. 558.95.
Elanco Products Co .....	Tylosin and sulfamethazine.	Swine .....	Sec. 558.630 .....	Sec. 558.630.
American Cyanamid Co., Fermenta Animal Health Co., Feed Specialties Co., Inc., Pfizer, Inc., PennField Oil Co., and VPO, Inc..	Chlortetracycline ..	Chickens, turkeys, swine, and cattle.	Sec. 558.128 .....	Sec. 558.128.
Merck Sharp & Dohme Research Labs., and Solvay Veterinary, Inc.	Procaine Penicillin	Chickens, turkeys, swine, pheasants, and quail.	Sec. 558.460 .....	Sec. 558.460.
Pfizer, Inc., PennField Oil Co. ..	Oxytetracycline ....	Sec. 558.450 .....	Sec. 558.450 .....	Sec. 558.450.
American Cyanamid Co .....	Chlortetracycline and sulfamethazine.	Cattle .....	Sec. 558.128 .....	Sec. 558.128.
Sanofi Animal Health, Inc. ....	Erythromycin .....	Cattle .....	37 mg per head per day.	Sec. 558.248.
Hoffman-La Roche, Inc .....	Sulfadimethoxine and ormetoprim.	Chickens and turkeys..	Sec. 558.575 .....	Sec. 558.575.
Pfizer, Inc. ....	Oxytetracycline and neomycin.	Chickens, turkeys, swine, and calves.	As provided in paragraph (g)(2) of this section.	As provided in paragraph (g)(2) of this section.
American Cyanamid Co. and Pfizer, Inc.	Chlortetracycline, sulfamethazine, and penicillin.	Swine .....	.....do .....	Do.
Fermenta Animal Health Co. ....	Chlortetracycline, sulfathiazole, and penicillin.	.....do .....	.....do .....	Do.

(2) The following is a list of drug combinations permitted when prepared from antibacterial Type A articles list-

ed in paragraph (g)(1) of this section. Drug combinations listed in subpart B of this part name their sponsors and

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are incorporated herein by reference since they are safe and effective by contemporary standards, or such sponsors have been notified of any additional safety or efficacy data required on an individual basis:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co. ....	Chlortetracycline and arsanilic acid.	Swine .....	10 to 50 g/ton and 0.005 to 0.01 percent.	Enhancement of growth and feed efficiency.
American Cyanamid Co .....	Chlortetracycline and sulfamethazine.	Cattle .....	Sec. 558.128 .....	Sec. 558.128.
Pfizer, Inc., PennField Oil Co., and VPO, Inc.	Oxytetracycline and neomycin base.	Chickens .....	50 g/ton and 35 to 140 g/ton.	Prevention of diseases from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do .....	.....do .....	Chickens (first 2 weeks).	50 to 100 g/ton and 35 to 140 g/ton.	Prevention of early chick mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do .....	.....do .....	Chickens .....	.....do .....	To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at time of stress. As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of bluecomb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do .....	.....do .....	.....do .....	100 to 200 g/ton and 35 to 140 g/ton.	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do .....	.....do .....	Turkeys .....	50 g/ton and 35 to 140 g/ton.	As an aid in the prevention of disease from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or non-specific enteritis).
Do .....	.....do .....	.....do .....	50 to 100 g/ton and 35 to 140 g/ton.	To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality prevention of hexamitiasis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or non-specific enteritis).
Do .....	.....do .....	Turkeys (first 4 weeks).	.....do .....	As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do .....	.....do .....	.....do .....	100 to 150 g/ton and 35 to 105 g/ton.	As an aid in reducing mortality in birds which have suffered an attack of air-sacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).
Do .....	.....do .....	Turkeys .....	.....do .....	As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or non-specific enteritis).
Do .....	.....do .....	.....do .....	100 to 200 g/ton and 35 to 140 g/ton.	Control of bluecomb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or non-specific enteritis).
Do .....	.....do .....	.....do .....	200 g/ton and 70 to 140 g/ton.	Control of infectious synovitis. For the treatment of bacterial enteritis and bluecomb (mud fever or nonspecific enteritis).

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Drug sponsor	Type A article	Species	Use levels	Indications for use
Do .....	.....do .....	Swine .....	50 g/ton and 35 to 140 g/ton.	As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibronic dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).
Do .....	.....do .....	.....do .....	50 to 150 g/ton and 70 to 140 g/ton.	As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.
Do .....	.....do .....	Calves .....	50 g/ton and 35 to 140 g/ton.	As an aid in the prevention of bacterial enteritis (scours).
Do .....	.....do .....	.....do .....	100 g/ton and 70 to 140 g/ton.	As an aid in the treatment of bacterial enteritis (scours).
Do .....	.....do .....	.....do .....	8 to 100 mg/gal and 100 to 200 mg/gal reconstituted milk replacer.	As an aid in the prevention of bacterial diarrhea (scours).
Do .....	.....do .....	.....do .....	40 to 200 mg/gal and 200 to 400 mg/gal reconstituted milk replacer.	As an aid in the treatment of bacterial diarrhea (scours).
The Upjohn Co. ....	Lincomycin, amprolium, and ethopabate.	Chickens .....	Secs. 558.58 and 558.325.	Secs. 558.58 and 558.325.
Do .....	Lincomycin and zoalene.	.....do .....	Secs. 558.325 and 558.680.	Secs. 558.325 and 558.680.
Do .....	Lincomycin, amprolium, ethopabate, and roxarsone.	.....do .....	Secs. 558.58, 558.325, and 558.530.	Secs. 558.58, 558.325, and 558.530.
Do .....	Lincomycin, monensin, and roxarsone.	.....do .....	Secs. 558.325, 558.355, and 558.530.	Secs. 558.325, 558.355, and 558.530.
Do .....	Nicarbazin and procaine penicillin.	Chickens .....	0.01 to 0.02 percent and 2.4 to 50 g/ton.	Do.
Do .....	Nicarbazin and bacitracin methylene disalicylate.	.....do .....	0.01 to 0.02 percent and 4 to 50 g/ton.	Do.
Do .....	Nicarbazin, bacitracin methylene disalicylate, and roxarsone.	.....do .....	0.01 to 0.02 percent, 4 to 50 g/ton, and 0.0025 to 0.005 percent.	Do.
Do .....	Nicarbazin, procaine penicillin, and roxarsone.	.....do .....	0.01 to 0.02 percent, 2.4 to 50 g/ton, and 0.0025 to 0.025 percent.	Do.
Do .....	Amprolium and bacitracin methylene disalicylate.	Chickens and turkeys.	0.0125 to 0.025 percent and 4 to 50 g/ton.	Secs. 558.55 and 558.76.
Do .....	Amprolium, ethopabate, and bacitracin methylene disalicylate.	Chickens .....	0.0125 to 0.025 percent, 0.0004 percent, and 4 to 50 g/ton.	Secs. 558.58 and 558.76.
Do .....	Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone.	.....do .....	0.0125 to 0.025 percent, 0.0004 percent, 4 to 50 g/ton, and 0.0025 to 0.005 percent.	Secs. 558.58, 558.76, and 558.530.
Do .....	Amprolium and procaine penicillin.	Chickens and turkeys.	0.004 to 0.025 percent and 2.4 to 50 g/ton.	Secs. 558.55 and 558.460.

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do .....	Amprolium, procaine penicillin, and roxarsone.	Chickens .....	0.004 to 0.025 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.	Secs. 558.55, 558.460, and 558.530.
Do .....	Amprolium, ethopabate, procaine penicillin, and erythromycin.	.....do .....	0.0125 to 0.025 percent, 0.0004 percent, 2.4 to 50 g/ton, and 4.6 to 18.5 g/ton.	Secs. 558.58 and 558.460.
Do .....	Amprolium and erythromycin.	.....do .....	0.0125 to 0.025 percent and 4.6 to 18.5 g/ton.	Sec. 558.55.
Do .....	Amprolium and ethopabate.	.....do .....	0.0125 to 0.025 percent and 0.0004 percent.	Sec. 558.58.
Do .....	Amprolium, arsanilic acid, and erythromycin.	.....do .....	0.0125 to 0.025 percent, 0.01 percent, and 4.6 to 18.5 g/ton.	Sec. 558.55.
Do .....	Amprolium, arsanilic acid, and ethopabate.	.....do .....	0.0125 to 0.025 percent, 0.01 percent, and 0.0004 percent.	Sec. 558.58.
Do .....	Amprolium, ethopabate, and bacitracin methylene disalicylate.	.....do .....	0.0125 percent, 0.004 percent, and 4 to 50 g/ton.	Do.
Do .....	Amprolium, ethopabate, bacitracin methylene disalicylate, and roxarsone.	.....do .....	0.0125 percent, 0.004 percent, 5 to 35 g/ton, and 0.00375 percent.	Do.
Pitman-Moore, Inc. ....	Bacitracin zinc, amprolium, and ethopabate.	.....do .....	4 to 50 g/ton, 0.0125 to 0.025 percent, and 0.0004 percent.	Prevention of coccidiosis. Growth promotion and feed efficiency. Sec.558.78.
Do .....	Bacitracin zinc, amprolium, ethopabate, and roxarsone.	.....do .....	4 to 50 g/ton, 0.0125 to 0.025 percent, 0.0004 percent, and 0.0025 to 0.005 percent.	Prevention of coccidiosis. Growth promotion and feed efficiency. Improving pigmentation. Sec. 558.78.
Do .....	Bacitracin zinc and arsanilic acid.	Swine .....	10 to 50 g/ton and 0.005 to 0.01 percent.	Increased rate of weight gain and improved feed efficiency.
Merck Sharp & Dohme Research Labs.	Amprolium, ethopabate, procaine penicillin, and roxarsone.	Chickens .....	0.125 to 0.025 percent, 0.0004 percent, 2.4 to 50 g/ton, and 0.0025 to 0.005 percent.	Secs. 558.58, 558.460 and 558.530.
A. L. Laboratories, Inc. ....	Zoalene and bacitracin methylene disalicylate.	Chickens .....	0.0125 percent and 4 to 50 g/ton.	Sec. 558.680.
Do .....	Zoalene, roxarsone, and bacitracin methylene disalicylate.	.....do .....	0.0125 percent, 0.005 percent, and 4 to 50 g/ton.	Do.
Do .....	Zoalene and bacitracin zinc.	.....do .....	0.0125 percent and 4 to 50 g/ton.	Do.
Do .....	Zoalene, roxarsone, and bacitracin zinc.	.....do .....	0.0125 percent, 0.0025 to 0.005 percent, and 4 to 50 g/ton.	Do.
Do .....	Zoalene and penicillin.	.....do .....	0.0125 percent and 2.4 to 50 g/ton.	Do.

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do .....	Zoalene, roxarsone, and penicillin.	.....do .....	0.0125 percent, 0.0025 to 0.005 percent, and 2.4 to 50 g/ton.	Do.
Do .....	Zoalene, arsanilic acid, and bacitracin methylene disalicylate or bacitracin zinc.	.....do .....	0.0125 percent, 0.01 percent, and 4 to 50 g/ton.	Do.
Do .....	Zoalene, arsanilic acid, and penicillin.	.....do .....	0.0125 percent, 0.01 percent, and 2.4 to 50 g/ton.	Do.
Do .....	Zoalene, and bacitracin methylene disalicylate.	.....do .....	0.004 to 0.0125 percent and 4 to 50 g/ton.	Do.
Do .....	Zoalene, roxarsone, and bacitracin methylene disalicylate.	.....do .....	0.004 to 0.0125 percent, 0.0025 to 0.005 percent, and 4 to 50 g/ton.	Do.
Whitmoyer Labs, Inc .....	Carbarsone and bacitracin.	Turkeys .....	Sec. 558.120 .....	Sec. 558.120.
Elanco Products Co. ....	Hygromycin B and tylosin.	Chickens .....	8 to 12 g/ton and 4 to 50 g/ton.	Sec. 558.274.
Do .....	.....do .....	Swine .....	12 g/ton and 10 to 100 g/ton.	Do.
A. L. Laboratories, Inc. ....	Nitarson and bacitracin zinc.	Turkeys .....	0.01875 percent, 4 to 50 g/ton.	As an aid in the prevention of blackhead. To increase rate of weight gain and improve feed efficiency.

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

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

**§ 558.35 Aklomide.**

(a) *Approvals.* Type A medicated articles: to 053501 in §510.600(c) of this chapter, as follows:

- (1) 50 percent aklomide.
- (2) 20 percent sulfanitran and 25 percent aklomide.
- (3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.
- (4) 50 percent aklomide and 10 percent roxarsone.

(b) *Related tolerances.* See §556.30 of this chapter.

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

- (1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).
- (i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix*.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption.

(2) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent).

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

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter.

(3) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent) + roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, and *E. acervulina*; growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before

slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(4) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella*, and *E. necatrix*; growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

[40 FR 13959, Mar. 27, 1975, as amended at 41 FR 8312, Feb. 25, 1976; 51 FR 7395, Mar. 3, 1986; 55 FR 8460, Mar. 8, 1990]

**§ 558.55 Amprolium.**

(a) *Approvals.* Type A medicated articles: 25 percent to 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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

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

(d) *Conditions of use—(1) Calves.* It is top-dressed on or thoroughly mixed in the daily feed ration as follows:

(i) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

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

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(ii) *Amount.* 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

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

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium.

(2) *Chickens and turkeys.* 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 (0.004% to 0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Feed as follows—	

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

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).	Arsanilate sodium 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i). Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Bacitracin 100 to 200	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).	
	Chlortetracycline 100 to 200.	Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate. Feed according to subtable in item (i).	
	Erythromycin 92.5 .....	1. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 72.6 to 113.5 (0.008% to 0.0125%).		2. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
	Erythromycin 185 .....	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).	
	Hygromycin B 8 to 12	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50 .....	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As procaine penicillin. Feed according to subtable in item (i).	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion, and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	.....	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> only.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilate sodium 90 (0.01%).	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%).	.....do .....	.....do .....	
	Bacitracin 100 to 200	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate, or zinc bacitracin.	
	Chlortetracycline 100 to 200.	Chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Hygromycin B 8 to 12	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> only; control of infestation of large round worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
Penicillin 2.4 to 50 .....	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; growth promotion and feed efficiency.	As procaine penicillin .....		

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 113.5 (0.0125%) ...	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	012799
	.....	1. Laying chickens; prevention of coccidiosis. 2. Laying chickens; treatment of coccidiosis.	..... For moderate outbreaks of coccidiosis; administer for 2 weeks.	
(iv) 113.5 to 227 (0.0125% to 0.025%).	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; roxarsone as provided by No. 053501 in §510.600(c) of this chapter, bambermycins by No. 012799; withdraw 5 d before slaughter.	
	Bambermycins 1 to 4	Growing turkeys; prevention of coccidiosis; increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 012799 in §510.600(c) of this chapter.	
	.....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis. 2. Turkeys; prevention of coccidiosis.	.....do .....	
	Arsanilate sodium 90 (0.01%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. .....do .....	
	Arsanilic acid 90 (0.01%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	.....do .....	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate or bacitracin zinc.  .....do .....	1012769
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis). 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic ry disease (air-sac infection), blue comb (nonspecific infectious enteritis).	.....do .....  As bacitracin zinc .....	
	Bacitracin 100 to 500	Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever).	.....do .....  As bacitracin zinc .....	
	Bacitracin plus penicillin 100 to 500 (of combination).	.....do .....	Feed contains 50% to 75% of bacitracin but not more than 125 g penicillin; as procaine penicillin; as bacitracin zinc.	
	Carbarstone 227 to 340.5.	Turkeys; aid in prevention of coccidiosis ( <i>Eimeria adenoides</i> , <i>E. meleagrimitis</i> , and <i>E. gallopavonis</i> ) and blackhead.	Feed continuously 2 weeks before coccidiosis and blackhead are expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; carbarstone by 046573 in §510.600(c) of this chapter.	000006
	Chlortetracycline 100 to 200.	Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 200 to 400.	Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate ....	
	Erythromycin 92.5 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.  Feed for 7 to 14 d; withdraw 24 h before slaughter.	
	Erythromycin 185 .....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Hygromycin B 8 to 12	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms ( <i>Heterakis gallinae</i> ) and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	As procaine penicillin .....  .....do .....	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.  .....do .....	
(v) 227 (0.025%) .....	.....	Laying chickens; treatment of coccidiosis.	For severe outbreaks of coccidiosis; administer for 2 weeks.	

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

(i) *Amount*. 0.0175 percent (159 grams per ton).

(ii) *Indications for use.* For the prevention of coccidiosis in growing pheasants caused by *Eimeria colchici*, *E. duodenalis*, and *E. phasiani*.

(iii) *Limitations.* Feed continuously as sole ration. Use as sole source of amprolium. Fertility, hatchability, and other reproductive data are not available on amprolium in breeding pheasants. Do not use in feeds containing bentonite.

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.58 Amprolium and ethopabate.**

(a) *Approvals.* Type A medicated articles: (1) 25 percent amprolium and 0.8

percent ethopabate; 25 percent amprolium and 8 percent ethopabate; 5 percent amprolium and 0.16 percent ethopabate; 5 percent amprolium and 1.6 percent ethopabate; to 000006.

(2) 0.15 percent amprolium and 0.004 percent ethopabate and 0.05 gram per pound bacitracin (as bacitracin methylene disalicylate) to 047019 in § 510.600(c) of this chapter.

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

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

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

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.	Not for laying hens; as sole source of amprolium.	
(ii) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).	Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone by No. 046573, bambermycins by No. 012799; withdraw 5 d before slaughter.	
	Lincomycin 2 to 4 ....	Broiler chickens; for increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	
	Lincomycin 2 to 4 plus roxarsone 45.4 (0.005%).	Broiler chickens; for increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until the past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combinations as provided by No. 050604.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) Amprolium 113.5 (0.0125%) and ethopabate 36.3 (0.004%).	.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur.	Not for chickens over 16 weeks of age.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improve pigmentation.	Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thiocyanate.	
	Bacitracin 4 to 50 ....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	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; as bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by Nos. 046573 and 063238 in §510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by No. 050604 in §510.600(c) of this chapter.	
	.....	2. Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis; bacitracin zinc as provided by Nos. 046573 and 063238 in §510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until market weight; combination as provided by Nos. 046573 and 063238..	046573 and 063238
	Bacitracin 5 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by Nos. 046573 and 063238 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter; combination as provided by No. 050604 in §510.600(c) of this chapter.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 20 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 in §510.600(c) of this chapter; roxarsone as provided by No. 046573 in §510.600(c) of this chapter; combination as provided by No. 050604 in §510.600(c) of this chapter.	
	Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter; bacitracin zinc as provided by Nos. 046573 and 063238 roxarsone as provided by No. 046573 combination as provided by Nos. 046573 and 063238.	046573, 063238
	Bacitracin 10 plus roxarsone 30 to 45.4 (0.0033% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency and improved pigmentation.	.....do .....	063238
	Bambermycins 1 to 3.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain, and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium; amprolium, ethopabate as provided by No. 050604 in §510.600(c) of this chapter, bambermycins as provided by No. 012799 in §510.600(c) of this chapter.	
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain; improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in §510.600(c) of this chapter, roxarsone by No. 046573 bambermycins by No. 012799. Withdraw 5 days before slaughter.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iv) Amprolium 113.5 to 227 (0.0125% to 0.025%) and ethopabate 3.6 (0.0004%).	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	Not for laying hens; withdraw 24 hours before slaughter; erythromycin thiocyanate.	000069
	Virginiamycin, 15 .....	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <i>Eimeria acervulina</i> , <i>E. brunetti</i> , and <i>E. maxima</i> is likely to occur, for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration, do not feed to laying hens, not for chickens over 16 weeks of age, as sole source of amprolium, amprolium and ethopabate as provided by 050604 in §510.600(c), virginiamycin as provided by 000069.	
	Virginiamycin, 5 to 15.	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <i>Eimeria acervulina</i> , <i>E. brunetti</i> , and <i>E. maxima</i> is likely to occur, for increased rate of weight gain.	.....do .....	
	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying hens .....	
	Arsanilic acid 90 (0.01%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation. 2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50 ....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate; not for laying hens.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 100 to 200.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis). 2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	.....do .....  As zinc bacitracin, not for laying hens.	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As bacitracin methylene disalicylate; not for laying hens; as sole source of organic arsenic; withdraw 5 d before slaughter.	
	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	
	Erythromycin 92.5 ...	1. For broiler chickens and for replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.  Feed for 7 to 14 d; withdraw 24 h before slaughter; not for laying hens.	
	Erythromycin 185 ...	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Penicillin 2.4 to 50 ...	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Not for laying hens; as procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(v) Amprolium 136.2 (0.015%) and ethopabate 3.6 (0.0004%).	Bacitracin 10 .....	Broiler chickens; as an aid in the prevention of coccidiosis; growth promotion and feed efficiency.	Feed as sole ration; use as sole source of amprolium; do not feed to laying hens; as bacitracin methylene disalicylate.	047019

(2) [Reserved]

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.58, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.59 Apramycin.**

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

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

(2) [Reserved]  
(b) [Reserved]

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

(d) *Conditions of use—(1) Swine—(i) Amount.* 150 grams per ton.

(ii) *Indications for use.* For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli*.

(iii) *Limitations.* Use for 14 days. Withdraw 28 days before slaughter.

(2) [Reserved]

[51 FR 9190, Mar. 18, 1986]

**§ 558.60 Arsanilate sodium.**

(a) *Approvals.* Type A medicated articles: 20, 50, or 100 percent to 015565 in § 510.600(c) of this chapter.

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

(c) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

(i) *Grams per ton.* 90 (0.01 percent).

(ii) *Indications for use.* For growth promotion and feed efficiency; improving pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Arsanilate sodium may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Zoalene in accordance with § 558.680.

[41 FR 10992, Mar. 15, 1976, as amended at 51 FR 7395, Mar. 3, 1986; 51 FR 33897, Sept. 24, 1986]

**§ 558.62 Arsanilic acid.**

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

(1) To 015565: 20, 50, and 100 percent for use as in the table in paragraph (c)(1), entry (ii), item 1; entry (ii), item 2; entry (iii); entry (iv); and entry (v) of this section.

(2) To 015565: 20 percent for use as in paragraph (c)(1), entry (i); entry (ii), item 3 of this section.

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

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

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 45 to 90 (0.005% to 0.01%).	.....	Swine; for increased rate of weight gain and improved feed efficiency in growing swine..	Withdraw 5 days before slaughter; as sole source of organic arsenic.	015565
(ii) 90 (0.01%) .....	.....	1. Chickens; growth promotion and feed efficiency; improving pigmentation.. 2. Turkeys; growth promotion and feed efficiency; improving pigmentation.	.....do .....	015565 015565

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Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) .....	Erythromycin 4.6 to 18.5.	3. Swine; and aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery). Chickens; growth promotion and feed efficiency; improving pigmentation.	.....do .....	015565  15565
(iv) .....	Erythromycin 92.5 ...	1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation. 2. Chickens; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 2 days before stress and 3 to 6 days after stress; withdraw 5 days before slaughter; as sole source of organic arsenic. As erythromycin thiocyanate; feed for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	015565  015565
(v) .....	Erythromycin 185 ...	Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 5 to 8 days; do not use in birds producing eggs for food purposes; withdraw 5 days before slaughter; as sole source of organic arsenic.	15565

(2) Arsanilic acid may be used in accordance with the provisions of this section in the combinations provided as follows:

- (i) Amprolium in accordance with § 558.55.
- (ii) Amprolium and ethopabate in accordance with § 558.58.
- (iii) Bacitracin zinc in accordance with § 558.78.
- (iv) Bacitracin and zoalene in accordance with § 558.680.
- (v) Zovalene in accordance with § 558.680.

[41 FR 10992, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 51 FR 7395, Mar. 3, 1986; 51 FR 33897, Sept. 24, 1986; 54 FR 18281, Apr. 28, 1989; 56 FR 19268, Apr. 26, 1991; 60 FR 39847, Aug. 4, 1995]

**§ 558.76 Bacitracin methylene disalicylate.**

(a) *Approvals.* Type A medicated articles: 10, 25, 30, 40, 50, 60, or 75 grams per pound to 046573 in § 510.600(c) of this chapter.

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

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

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

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50 .....	.....	Chickens, turkeys, and pheasants; increased rate of weight gain and improved feed efficiency <sup>1</sup> .	.....	046573
(ii) 5 to 20 .....	.....	Quail not over 5 weeks of age; increased rate of weight gain and improved feed efficiency <sup>1</sup> .	.....	046573
(iii) 10 to 25 .....	.....	Chickens; for increased egg production and improved feed efficiency for egg production.	For first 7 months of production	046573
(iv) 10 to 30 .....	.....	Swine; for increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	000004 and 046573

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(v) [Reserved] (vi) 50 .....	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed for not more than 14 days to provide 10 milligrams of chlortetracycline per pound of body weight per day; as chlortetracycline provided by Nos. 000004 and 046573 in §510.600(c) of this chapter. Type C feed may be prepared from Type B feed containing 1 to 3 grams per pound BMD with 400 grams per pound CTC, to 046573 in §510.600(c).	000004 and 046573
(vii)—(viii) [Reserved] (ix) 100 to 200 .....	.....	Broiler chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	.....	046573
.....	.....	Replacement chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration	046573
.....	.....	Broiler chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	.....	046573
.....	.....	Replacement chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/t).	046573
(x) 200 .....	.....	Turkeys; as an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylene disalicylate.	.....	046573
.....	.....	Quail; for the prevention of ulcerative enteritis in growing quail due to <i>Clostridium colinum</i> susceptible to bacitracin methylene disalicylate	From Type A medicated articles containing 25, 40, or 50 grams of bacitracin methylene disalicylate. Feed continuously as the sole ration.	046573
(xi) 250 .....	.....	1. Growing/Finishing Swine: For control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition.	As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.	046573

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	.....	2. Pregnant sows: For control of clostridial enteritis caused by <i>C. perfringens</i> 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 a veterinarian when results are not satisfactory.	

<sup>1</sup> These conditions are NAS/NRC reviewed and found effective. Applications for these uses may not require effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) It is used as bacitracin methylene disalicylate in feed for animals as follows:

(i) *Amount.* 70 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continuously throughout the feeding period.

(ii) *Amount.* 250 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) It is used as bacitracin methylene disalicylate in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium with ethopabate in accordance with § 558.58.

(iii) Arsanilic acid with zoalene in accordance with § 558.680

(iv) Carbarsone (not U.S.P.) in accordance with § 558.120.

(v) Nicarbazin as in § 558.366.

(vi) Hygromycin B in accordance with § 588.274.

(vii) Monensin in accordance with § 588.355.

(viii) Lasalocid sodium alone or with roxarsone as in § 558.311.

(ix) Monensin and roxarsone in accordance with § 558.355.

(x) Salinomycin alone or with roxarsone as in § 558.550.

(xi) Halofuginone hydrobromide and roxarsone in accordance with § 558.265.

(xii) Halofuginone in accordance with § 558.265.

(xiii) Narasin alone or in combination with roxarsone as in § 558.363.

(xiv) Semduramicin alone or in combination with roxarsone as in § 558.555.

(xv) Zoalene alone or in combination as in § 558.680.

(xvi) Nitarsone alone or in combination as in § 558.369.

(xvii) Decoquinatate and roxarsone as in § 558.195.

(xviii) Decoquinatate as in § 558.195.

(xix) Narasin and nicarbazin as in § 558.366.

(xx) Ivermectin as in § 558.300.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.76, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.78 Bacitracin zinc.**

(a) *Approvals.* To sponsors listed in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) To 046573: 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(iv), and (d)(2) of this section.

(2) To 063238: 10, 25, 40, and 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(v), (d)(1)(vi), (d)(2), and (d)(3) of this section.

(3) To 000010: 5 and 50 grams per pound for chickens as in paragraph (d)(1)(i) of this section.

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

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

(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, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency.	Growing chickens, turkeys, and pheasants.	063238, 046573
(ii) 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.	063238, 046573
(iii) 10 to 25 .....	.....	Laying chickens; improved feed efficiency and increased egg production.	.....	046573
(iv) 10 to 50 .....	.....	Swine; increased rate of weight gain and improved feed efficiency.	Growing and finishing swine .....	046573
(v) 20 .....	.....	Growing-finishing swine; increased rate of weight gain.	In Type C feed .....	063238
(vi) 20 to 40 .....	.....	Growing-finishing swine; improved feed efficiency.	.....do .....	063238

(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 063238.

(3) Bacitracin zinc may be used as approved in combination as follows:

- (i) Amprolium as in § 558.55.
- (ii) Amprolium and roxarsone as in § 558.55.
- (iii) Amprolium and ethopabate as in § 558.58.
- (iv) Amprolium and ethopabate with roxarsone as in § 558.58.
- (v) Carbarsone as in § 558.120.
- (vi) Clopidol as in § 558.175.
- (vii) Clopidol and roxarsone as in § 558.175.
- (viii) Decoquinatate as in § 558.195.
- (ix) Decoquinatate and roxarsone as in § 558.195.
- (x) Hygromycin B as in § 558.274.
- (xi) Hygromycin B and penicillin as in § 558.274.
- (xii) Lasalocid sodium and roxarsone as in § 558.311.
- (xiii) Monensin as in § 558.355.
- (xiv) Monensin and roxarsone as in § 558.355.
- (xv) Robenidine as in § 558.515.
- (xvi) Salinomycin as in § 558.550.
- (xvii) Salinomycin and roxarsone as in § 558.550.
- (xviii) Zoalene as in § 558.680.
- (xix) Zoalene and arsanilic acid as in § 558.680.

(xx) Zoalene and roxarsone as in § 558.680.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.95 Bambermycins.**

(a) *Approvals.* To sponsors identified by drug labeler codes in § 510.600(c) of this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

- (1) To 012799: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.
- (2) To 012799: 0.4 gram for use as in paragraph (d)(2) of this section.
- (3) To 011490: 0.4 and 2 grams for use as in paragraph (d)(2) of this section.
- (4) To 012286, 016968, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.
- (5) To 012799: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

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

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for

the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

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

(i) *Amount per ton*. 1 to 2 grams.

(a) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(b) *Limitations*. Feed continuously as the sole ration.

(ii) *Amount per ton*. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 36.3 grams (.004 percent).

(a) *Indications for use*. As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain and improved feed efficiency.

(b) *Limitations*. Feed continuously as the sole ration; as sole source of amprolium; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter.

(iii) *Amount per ton*. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 36.3 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-.00375 percent).

(a) *Indications for use*. As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations*. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(iv) *Amount per ton*. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 3.63 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-.00375 percent).

(a) *Indications for use*. As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations*. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(v) *Amount per ton*. Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus roxarsone, 22.8 to 34.1 grams (.0025-.00375 percent).

(a) *Indications for use*. As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations*. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(vi) *Amount per ton*. Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams.

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

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bambermycins provided by No. 012799 in § 510.600(c) of this chapter.

(vii) *Amount per ton*. Bambermycins, 1 gram plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent).

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

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 days before slaughter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bambermycins provided by No. 012799 in § 510.600(c) of this chapter; as

roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent).

(a) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; zoalene as provided by No. 025700 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; feed as sole source of organic arsenic; withdraw 5 days before slaughter; zoalene as provided by No. 025700, roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(x) *Amount per ton.* Bambermycins, 1 gram plus lasalocid sodium, 68 to 113 grams (0.0075 to 0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent).

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

(b) *Limitations.* For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone as provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, and lasalocid sodium as provided by .000004 in § 510.600(c) of this chapter.

(xi) *Amount per ton.* Bambermycins 1 to 2 grams, plus roxarsone 45.4 grams, and salinomycin 40 to 60 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. tenella*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for improved feed efficiency.

(b) *Limitations.* For broiler chickens only; do not feed to laying chickens; feed continuously as sole ration; as sole source or organic arsenic; withdraw 5 days before slaughter; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; as roxarsone provided by No. 011526 or 046573 in § 510.600(c) of this chapter; as salinomycin sodium biomass provided by Nos. 012799 and 063238 in § 510.600(c) of this chapter.

(xii) *Amount per ton.* Bambermycins 1 to 3 grams, plus salinomycin 40 to 60 grams.

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

(b) *Limitations.* For broiler chickens only; Do not feed to laying chickens; feed continuously as sole ration; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; as salinomycin sodium biomass provided by Nos. 012799 and 063238 in § 510.600(c) of this chapter.

(xiii) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to 0.005 percent).

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

(b) *Limitations.* See paragraph (b)(1)(vii)(b) of this section.

(2) *Growing-finishing swine.* It is used as follows:

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

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

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

(b) *Limitations.* Feed continuously as sole ration.

(3) *Growing turkeys.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

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

(b) *Limitations.* Feed continuously as the sole ration.

- (ii) *Amount per ton.* 2 grams.
- (a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.
- (b) *Limitations.* Feed continuously as sole ration.
- (iii) *Amount per ton.* Bambermycins, 1 to 4 grams plus amprolium, 113.5 grams (.0125 percent).
- (a) *Indications for use.* For prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.
- (b) *Limitations.* Feed continuously as the sole source of amprolium; amprolium as provided by No. 050604 in § 510.600(c) of this chapter.
- (iv) *Amount per ton.* Bambermycins, 1 or 4 grams plus carbarstone, 227 grams (0.025 percent).
- (a) *Indications for use.* For improved feed efficiency (1 gram per ton) or increased rate of weight gain (4 grams per ton); as an aid in the prevention of blackhead.
- (b) *Limitations.* Feed continuously 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of organic arsenic; carbarstone by 046573 in § 510.600(c) of this chapter.

- (4) *Cattle*—(i) *Amount per ton.* 1 to 4 grams.
- (a) *Indications for use.* For increased rate of weight gain and improved feed efficiency.
- (b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C medicated feed at a rate of 10 to 20 milligrams of bambermycins per head per day. Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.
- (ii) *Amount per ton.* 4 to 20 grams.
- (a) *Indications for use.* For increased rate of weight gain.
- (b) *Limitations.* Feed continuously to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) at a rate of 10 to 20 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed.
- (iii) 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	15.24
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). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 5.33 ounces per head per

- day. Feed continuously to provide 10- to 20-milligrams bambermycins per head per day. Each use of this free-choice Type C medicated feed must be the subject of an approved Form FDA 1900 as required by 21 CFR 510.455.
- (iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle, and dairy

and beef replacement heifers) as follows:

(a) *Amount.* Feed continuously to provide 10 to 20 milligrams of bambamycins 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.

(5) Bambamycins may be used as in this section in combination with:

(i) Halofuginone as in § 558.265.

(ii) Narasin as in § 558.363.

(iii) Narasin and roxarsone as in § 558.363.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.105 [Reserved]

#### § 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2 percent (10 grams per pound) to 000069 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 breed-

ing 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.

[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]

#### § 558.120 Carbarson (not U.S.P.).

(a) *Approvals.* Type A medicated articles: (1) 37.5 percent to 046573 in § 510.600(c) of this chapter.

(2) 25 percent carbarson and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 046573 in § 510.600(c) of this chapter.

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

(c) [Reserved]

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

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(a) *Indications for use.* As an aid in the prevention of blackhead.

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarson plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(a) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarson plus 4 to 45 grams per ton bacitracin from bacitracin zinc.

(a) *Indications for use.* As an aid in the prevention of blackhead, increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. As sole source of organic arsenic; as bacitracin zinc provided by Nos. 046573 and 063238 in §510.600(c) of this chapter.

(2) Carbarson (not U.S.P.) may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Zoalene in accordance with §558.680.

(ii) Amprolium as in §558.55.

(iii) Bambermycins as in §558.95.

[41 FR 10995, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 46 FR 46797, Sept. 22, 1981; 48 FR 2758, Jan. 21, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2687, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 57 FR 7652, Mar. 4, 1992; 61 FR 515, Jan. 8, 1996; 61 FR 18082, Apr. 24, 1996; 62 FR 61011, Nov. 14, 1997; 63 FR 27845, May 21, 1998]

**§ 558.128 Chlortetracycline.**

(a) *Approvals.* Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

(1) 50 to 100 grams per pound to 063238 in §510.600(c) of this chapter.

(2) 50 to 100 grams per pound to 000069.

(3) 50 to 100 grams per pound to 046573.

(4) 50 grams per pound to 017519.

(5) 50 to 100 grams per pound to 053389.

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

(c) [Reserved]

(d)(1) It is used in feeds as follows:

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/t		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	063238.  000069, 017519, 046573, 053389.
		2. Growing turkeys; increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	000069, 017519, 046573, 053389, 063238.
		3. Growing swine; increased rate of weight gain and improved feed efficiency.		Do.
(ii) 20 to 50 g/t		Growing sheep; increased rate of weight gain and improved feed efficiency.		000069, 046573, 053389, 063238.
(iii) 50 to 100 g/t		Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E. <i>Streptococci</i> susceptible to chlortetracycline.		000069, 017519, 046573, 053389, 063238.
(iv) 100 to 200 g/t		Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	063238.
			2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	000069, 017519, 046573, 053389.

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/t		Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	000069, 017519, 046573, 053389, 063238.
(vi) 200 to 400 g/t		1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.  2. Ducks; control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.  2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.  Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.	063238.  000069, 017519, 046573, 053389, 063238.
(vii) 400 g/t		1. Turkeys; control of hexamitiasis caused by <i>Hexamita meleagrides</i> susceptible to chlortetracycline.  2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.  3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.    Feed continuously for not more than 14 d.	000069, 017519, 046573, 053389, 063238. Do.  Do.
(viii) 500 g/t		Chickens; reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	1. Feed for 5 d.  2. Feed for 5 d; do not feed to chickens producing eggs for human consumption.	063238.  000069, 017519, 046573, 053389.
(ix) 10 mg/g of finished feed daily.		Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. <i>Warning:</i> "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."	00004
(x) 0.1 mg/lb of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	In milk replacers or starter feed; include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."	063238, 000069, 017519, 046573, 053389



Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
		2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline.	.....do	Do.

(2) For sponsor 000004: it is used in free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles; such feeds are given to beef cattle and nonlactating dairy cattle to provide a daily intake of 0.5 to 2.0 milligrams of chlortetracycline per pound of body weight to aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; the use of these Type A articles to make specific free-choice feed formulations must be approved under section 512(b) of the act and be based on a demonstration of drug stability and consumption which is consistent with the effective dose; the specific free-choice feed formulations approved in this paragraph can be manufactured under section 512(m) of the act.

(3) Chlortetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

- (i) Amprolium in accordance with § 558.55.
- (ii) Amprolium plus ethopabate in accordance with § 558.58.
- (iii) Bacitracin methylene disalicylate in accordance with § 558.76.
- (iv) Clopidol in accordance with § 558.175.
- (v) Decoquate in accordance with § 558.195.
- (vi) Hygromycin B in accordance with § 558.274.
- (vii) Monensin in accordance with § 558.355.
- (viii) Roxarsone and salinomycin in accordance with § 558.550.
- (ix) Robenidine hydrochloride in accordance with § 558.515.
- (x) Roxarsone in accordance with § 558.530.
- (xi) Salinomycin in accordance with § 558.550.
- (xii) Zoalene in accordance with § 558.680.

(xiii) Tiamulin in accordance with § 558.600.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.128, see the List of Sections Affected in the Finding Aids section of this volume.

**§ 558.140 Chlortetracycline and sulfamethazine.**

(a) *Approvals.* Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 063238 in § 510.600(c) of this chapter.

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

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day.* Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

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

(3) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter.

[61 FR 35954, July 9, 1996, as amended at 64 FR 15684, Apr. 1, 1999]

**§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.**

(a) *Approvals.* Type A medicated articles: (1) 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to 046573 and 063238 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to 063238 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

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

(c) *Related tolerances.* See §§ 556.150, 556.510, and 556.670 of this chapter.

(d) *Conditions of use.* (1) It is administered to swine in a Type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 15 days prior to slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 19385, May 5, 1978; 47 FR 39814, Sept. 10, 1982; 48 FR 30615, July 5, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 56 FR 14019, Apr. 5, 1991; 61 FR 18082, Apr. 24, 1996; 62 FR 14300, Mar. 26, 1997; 63 FR 27845, May 21, 1998]

**§ 558.155 Chlortetracycline, sulfathiazole, penicillin.**

(a) *Approvals.* Type A medicated articles: (1) 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and procaine penicillin equivalent to 10 grams of penicillin per pound to 000004 and 000010 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline hydrochloride, 8.8 percent (40 grams) sulfathiazole and procaine penicillin equivalent in activity to 20 grams of penicillin per pound to Nos. 000004 and 000010 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(c) *Related tolerances.* See §§ 556.150, 556.510, and 556.690 of this chapter.

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

(1) *Amount per ton.* Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) *Indications for use.* For reduction of incidence of cervical abscesses. Treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery). Maintenance of weight gains in the presence of atrophic rhinitis. Swine 10 pounds of body weight to 6 weeks post-weaning: Increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks post-weaning: Increased rate of weight gain.

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture. Feed as sole ration. Withdraw 7 days prior to slaughter.

MINIMUM AMOUNT OF TYPE C FEED WHICH THE ANIMAL SHOULD CONSUME

Type of feed	Approximate body weight in pounds	Minimum desired daily feed intake in pounds
Prestarter (up to 6 weeks postweaning) .....	20	1
Starter (up to 6 weeks postweaning) .....	50	1½
Grower (6-16 weeks postweaning)	80	2
Finisher (6-16 weeks postweaning) .....	150	3

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7397, Mar. 3, 1986; 51 FR 28547, Aug. 8, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 2415, Jan. 26, 1996; 62 FR 35077, June 30, 1997; 62 FR 67725, Dec. 30, 1997; 63 FR 11599, Mar. 10, 1998]

**§ 558.175 Clopidol.**

(a) *Approvals.* Type A medicated articles: (1) 25 percent to 011526 in § 510.600(c) of this chapter.

(2) 25 percent of clopidol, 10 percent of roxarsone, and 4, 10, 15, or 25 grams of bacitracin methylene disalicylate per pound to 011526 in § 510.600(c) of this chapter.

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

(c) [Reserved]

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

(1) *Broiler chickens*—(i) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E.*

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

(b) *Limitations*. Do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton*. Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) *Indications for use*. Aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; growth promotion and feed efficiency; improved pigmentation.

(b) *Limitations*. Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton*. Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent) plus bacitracin, 4–25 grams.

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

(b) *Limitations*. Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by No. 046573 in § 510.600(c) of this chapter; or as zinc bacitracin provided by Nos. 046573 and 063238 in § 510.600(c) of this chapter.

(iv) *Amount per ton*. Clopidol, 113.5 grams (0.0125%) plus zinc bacitracin, 5 to 25 grams.

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

(b) *Limitations*. Feed continuously as sole ration. Zinc bacitracin as provided by Nos. 046573 and 063238 of § 510.600(c) of this chapter.

(v) *Amount per ton*. Clopidol, 113.5 grams (0.0125 percent) plus bacitracin methylene disalicylate, 4 to 50 grams per ton.

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

(b) *Limitations*. Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton*. Clopidol, 113.5 grams (0.0125 percent) plus lincomycin, 2–4 grams.

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

(b) *Limitations*. As lincomycin hydrochloride monohydrate; do not feed to chickens over 16 weeks of age.

(2) *Broiler chickens and replacement chickens*—(i) *Amount per ton*. Clopidol, 113.5 or 227 grams (0.0125 or 0.025 percent).

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

(b) *Limitations*. Feed up to 16 weeks of age if intended for use as caged layers; feed continuously as the sole ration; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.

(ii) *Amount per ton*. Clopidol, 113.5 grams (0.0125 percent) plus chlortetracycline 100 to 200 grams.

(a) *Indications for use*. Aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(b) *Limitations*. Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.

(3) [Reserved]

(4) *Replacement chickens*—(i) *Amount per ton*. Clopidol 113.5 grams (0.0125 percent).

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

(b) *Limitations*. For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent) plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(5) *Turkeys—(i) Amount per ton.* Clopidol 113.5 or 227 grams (0.0125 or 0.025 percent).

(ii) *Indications for use.* Aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi*.

(iii) *Limitations.* For turkeys grown for meat purposes only; to be administered continuously in feed at 0.0125 or 0.025 percent clopidol as the sole ration depending upon management practices, degree of exposure, and amount of feed eaten; withdraw medication 5 days before slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 31935, July 30, 1975; 40 FR 52723, Nov. 12, 1975; 41 FR 1062, Jan. 6, 1976; 41 FR 53002, Dec. 3, 1976; 44 FR 20676, Apr. 6, 1979; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 54 FR 6518, Feb. 13, 1989; 61 FR 35954, July 9, 1996; 62 FR 61626, Nov. 19, 1997; 62 FR 61912, Nov. 20, 1997; 62 FR 62243, Nov. 21, 1997; 63 FR 17948, Apr. 13, 1998; 63 FR 27845, May 21, 1998]

#### § 558.185 Coumaphos.

(a) *Approvals.* Type A medicated articles:

(1) [Reserved]

(2) 1.12 and 11.2 percent to 017800 in § 510.600(c) of this chapter for use as in paragraph (d)(1)(ii) of this section.

(b) *Special considerations.* Adequate directions and warnings for use must be given and shall include a statement that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment to any other cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

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

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

(1) *Beef and dairy cattle—(i) Amount.* Coumaphos 0.00012 lb. (0.054 gram) per 100 lb. body weight per day.

(a) *Indications for use.* As an aid in the reduction of fecal breeding flies through control of fly larvae.

(b) *Limitations.* Feed for the duration of fly season in a Type C feed containing 0.0033 percent or in a feed Type B feed containing not over 0.0066 percent coumaphos; do not feed to animals less than 3 months old; not for use in pelleted feeds.

(ii) *Amount.* Coumaphos, 0.0002 lb. (0.091 gram) per 100 lb. body weight per day.

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

(b) *Limitations.* Feed 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days in the normal grain ration to which the animals are accustomed but not in rations containing more than 0.1 percent coumaphos; do not feed to animals less than 3 months old; do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks; do not feed in conjunction with oral drenches or with feeds containing phenothiazine. Should conditions warrant, repeat treatment at 30-day intervals.

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

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

(iii) *Limitations.* In Type C feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than

white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

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

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

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

treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 1463, Jan. 7, 1977; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 34729, July 3, 1996]

**§ 558.195 Decoquate.**

(a) *Approvals*. Type A medicated articles: 6 percent to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances in edible products*. See § 556.170 of this chapter.

(c) *Special considerations*. (1) Bentonite should not be used in decoquate feeds.

(2) Type A medicated articles containing 6 percent decoquate may be used to make dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraph (d) of this section.

(3) Type A medicated articles containing 6 percent decoquate may be used to manufacture dry or liquid Type B cattle feeds as indicated in paragraph (d) of this section.

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

Decoquate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
13.6 (0.00149 pct) .....	.....	Young goats; for the prevention of coccidiosis caused by <i>Eimeria christenseni</i> and <i>E. ninakohlyakimovae</i> .	Feed at a rate to provide 22.7 mg per 100 lbs of body weight per day (0.5 mg per kilogram); do not feed to goats producing milk for food; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard.	046573
13.6 (0.0015 pct) .....	.....	Young sheep; for the prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. crandallis</i> , <i>E. parva</i> , <i>E. bakuensis</i> .	Feed Type C feed at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per 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 sheep producing milk for food.	046573

Decoquinatate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
13.6 to 27.2 (0.0015 to 0.003 pct).	.....	Cattle; for the prevention of coccidiosis in ruminating and non-ruminating calves and cattle caused by <i>Eimeria bovis</i> and <i>E. zumii</i> .	Feed Type C feed at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day. May be prepared from dry or liquid Type B feed containing 0.0125 to 0.5 pct decoquinatate. Liquid Type B feed must have a pH range of 5.0 to 6.5 and contain a suspending agent to maintain a viscosity of not less than 500 centipoises. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food.	
13.6 to 535.7 (0.0015 to 0.059 pct).	.....	Cattle: prevention of coccidiosis in ruminating and nonruminating calves (including veal calves) and cattle caused by <i>Eimeria bovis</i> and <i>E. zumii</i> .	Feed Type C feed (including dry milk replacer) to provide 22.7 mg per 100 lb body weight (0.5 mg per kg) per day. May be prepared from dry Type B feed containing 0.06 to 0.6 pct decoquinatate or liquid Type B feed containing 0.0125 to 0.05 pct decoquinatate. The liquid Type B feed must have pH 5.0 to 6.5 and contain a suspending agent to maintain a viscosity of not less than 500 centipoises. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food.	046573
	.....	Young sheep: prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. parva</i> , <i>E. bakuensis</i> , <i>E. crandallii</i> .	.....do .....	.....do
	.....	Young goats: prevention of coccidiosis caused by <i>Eimeria christenseni</i> , <i>E. ninakohlyakimovae</i> .	.....do .....	.....do
27.2 (0.003 pct) .....	.....	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> and <i>E. brunetti</i> .	Do not feed to laying chickens ..	046573
	Bacitracin 4 to 50 ....	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> , and for increased rate of weight gain and improved feed efficiency..	Do not feed to laying chickens; feed continuously as sole ration; bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter..	046573
	Bacitracin 10 to 50 ..	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as zinc bacitracin provided by Nos. 046573 and 011716 in sec. 510.600(c) of this chapter.	046573

Decoquinatate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin methylene disalicylate 50 and roxarsone 22.7–45.4.	Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> ; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying chickens. Not for use in breeder chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of drinking water may result in leg weakness or paralysis. Decoquinatate, bacitracin methylene disalicylate, and roxarsone, as provided by No. 046573 in § 510.600(c) of this chapter.	046573
	Chlortetracycline 100 to 200.	Chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; in low calcium feed containing 0.8 pct. of calcium; feed continuously 7 to 14 days.	046573
	Chlortetracycline 200 to 400.	Chickens; for the prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	.....do .....	046573
	Roxarsone 45.4 (0.005 pct.).	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; growth promotion and feed efficiency; improving pigmentation.	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	046573
	Lincomycin 2 .....	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. mivati</i> , and <i>E. brunetti</i> ; for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in sec. 510.600(c) of this chapter.	000009, 046573
	Roxarsone 11 to 45 (0.0012–0.005 pct.) plus Bacitracin 12 to 50.	Broiler chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. mivati</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; as zinc bacitracin provided by Nos. 011716, 046573, and 063238 in sec. 510.600(c) of this chapter; as roxarsone provided by No. 046573 in sec. 510.600(c) of this chapter.	046573

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.195, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.205 Dichlorvos.**

(a) *Approvals.* Type A medicated articles: 3.1 and 9.6 percent to 000010 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry

when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### § 558.235 Efrotomycin.

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

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

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

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

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

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

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

(2) [Reserved]

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

#### § 558.248 Erythromycin thiocyanate.

(a) *Approvals.* Type A medicated articles: (1) 2.2 percent to 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 5 and 10 percent to 050604 for use in paragraphs (d)(1)(i) and (ii) of this section.

(b) *Special considerations.* The levels of antibiotic are expressed in terms of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

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

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

Erythromycin thiocyanate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 18.5		Chickens; growth promotion and feed efficiency.		050604
(ii) 9.25 to 18.5		Turkeys; growth promotion and feed efficiency.	For turkeys not over 12 weeks of age.	050604
(iii) 9.25 to 64.75		Swine; increase in weight gain, improved feed efficiency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).	Starter ration for animals up to 35 lb body weight.	050604
(iv) 18.5		Laying chickens; aids in increasing egg production.		050604
(v) 92.5		1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Chickens; as an aid in the prevention of infectious coryza. 3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed for 2 d before stress and 3 to 6 d after stress.	050604
(vi) 185		1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease. 2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed for 5 to 8 d; do not use in birds producing eggs for food purposes.	050604 050604

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

(3) Erythromycin thiocyanate may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Arsanilic acid in accordance with § 558.62.

(iv) Zoalene in accordance with § 558.680.

[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]

**§ 558.254 Famphur.**

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

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

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

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

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

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

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows

and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

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

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

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

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

#### § 558.258 Fenbendazole.

(a) *Approvals.* Type A medicated articles: 4 percent (18.1 grams per pound), 8 percent (36.2 grams per pound), and 20 percent (90.7 grams per pound) fenbendazole and all combinations provided for in this section to 012799 in § 510.600(c) of this chapter.

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

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

(i) *Amount.* Fenbendazole, 10 to 80 grams per ton (to provide 9 milligrams per kilogram of body weight) given over a 3- to 12-day period.

(A) *Indications for use.* For the removal of: adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).

(B) Feed as sole ration.

(ii) *Amount.* Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 20 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for increased rate of gain in growing-finishing swine.

(B) *Limitations.* Feed as sole ration. Do not feed to swine that weigh more than 250 pounds; as lincomycin pro-

vided by 000009 in § 510.600(c) of this chapter.

(iii) *Amount.* Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 40 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred.

(B) *Limitations.* Feed as sole ration. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(iv) *Amount.* Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 100 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for the treatment of swine dysentery.

(B) *Limitations.* Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(v) *Amount.* Fenbendazole 10 to 80 grams per ton (to provide 9 milligrams per kilogram body weight) and lincomycin 200 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph (c)(1)(i)(A) of this section) and for reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

(B) *Limitations.* Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pounds; as lincomycin provided by 000009 in § 510.600(c) of this chapter.

(2) It is used in the feed of beef and dairy cattle as follows:

(i) *Amount.* 5 milligrams fenbendazole per kilogram body weight (2.27 milligrams per pound).

(ii) *Indications for use.* For the removal and control of lungworms (*Dictyocaulus viviparus*); barberpole worms (*Haemonchus contortus*); brown stomach worms (*Ostertagia ostertagi*); small stomach worms (*Trichostrongylus*

*axeii*); hookworms (*Bunostomum phlebotomum*); thread-necked intestinal worms (*Nematodirus helvetianus*); small intestinal worms (*Cooperia punctata*

(iii) *Limitations*. Feed as sole ration for one day. Do not use within 13 days of slaughter.

(3) It is used in free-choice beef and dairy cattle feed as follows:

(i) *Amount*. 5 milligrams fenbendazole per kilogram body weight (2.27 milligrams per pound).

(ii) *Indications for use*. For the removal and control of infections of lungworms (*Dictyoacaulus viviparus*), barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*), hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia oncophora* and *C. punctata*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*) in cattle.

(iii) *Limitations*. Feed a total of 5 milligrams of fenbendazole per kilogram (2.27 milligrams per pound) of body weight to cattle over a 3 to 6 day period. Retreatment may be needed after 4 to 6 weeks. Do not slaughter within 13 days following last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(iv) May be fed in a Type C feed as follows:

Ingredient	Percent	International feed No.
(A) Ingredient:		
Copper sulfate .....	0.45	6-01-720
Dried Cane Molasses .....	3.12	4-04-695
Monosodium phosphate .....	31.16	6-04-288
Salt (sodium chloride) .....	59.00	6-04-152
Zinc sulfate .....	0.76	6-05-556
Fenbendazole Type A article (200 grams per kilogram) .....	5.51	
(B) Ingredient:		
Dicalcium phosphate .....	32.31	6-00-080
Limestone .....	17.13	6-02-632
Magnesium oxide .....	9.79	6-02-756
Zinc sulfate .....	1.47	6-05-556
Copper sulfate .....	0.29	6-01-720
Potassium iodide .....	0.0098	6-03-759
Dried Cane Molasses .....	0.98	4-04-695
Selenium .....	0.0002	
Salt .....	35.93	6-04-152

Ingredient	Percent	International feed No.
Fenbendazole Type A article (200 grams per kilogram) .....	2.09	

(C) The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium must comply with published regulations.

(4) *Zoo and wildlife animals*. For removal and control of internal parasites in hoofed zoo and wildlife animals as follows:

(i) *Feral swine (Suis scrofa)*: 3 milligrams per kilogram per day for 3 days. Treatment for kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*).

(ii) *Ruminants* (subfamily *Antilopinae*, *Hippotraginae*, *Caprinae*): 2.5 milligrams per kilogram per day for 3 days. Treatment for small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.).

(iii) *Rocky mountain bighorn sheep (Ovis c. canadensis)*: 10 milligrams per kilogram per day for 3 days. Treatment and control of *Protostrongylus* spp.

(iv) *Limitations*. Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not use 14 days before or during the hunting season.

[49 FR 3846, Jan. 31, 1984, as amended at 51 FR 7397, Mar. 3, 1986; 53 FR 14788, Apr. 26, 1988; 54 FR 36963, Sept. 6, 1989; 55 FR 48231, Nov. 20, 1990; 57 FR 34516, Aug. 5, 1992; 58 FR 47973, Sept. 13, 1993; 59 FR 35252, July 11, 1994; 61 FR 29478, June 11, 1996]

**§ 558.265 Halofuginone hydrobromide.**

(a) *Approvals*. Type A medicated articles: 6 grams per kilogram (2.72 grams per pound) to 012579 in § 510.600(c) of this chapter.

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

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

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

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

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

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

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

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

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

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

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

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

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

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) *Amount per ton.* Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams.

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

increased rate of weight gain; and for improved feed efficiency.

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

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

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

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

(vii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus lincosmycin 2 to 4 grams.

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

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

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

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

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

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

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

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

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before

slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

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

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

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

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

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

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

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Withdraw 4 days before slaughter. Do not feed to laying chickens or water fowl. Halofuginone hydrobromide is toxic to fish and aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an irritant to eyes and skin. Avoid contact with skin, eyes, and clothing.

(ii) [Reserved]

[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]

**§ 558.274 Hygromycin B.**

(a) *Approvals.* (1) Type A medicated articles: 2.4 and 8 grams per pound to 000986 in §510.600(c) of this chapter for use as in paragraph (c) of this section.

(2) 2.4 grams per pound to 016968 and 043733 in §510.600(c) of this chapter for use in swine feed as in paragraph (c)(1)(ii) of this section.

(3) 1.2 grams per pound to 016968 in §510.600(c) of this chapter for use in swine as in paragraph (c)(1)(ii) of this section.

(4) 0.6 gram per pound to 016968, 017790, 043733, and 050639 in §510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(5) 0.48 and 2.4 grams per pound to 026186 in §510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(6) [Reserved]

(7) 2.4 grams per pound to 011790 and 017519 in §510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) and in swine as in paragraph (c)(1)(ii) of this section.

(8) 0.6 and 1.6 grams per pound granted to 046573 in §510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) and in swine as in paragraph (c)(1)(ii) of this section.

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

(c) *Conditions of use.* (1) It may be used as follows:

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12 .....	.....	Chickens: control of infestation of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ).	Withdraw 3 days before slaughter.	000986, 016968, 017519, 017790, 026186, 043733, 046573, 050639

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 100 .....	Chickens; control of infestation of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or zinc bacitracin; withdraw 3 days before slaughter.	
	Bacitracin plus penicillin (100 to 200 of combination).	<ol style="list-style-type: none"> <li>1. Chickens; control of infestation of large roundworms (<i>Ascaris galli</i>), cecal worms (<i>Heterakis gallinae</i>), and capillary worms (<i>Capillaria obsignata</i>); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</li> <li>2. Chickens; control of infestation of large roundworms (<i>Ascaris galli</i>), cecal worms (<i>Heterakis gallinae</i>), and capillary worms (<i>Capillaria obsignata</i>); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</li> <li>3. Chickens, control of infestation of large roundworms (<i>Ascaris galli</i>), cecal worms (<i>Heterakis gallinae</i>), and capillary worms (<i>Capillaria obsignata</i>); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).</li> </ol>	<p>Feed containing not less than 25% of penicillin plus not less than 50% of bacitracin; as procaine penicillin plus bacitracin methylene disalicylate; withdraw 3 days before slaughter.</p> <p>Combination containing not less than 50% nor more than 75% of bacitracin, except that it contains not more than 125 g of penicillin; as procaine penicillin plus zinc bacitracin; withdraw 3 days before slaughter.</p> <p>Combination containing 50% to 75% bacitracin, but not more than 125 g of penicillin, as procaine penicillin; withdraw 3 days before slaughter..</p>	
	Chlortetracycline 100 to 200.	Chickens; control of infestation of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ); control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter.	
	Chlortetracycline 200 to 400.	Chickens; control of infestation of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>H. Gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ); control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	.....do .....	
	Penicillin 100 .....	Chickens; control of infestation of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As procaine penicillin; withdraw 3 days before slaughter.	

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 12 .....	Tylosin 4 to 50 .....	Chickens: Control of infestations of large roundworms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ); growth promotion and feed efficiency.	As tylosin phosphate; withdraw 3 days before slaughter.	000986
	.....	Swine: control of infestation of large roundworms ( <i>Ascaris suis</i> ), nodular worms ( <i>Oesophagostomum dentatum</i> ), and whipworms ( <i>Trichuris suis</i> ).	Withdraw 15 days before slaughter.	000986, 016968, 017519, 017790, 026186, 043733, 046573, 050639
	Chlortetracycline 400..	Swine; control of infestation of large roundworms ( <i>Ascaris suis</i> ), nodular worms ( <i>Oesophagostomum dentatum</i> ) and whipworms ( <i>Trichuris suis</i> ); treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline..	Withdraw 15 d before slaughter.	
	Tylosin 10 to 100 .....	Swine: Control of infestations of large roundworms ( <i>Ascaris suis</i> ), nodular worms ( <i>Oesophagostomum dentatum</i> ), and whipworms ( <i>Trichuris suis</i> ); growth promotion and feed efficiency.	As tylosin phosphate; withdraw 15 days prior to slaughter; feed continuously as follows: Animal wt.(lbs.): Up to 40.....20 to 100 <sup>1</sup> 41 to 100.....20 to 40 <sup>1</sup> 101 to market wt.....10 to 20 <sup>1</sup>	000986

<sup>1</sup> Amount of Tylosin (g/t).

(2) Hygromycin B may also be used in combination with:

- (i) Amprolium in accordance with § 558.55.
- (ii) Zoalene in accordance with § 558.680.

[41 FR 11000, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.274, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.295 Iodinated casein.**

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

(b) *NAS/NRC status.* The use of this drug is NAS/NRC reviewed and found effective. Applications for these uses need not include efficacy data as required by § 514.111 of this chapter but may require bioequivalency or safety data.

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

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

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

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

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

[45 FR 41631, June 20, 1980]

**§ 558.300 Ivermectin.**

(a) *Approvals.* (1) Type A medicated articles: 0.6 percent (2.72 grams per pound; 6 grams per kilogram) to 050604 in § 510.600(c) of this chapter, and

(2) Type B medicated feeds for ivermectin alone or with lincomycin. See § 558.4 of this chapter for maximum drug levels to 050604 in § 510.600(c) of this chapter.

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

(c) [Reserved]

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

(1) *Amount per ton.* For weaned, growing-finishing swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, feed 1.8 to 11.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, may be top-dressed on daily ration for individual treatment at levels of 18.2 to 1180 grams (to provide 0.1 milligram per kilogram of body weight per day).

(i) *Indications for use.* 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*).

(ii) *Limitations.* For use in swine feed only. Feed as only feed for 7 consecutive days. Withdraw 5 days before slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Amount per ton.* 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 20 grams of lincomycin.

(i) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var. *suis*). For increased rate of weight gain.

(ii) *Limitations.* For weaned, growing-finishing swine. Feed as only feed for 7 consecutive days. Withdraw 5 days before slaughter. A separate feed containing 20 grams per ton lincomycin may be continued. Not to be fed to swine that weigh more than 250 pounds. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Amount per ton.* 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 40 grams of lincomycin.

(i) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var. *suis*). For control of swine dysentery. For use in swine on premises with a history of swine dysentery, but where symptoms have not yet occurred.

(ii) *Limitations.* For weaned, growing-finishing swine. Feed as only feed for 7 consecutive days. Withdraw 5 days before slaughter. A separate feed containing 40 grams per ton lincomycin may be continued. Not to be fed to swine that weigh more than 250 pounds. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

(4) *Amount per ton.* 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 100 grams of lincomycin.

(i) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops*

*strongylina*, adults; *Hyostrogylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var. *suis*). Treatment of swine dysentery.

(ii) *Limitations*. For weaned, growing-finishing swine. Feed as only feed for 7 consecutive days followed by a separate feed containing 100 grams per ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 pounds. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(5) *Amount per ton*. 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day) with 200 grams of lincomycin.

(i) *Indications for use*. For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrogylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var. *suis*). For reduction in severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

(ii) *Limitations*. For weaned, growing-finishing swine. Feed as only feed for 7 consecutive days followed by a separate feed containing 200 grams per ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 pounds. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species

may result in severe gastrointestinal effects. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) *Amount per ton*. For weaned, growing-finishing pigs, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate. For adult and breeding swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate.

(i) *Indications for use*. For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrogylus 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*). For increased rate of weight gain and improved feed efficiency in growing and finishing swine. For control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets. 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 disease condition.

(ii) *Limitations*. For use in swine feed only. Feed as the only feed for 7 consecutive days. For weaned growing and finishing swine, feed bacitracin methylene disalicylate Type C medicated feed from weaning to market weight for increased rate of weight gain and improved feed efficiency. For pregnant sows, feed bacitracin methylene disalicylate to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial

scours. Withdraw ivermectin-containing feeds 5 days before slaughter.

[58 FR 58653, Nov. 3, 1993, as amended at 60 FR 39848, Aug. 4, 1995; 61 FR 32652, June 25, 1996; 62 FR 63271, Nov. 28, 1997; 63 FR 54353, Oct. 9, 1998; 64 FR 13342, Mar. 18, 1999]

**§ 558.305 Laidlomycin propionate potassium.**

(a) *Approvals.* Type A medicated articles: 50 grams per pound to 063238 in § 510.600(c) of this chapter.

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

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

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

(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.

(c) [Reserved]

(d) *Conditions of use.* Used in cattle feed as follows:

(1) *Amount.* Laidlomycin propionate potassium, 5 grams per ton.

(i) *Indications for use.* For improved feed efficiency and increased rate of weight gain.

(ii) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 75 milligrams per head per day.

(2) *Amount.* Laidlomycin propionate potassium, 5 to 10 grams per ton.

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

(ii) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C feed at a rate of 30 to 150 milligrams per head per day.

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

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

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

[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]

**§ 558.311 Lasalocid.**

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

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

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No. 000004 for use as in paragraphs (e)(1) (i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 000069 as provided by No. 063238 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 063238 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. 063238 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) and (e)(3) of this section.

(5) 15 percent activity to 021930 (Type A article provided by 063238) for use in free-choice vitamin-mineral Type C cattle feeds as in paragraph (e)(1)(xi).

(6) 20 percent activity as a liquid Type A article to No. 063238 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. 063238 for use as follows:

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

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

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

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

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

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

(2) A positionally stable lasalocid liquid Type B feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months. Form FDA 1900 must indicate the pH and centipoises per second for such lasalocid liquid Type B feed.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (2) of this section, the manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish positional stability; and (iii) requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manu-

facture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the supplement new animal drug application will be approved. Approval of the supplement will not be published in the FEDERAL REGISTER because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for liquid Type B feed. A manufacturer who seeks to market a positionally unstable lasalocid liquid Type B feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

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

(5) Required label statements:

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

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

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

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

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	For broiler or fryer chickens only; feed continuously as the sole ration.	000004
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> and as an aid in the reduction of lesions due to <i>E. tenella</i> .	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter.	000004
	Roxarsone 45.4 plus bambarmycins 1 (0.00011 pct).	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bambarmycins provided by No. 012799.	000004
	Roxarsone 45.4 plus lincomycin 2.0.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, lincomycin provided by No. 000009.	000004
	Roxarsone 45.4 plus bacitracin 10 to 25.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004
	Roxarsone 45.4 plus bacitracin 10 or 30.	For prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin zinc provided by No. 000004.	000004
	Roxarsone 45.5 plus bacitracin methylene disalicylate 50.	Prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; reduction of lesions due to <i>E. tenella</i> ; prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other susceptible organisms.	Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter.	046573
(iii) 68 (0.0075 pct) ....	Lincomycin 2 (0.00022 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ; for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	000004

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 3 days before slaughter bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004
(v) 68 (0.0075 pct) to 113 (0.0125 pct).	Virginiamycin 20 .....	For prevention of coccidiosis caused by <i>Eimeria tenella</i> <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 063238 in § 510.600(c) of this chapter.	063238
(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.	000004
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C <sub>8</sub> -C <sub>18</sub> ) trimethyl ammonium oxytetracycline.	000004
(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.	000004
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C <sub>8</sub> -C <sub>18</sub> ) trimethyl ammonium oxytetracycline.	000004
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	.....	Sheep: for the prevention of coccidiosis caused by <i>Eimeria ovina</i> , <i>E. crandallis</i> , <i>E. ovinoidalis</i> ( <i>E. ninakohlyakimovae</i> ), <i>E. parva</i> , and <i>E. intricata</i> .	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	000004
(ix) .....	.....	Cattle; for increased rate of weight gain.	For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed.	000004
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50 ....	Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; withdraw 3 days before slaughter; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000004

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xi) .....	.....	Cattle; for increased rate of weight gain.	For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) only; feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day. Each use in a free-choice Type C feed must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.	000004, 021930
(xii) .....	.....	Cattle; for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> .	For cattle; hand fed 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.	000004
(xiii) 113 (0.0125 pct).	.....	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria legionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	000004
(xiv) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .	Feed continuously as sole ration	000004
(xv) .....	.....	Replacement calves; for control of coccidiosis caused by <i>E. bovis</i> and <i>E. zuernii</i> .	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	000004
(xvi) 113 (0.0125 pct).	.....	Rabbits; for prevention of coccidiosis caused by <i>Eimeria stiedae</i> .	Feed continuously as sole ration up to 6 1/2 weeks of age.	000004

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

(i) *Specifications.*

Ingredient	Per-cent	Inter-national feed No.
Defluorinated Phosphate (20.5 percent Calcium, 18.5 percent Phosphorus) ....	35.9	6–01–080
Sodium Chloride (Salt) .....	20.0	6–04–152
Calcium Carbonate (38 percent Calcium)	18.0	6–01–069
Cottonseed Meal .....	10.0	5–01–621
Potassium Chloride .....	3.0	6–03–755
Selenium Premix (0.02 percent Selenium) <sup>1</sup> .....	3.0	.....
Dried Cane Molasses .....	2.5	4–04–695
Magnesium Sulfate .....	1.7	6–02–758
Vitamin Premix <sup>1</sup> .....	1.4	.....
Magnesium Oxide .....	1.2	6–02–756
Potassium Sulfate .....	1.2	6–06–098
Trace Mineral Premix <sup>1</sup> .....	1.04	.....

Ingredient	Per-cent	Inter-national feed No.
Bovatec Premix (68 grams per pound) ...	1.06	.....

<sup>1</sup> 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. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with published regulations. For selenium (21 CFR 573.920): up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(ii) *Amount.* 1,440 grams per ton (0.16 percent).

(iii) *Indications for use.* Cattle, for increased rate of weight gain.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 200 milligrams lasalocid per head per day; each use of this Type C free-choice feed must be

the subject of an approved FD-1900 as provided in § 510.455 of this chapter.

(v) *Sponsor.* See No. 063238 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	N/A
50% Urea Solution (23% N) .....	12.0	N/A
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	N/A
Trace Mineral Mix <sup>1</sup> .....	0.5	N/A
Vitamin Premix <sup>1</sup> .....	0.2	N/A
Bovatec Liquid 20 (90.8 gm/lb) <sup>2</sup> .....	0.083	N/A

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

<sup>2</sup> To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of Bovatec Liquid 20 (90.8 gm/lb). If dry Bovatec-68 (68 gm/lb) is used, use 2.206 lbs per ton (0.111%), replacing molasses.

(ii) *Amount.* 150 grams per ton (.017 percent).

(iii) *Indications for use.* Cattle: for increased rate of weight gain.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 200 milligrams lasalocid per head per day. Each use of this free-choice liquid Type C feed must be the subject of an approved FD-1900 as in § 510.455 of this chapter.

(v) *Sponsor.* See No. 063238 in § 510.600(c) of this chapter.

(4) *Additional combinations.* Lasalocid may be used in accordance with the provisions of this section in combination as follows:

(i) Melengestrol acetate alone or in combination with tylosin in accordance with § 558.342.

(ii) [Reserved]

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.315 Levamisole hydrochloride (equivalent).**

(a) *Approvals.* Type A medicated articles: 227 grams per pound to 043781 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.350 of this chapter.

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

(1) *Cattle—(i) Amount per pound.* 0.36-3.6 grams (0.08-0.8 percent).

(ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated feed is consumed resume normal feeding; medicated feed is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feeds only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine—(i) Amount per pound.* 0.36 grams (0.08 percent).

(ii) *Indications for use.* Treatment of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), swine kidney worms (*Stephanurus dentatus*).

(iii) *Limitations.* It is recommended that regular feed be withheld overnight and worming feed administered the following morning; dilute supplement with nonmedicated feed as directed; feed the equivalent of 1 lb. of 0.08 percent worming feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 43 FR 39351, Sept. 5, 1978; 43 FR 16013, Mar. 16, 1979; 51 FR 7398, Mar. 3, 1986]

**§ 558.325 Lincomycin.**

(a) *Approvals.* Type A articles and Type B feeds approved for sponsors in § 510.600(c) of this chapter for specific uses as in paragraph (c) of this section as follows:

(1) No. 000009: (i) 4 grams per pound as in paragraphs (c) (1) and (3) of this section.

(ii) 20 grams per pound as in paragraphs (c) (1) through (3) of this section.

(iii) 50 grams per pound as in paragraphs (c) (1) and (2) of this section.

(iv) 10 grams per pound as in paragraphs (c)(1) and (2) (i) through (iv) of this section.

(2)-(4) [Reserved]

(5) No. 043733 for 8 and 20 grams per pound as in paragraphs (c)(2) (i) through (iii) of this section.

(6)-(12) [Reserved]

(13) No. 017800 for 2.5 and 8 grams per pound as in paragraphs (c)(2) (i) through (iv) of this section.

(14)-(15) [Reserved]

(b) *Related tolerances in edible products.* See § 556.360 of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Broilers:*

(i) *Amount per ton.* 2 to 4 grams.

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

(b) *Limitations.* As lincomycin hydrochloride monohydrate.

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

(a) *Indications for use.* For control of necrotic enteritis caused by *Clostridium* spp. or other susceptible organisms.

(b) *Limitations.* As lincomycin hydrochloride monohydrate.

(2) *Swine—(i) Amount per ton.* 40 grams.

(a) *Indications for use.* For control of swine dysentery.

(b) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more than 250 pounds.

(ii) *Amount per ton.* 100 grams; 40 grams.

(a) *Indications for use.* For treatment and control of swine dysentery.

(b) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds.

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

(a) *Indications for use.* For treatment of swine dysentery.

(b) *Limitations.* Feed as sole ration for 3 weeks or until signs of disease disappear; not to be fed to swine that weigh more than 250 pounds.

(iv) *Amount per ton.* 200 grams.

(a) *Indications for use.* For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

(b) *Limitations.* Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds.

(v) *Amount per ton.* 20 grams.

(a) *Indications for use.* For increased rate of weight gain in growing-finishing swine.

(b) *Limitations.* Feed as sole ration; not for use in swine weighing over 250 pounds.

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

(i) Amprolium, ethopabate, and roxarsone in accordance with §§ 558.58 and 558.530.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Clopidol in accordance with § 558.175.

(iv) [Reserved]

(v) Decoquinatate in accordance with § 558.195.

(vi) Zoalene in accordance with § 558.680.

(vii) Monensin in accordance with § 558.355.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) Roxarsone, monensin sodium in accordance with §§ 558.355 and 558.530.

(x) Lasalocid sodium in accordance with § 558.311.

(xi) Nicarbazine and roxarsone as in § 558.366.

(xii) Nicarbazine with or without narasin as in § 558.366.

(xiii) Lasalocid sodium and roxarsone as in § 558.311.

(xiv) Halofuginone in accordance with § 558.265.

(xv) Salinomycin with or without roxarsone as in § 558.550.

(4) Lincomycin may also be used for swine in combination with:

(i) Pyrantel tartrate as in § 558.485.

(ii) Fenbendazole as provided in § 558.258.

(iii) Ivermectin as in § 558.300.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.325, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.340 Maduramicin ammonium.

(a) *Approvals.* Type A medicated articles: 4.54 grams per pound to 063238 in § 510.600(c) of this chapter.

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

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

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

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

(2) [Reserved]

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

#### § 558.342 Melengestrol acetate.

(a) *Approvals.* Dry Type A medicated articles containing 100 or 200 milligrams per pound or liquid Type A article containing 500 milligrams per pound to 000009 in § 510.600(c) of this chapter.

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

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

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

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

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

(1) *Amount.* Melengestrol acetate, 0.25 to 0.50 milligram per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) *Limitations:* Heifers being fed for slaughter; administer 0.5 to 2.0 pounds per head per day of medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to provide 0.25 to 0.50 milligram of melengestrol acetate per head per day. Melengestrol acetate as provided by No. 000009 in §510.600(c) of this chapter.

(2) *Amount:* Melengestrol acetate, 0.25 to 0.40 milligram per head per day, plus monensin (as monensin sodium), 50 to 360 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) *Limitations:* Heifers being fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 0.80 milligram of melengestrol acetate per pound to a feed containing 5 to 30 grams of monensin per ton; or, add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 0.80 milligram of melengestrol acetate plus 25 to 720 milligrams of monensin per pound to a nonmedicated feed to provide 0.25 to 0.40 milligram of melengestrol acetate and 50 to 360 milligrams of monensin per head per day. The liquid medicated feeds must be manufactured in accordance with §558.355(f)(3)(i). Melengestrol acetate and monensin as provided by Nos. 000009 and 000986, respectively, in §510.600(c) of this chapter.

(3) *Amount.* Melengestrol acetate, 0.25 to 0.50 milligram per head per day in combination with lasalocid (as lasalocid sodium), 100 to 360 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(ii) *Limitations.* Heifers being fed in confinement for slaughter. The liquid medicated feeds are required to be manufactured in accordance with §558.311(d). Add at the rate of 0.5 to 2.0 pounds per head per day a medicated

feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 10 to 30 grams of lasalocid per ton; or, add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate plus 50 to 720 milligrams of lasalocid per pound to a ration of nonmedicated feed to provide 0.25 to 0.5 milligram of melengestrol acetate and 100 to 360 milligrams of lasalocid per head per day. Melengestrol acetate and lasalocid as provided by Nos. 000009 and 063238, respectively, in §510.600(c) of this chapter.

(4) *Amount.* Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus tylosin (as tylosin phosphate), 90 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses.

(ii) *Limitations.* Heifers being fed in confinement for slaughter. Melengestrol acetate and tylosin as provided by Nos. 000009 and 000986, respectively, in §510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate with 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate (from a dry Type A article) plus 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.

(5) *Amount.* Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus monensin (as monensin sodium) at 50 to 360 milligrams per head per day, plus

tylosin (as tylosin phosphate), 90 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses.

(ii) *Limitations.* Heifers being fed in confinement for slaughter. The liquid medicated feeds are required to be manufactured in accordance with § 558.355(f)(3)(i). Melengestrol acetate as provided by No. 000009 and monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate to 50 to 360 milligrams of monensin plus 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 5 to 30 grams of monensin and 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 25 to 720 milligrams of monensin per pound to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry medicated feed containing 0.125 to 1.0 milligram melengestrol acetate (from a dry Type A article), 25 to 600 milligrams of monensin, and 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.

(6) *Amount.* Melengestrol acetate, 0.25 to 0.50 milligram per head per day, plus lasalocid (as lasalocid sodium), 100 to 360 milligrams per head per day, and tylosin (as tylosin phosphate), 90 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses.

(ii) *Limitations.* Heifers being fed in confinement for slaughter. The liquid medicated feeds are required to be manufactured in accordance with § 558.311(d). Lasalocid, melengestrol acetate, and tylosin as provided by Nos. 000009, 000986, and 063238 respectively,

in § 510.600(c) of this chapter. To administer 0.25 to 0.50 milligram of melengestrol acetate plus 100 to 360 milligrams of lasalocid plus 90 milligrams of tylosin per head per day:

(A) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a medicated feed containing 10 to 30 grams of lasalocid and 8 to 10 grams of tylosin per ton; or

(B) Add 0.5 to 2.0 pounds per head per day of a liquid or dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 50 to 720 milligrams of lasalocid per pound to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 grams of tylosin per ton; or

(C) Add 0.5 to 2.0 pounds per head per day of a dry pelleted medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate (from a dry Type A article), 50 to 720 milligrams of lasalocid, and 45 to 180 milligrams of tylosin per pound to a ration of nonmedicated feed.

(7) *Amount.* 0.5 milligram per head per day.

(i) *Indications for use.* For suppression of estrus (heat).

(ii) *Limitation.* Heifers intended for breeding. Do not exceed 24 days of feeding. Administer 0.5 to 2.0 pounds per head per day of Type C feed containing 0.25 to 1.0 milligram of melengestrol acetate per pound to provide 0.5 milligram of melengestrol acetate per head per day. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.

(8) *Amount.* Melengestrol acetate, 0.25 to 0.5 milligram per head per day, plus oxytetracycline, 75 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduction of liver condemnation due to liver abscesses.

(ii) *Limitations.* Heifers fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 6 to 10 grams of oxytetracycline per ton; or add at the rate of

0.5 to 2.0 pounds per head per day a dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 37.5 to 150 milligrams of oxytetracycline per pound to provide 0.25 to 0.5 milligram of melengestrol acetate and 75 milligrams of oxytetracycline per head per day. Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement. Melengestrol acetate as provided by 000009, oxytetracycline by 000069, in § 510.600(c) of this chapter.

[42 FR 28535, June 3, 1977, as amended at 46 FR 18967, Mar. 27, 1981; 49 FR 39842, Oct. 11, 1984; 50 FR 1843, Jan. 14, 1985; 50 FR 16228, Apr. 25, 1985; 51 FR 7398, Mar. 3, 1986; 51 FR 36222, Oct. 9, 1986; 52 FR 2685, Jan. 26, 1987; 52 FR 33804, Sept. 8, 1987; 53 FR 27959, July 26, 1988; 55 FR 31828, Aug. 6, 1990; 57 FR 5053, Feb. 12, 1992; 59 FR 41241, Aug. 11, 1994; 60 FR 11028, Mar. 1, 1995; 62 FR 8373, Feb. 25, 1997; 62 FR 14304, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 63 FR 41191, Aug. 3, 1998; 63 FR 66018, Dec. 1, 1998]

#### § 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

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

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

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

[47 FR 6617, Feb. 16, 1982]

#### § 558.355 Monensin.

(a) *Specifications.* Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the  $R_f$  value must be comparable to a reference standard (the  $R_f$  value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line), or, using High Performance Liquid Chromatography, the factor distribution of monensin Factor A or B is calculated as the percentage of total biopotency of all peaks. The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

(b) *Approvals.* Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 36.3 (for export only), 44, 45, or 60 grams per pound, paragraphs (f) (1)(i) and (4) of this section.

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

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(2) of this section.

(5) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiii), (xx), and (xxi) of this section.

(6) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(5) of this section.

(7) To 000986: 20, 30, 45, 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

(8) To 063238: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 063238: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 012799: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiv), (xviii), (xix), (xxiii), (xxiv), (xxv), (xxvi), and (xxvii) of this section.

(12) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.

(13) To 021930: 60 and 80 grams per pound, paragraph (f)(3)(v) of this section.

(14) To 000986: 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(6) of this section.

(c) [Reserved]

(d) *Special considerations.* (1) Type C chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2) Type C cattle feeds containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.

(3) Type C goat feeds shall bear an expiration date of 30 days after date of manufacture.

(4) [Reserved]

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

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

(7) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in cattle shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated cattle feed is safe for use in cattle 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.

(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 dairy cows.

(8) The labeling of complete feeds containing monensin intended for use in cattle shall bear the caution statements specified in paragraphs (d)(6) and (7)(i) and (v) of this section.

(9) The labeling of Type A articles containing monensin intended for use in chickens shall bear the caution statements specified in paragraphs (d)(6) and (7)(iii) and (iv) of this section.

(10) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated goat feed is safe for use in goats only. Consumption by unapproved species may result in toxic reactions.

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

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

(iv) Do not feed undiluted.

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

(11) The labeling of complete feeds containing monensin intended for use in goats shall bear the caution statements specified in paragraphs (d)(6) and (d)(10)(i) and (v) of this section.

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

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

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

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

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

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 063238 in § 510.600(c) of this chapter; as monensin sodium.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal

period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 063238 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams plus bambarmycins, 1 to 2 grams. See § 558.95(b)(1)(vi).

(vii) *Amount per ton.* Monensin, 90 to 110 grams plus bambarmycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See § 558.95(b)(1)(vii).

(viii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*.

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

(ix) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

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

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

(x) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573,

§ 510.600(c) of this chapter; as monensin sodium provided by No. 000986, § 510.600(c) of this chapter; as lincomycin provided by No. 000009, § 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as lincomycin provided by No. 000009 in § 510.600(c) of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 10 to 25 grams, and roxarsone, 11.3 to 45.4 grams.

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600 of this chapter; as roxarsone provided by No. 011526 or 046573 in § 510.600 of this chapter.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 000007 in § 510.600 of this chapter.

(xiv) *Amount per ton.* Monensin, 90 to 110 grams, plus 500 grams chlortetracycline.

(a) *Indications for use.* As an aid in the reduction of mortality due to *Escherichia coli* infections susceptible to such treatment. As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed for 5 days as the sole ration; withdraw 24 hours before slaughter; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; not to be fed continuously for more than 5 days; as monensin sodium; as chlortetracycline hydrochloride provided by Nos. 046573 and 063238 in § 510.600(c) of this chapter.

(xv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 10 grams, and roxarsone, 15 grams (0.0017 percent).

(a) *Indications for use.* For increase in rate of weight gain; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by Nos. 063238 and 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvi) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 15 to 45.4 grams (0.0017 percent to 0.005 percent).

(a) *Indications for use.* For improved feed efficiency; for improved pigmentation by enhancing carotenoid and xanthophyll utilization; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole

ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by Nos. 046573 and 063238 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvii) *Amount per ton.* Monensin, 90 to 110 grams plus bambarmycins, 1 to 2 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to 0.005 percent). See § 558.95(b)(1)(xiii) of this chapter.

(xviii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 34.0 grams (0.0025 percent to .00375 percent).

(a) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xix) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to .005 percent).

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No.

000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xx) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams, and roxarsone, 22.7 grams (0.0025 percent).

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium; as roxarsone provided by Nos. 046753 and 011526 in § 510.600(c) of this chapter.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 000007 in § 510.600 of this chapter.

(xxii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 500 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. Mivati*, and *E. maxima*; as an aid in the reduction of mortality due to air-sacculities (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.

(b) *Limitations.* Feed for 5 days as sole ration. Do not feed to laying chickens. Withdraw 24 hours before slaughter. As monensin sodium provided by No. 000986 in § 510.600(c) of this chapter. As mono-alkyl (C<sub>8</sub>-C<sub>18</sub>) trimethylammonium oxytetracycline provided by No. 000069 in § 510.600(c) of this chapter.

(xxiii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to

50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to 0.005 percent).

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in §510.600(c) of this chapter; as bacitracin zinc provided by No. 046573 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

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

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

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin zinc provided by No. 046573 in §510.600(c) of this chapter, as monensin sodium.

(xxvi) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 34.0 grams.

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

(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for dif-

ferent levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter.

(xxvii) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 45.4 grams.

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

(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter.

(2) *Turkeys—(i) Amount per ton.* Monensin, 54 to 90 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoides*, *E. meleagrimitis*, and *E. gallopavonis*.

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

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

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

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

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

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

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

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

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

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, ma-

ture turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 000069 in § 510.600(c) of this chapter.

(3) *Cattle—(i) Amount per ton.* Monensin, 5-30 grams.

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

(b) *Limitations. (1)* Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 360 milligrams of monensin per head per day; as monensin sodium. Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions. Mixing directions for liquid Type B feeds stored in recirculating tank systems are: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily, as directed in this paragraph, even when Type B feed is not used. Mixing directions for liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems are: 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 directed in this paragraph, even when Type B feed is not used. The liquid Type B feed must bear directions to mix thoroughly with grain and/or roughage prior to feeding and must bear caution statements as follows: Inadequate mixing, (recirculation or agitation), of liquid Type B feeds has resulted in increased monensin concentration which has been fatal to cattle.

(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(3)(i)(b)(1) of this section. A manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing

an NADA for the product or by establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish positional stability; and (iii) requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the FEDERAL REGISTER because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(3)(i)(b)(1) of this section may also follow this procedure.

(ii) *Amount per ton.* Monensin, 5 to 30 grams, plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 360 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate.

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

(a) *Indications for use.* For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1

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

(iv) *Amount per ton.* Monensin, 5 to 30 grams per ton (to provide 50 to 360 milligrams per head per day), plus melengestrol acetate, 0.25 to 1.6 grams per ton (to provide 0.25 to 0.40 milligram per head per day). See § 558.342(c)(2).

(a) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(b) *Limitations.* Heifers being fed in confinement for slaughter: Administer melengestrol acetate and monensin by: (1) Adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound to Type C medicated feeds containing monensin at 5 to 30 grams per ton, (2) adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound and monensin from a separate Type B feed containing 50 to 1,200 grams per ton to Type C medicated feeds, (3) adding melengestrol acetate and monensin which are contained in the same dry Type B feed at the ranges in paragraph (f)(3)(iv)(b) (1) and (2) of this section to Type C medicated feeds, or (4) using a liquid Type B feed containing 0.125 to 0.8 milligram melengestrol acetate per pound and 25 to 600 milligrams monensin per pound (50 to 1,200 grams per ton) to make Type C medicated feeds. Type C medicated feeds in paragraph (f)(3)(iv)(b) (1) and (2) of this section may be manufactured from monensin liquid Type B feeds in accordance with paragraph (f)(3)(i)(b) of this section.

(v) *Amount.* 150 milligrams per pound (0.033 percent).

(a) *Indications for use.* Increased rate of weight gain.

(b) *Limitations.* As protein-mineral blocks to be fed free choice to cattle (slaughter, stocker, feeder, and dairy

and beef replacement heifers) on pasture which may require supplemental feed. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds) 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. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established. Approval must comply with §510.455 of this chapter.

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

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

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

(vii) *Amount per ton.* Monensin, 10 to 30 grams.

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

(b) *Limitations.* For feedlot cattle, feed continuously to provide 50 to 360 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 the severity of challenge, up to maximum of 360 milligrams per head per day.

(viii) *Additional combinations.* Monensin may be used for heifers being fed in confinement for slaughter with melengestrol acetate with or without tylosin as in §558.342.

(ix) *Amount.* To 000986: To make liquid Type B medicated feed containing 400 grams per ton monensin sodium with 150 grams per ton tylosin phosphate used to make a dry Type C medicated feed containing 21.4 to 26.8 grams per ton monensin plus 8 to 10 grams per ton tylosin.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid Type B medicated feed must bear an expiration date of 14 days after date of manufacture. The mixing directions for this liquid Type B medicated feed stored in recirculation or agitation tank systems are: Recirculate or agitate immediately prior to use for not less than 10 minutes, moving at least 1 percent of the tanks contents per minute from the bottom of the tank to the top. Recirculate or agitate as directed daily, even when the Type B medicated feed is not used. Inadequate mixing (recirculation or agitation) of liquid Type B medicated feeds may result in increased monensin concentrations which have been fatal to cattle. Both an approved NADA and an approved medicated feed application are required to make this liquid Type B medicated feed.

(x) *Amount per ton.* Monensin, 1,620 grams as monensin sodium (810 milligrams per pound).

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

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

Ingredient	Percent	International feed no.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.25	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 <sup>1</sup>	2.5	
Monensin Type A article, 80 grams per pound	1.01	
Antidusting oil	1.0	

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

(c) *Limitations.* Medicated mineral granules to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at the rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or water deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using this product. Do not feed to lactating dairy cattle. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. The product's effectiveness in cull cows and bulls has not been established. Each use of this free-choice Type C feed must be the subject of an approved medicated feed application (MFA or Form FDA 1900) or supplemental MFA as required by §510.455 of this chapter.

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

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

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

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

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

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium; do not feed to chickens over 16 weeks of age.

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

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

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

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

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

(b) *Limitations.* (1) Feed only to goats being fed in confinement. Do not feed to lactating goats. Feed continuously in Type C feed as monensin sodium. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions. Mixing directions for liquid Type B feeds stored in recirculating tank systems are: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily, as directed in this paragraph, even when Type B feed is not used. Mixing directions for liquid Type B feeds stored in mechanical, air, or other agitation-type tank

systems are: 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 directed in this paragraph, even when Type B feed is not used. The liquid Type B feed must bear directions to mix thoroughly with grain and/or roughage prior to feeding and must bear caution statement as follows: Inadequate mixing (recirculation or agitation), of liquid Type B feeds has resulted in increased monensin concentration which could be fatal to goats.

(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(6)(i)(b)(1) of this section. A manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing an NADA for the product or by establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish positional stability; and (iii) requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the FEDERAL REGISTER because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(6)(i)(b)(1) of this section may also follow this procedure.

(ii) [Reserved]

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 000069 in § 510.600(c) of this chapter.

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

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

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

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

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

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

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

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

#### § 558.363 Narasin.

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

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

(2) To 000986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.

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

(4) To 012799: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambermycins, paragraph (d)(1)(iv) of this section.

(5) To 012799: 45 grams per pound, with 4 and 10 grams per pound bambermycins, and 45.4, 90, and 227 grams per pound roxarsone, paragraph (d)(1)(vii) of this section.

(6) To 046573: 45 grams per pound with 10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate and 45.4, 90, or 227 grams per pound roxarsone, paragraphs (d)(1)(viii) and (d)(1)(ix) of this section.

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

(c) [Reserved]

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

(1) *Broiler chickens*—(i) *Amount per ton.* Narasin, 54 to 72 grams.

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

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

(ii) *Amount per ton.* Narasin, 54 to 72 grams, plus roxarsone 45.4 grams (0.005 percent).

(A) *Indications for use.* For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* including some field strains of *E. tenella* which are more susceptible to roxarsone combined with narasin than to narasin alone.

(B) *Limitations.* For broiler chickens only; feed continuously as the sole ration; do not feed to laying chickens; may be fatal if accidentally fed to adult turkeys or to horses; withdraw 5

days before slaughter; as sole source of organic arsenic; not approved for use with pellet binders.

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

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

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

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

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

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. May be fatal if fed to adult turkeys, horses, or other equines.

(v) *Amount per ton.* Narasin 54 to 72 grams, roxarsone 22.7 to 45.4 grams, and bacitracin methylene disalicylate 10 to 50 grams.

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

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Drug overdose or lack of water may result in leg weakness. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986,

roxarsone by 046573, bacitracin methylene disalicylate by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Narasin 54 to 72 grams, and bacitracin methylene disalicylate 10 to 50 grams.

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

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin methylene disalicylate by 046573 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Narasin 54 to 72 grams, bambermycins 1 to 2 grams, and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* 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, improved feed efficiency, and improved pigmentation in broiler chickens.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys or horses or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Narasin as provided by 000986 in § 510.600(c) of this chapter, bambermycins by 012799, and roxarsone by 046573.

(viii) *Amount per ton.* Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 50 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clos-*

*tridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. 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. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 100 to 200 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. 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. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(2) Narasin may also be used for broilers in combination with:

(i) Nicarbazine with lincomycin as in § 558.366.

(ii) Nicarbazin and bacitracin methylene disalicylate as in § 558.366.

[51 FR 29098, Aug. 14, 1986, as amended at 53 FR 24260, June 28, 1988; 54 FR 1928, Jan. 18, 1989; 54 FR 5930, Feb. 7, 1989; 54 FR 9430, Mar. 7, 1989; 54 FR 29335, July 12, 1989; 55 FR 8460, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 57 FR 32176, July 21, 1992; 63 FR 13124, Mar. 18, 1998; 63 FR 51823, Sept. 29, 1998; 63 FR 57248, Oct. 27, 1998; 64 FR 4966, Feb. 2, 1999]

**§ 558.365 Nequinatate.**

(a) *Approvals.* Type A medicated articles: 4 percent to 017800 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.440 of this chapter.

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

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

(1) *Broiler or fryer chickens—(i) Amount per ton.* Nequinatate, 18.16 grams.

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

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Nequinatate, 18.16 grams (0.002 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, and *E. mivati*; growth promotion and feed efficiency; for improving pigmentation.

(b) *Limitations.* Feed continuously as sole ration throughout the starting pe-

riod; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Nequinatate, 18.16 grams (0.002 percent) plus oxytetracycline, 200 grams.

(a) *Indications for use.* For control of complicated chronic respiratory disease (air-sac infection), infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).

(b) *Limitations.* As monoalkyl (C<sub>8</sub>-C<sub>18</sub>) trimethylammonium oxytetracycline as provided by No. 000069 in § 510.600(c) of this chapter.

(2) *Roaster chickens or replacement chickens for caged layers—(i) Amount per ton.* Nequinatate, 18.16 grams (0.002 percent).

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

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2685, Jan. 26, 1987]

**§ 558.366 Nicarbazin.**

(a) Type A medicated articles: 25 percent to 000986, 060728, and 063271 in § 510.600(c) of this chapter for use as indicated in the table in paragraph (c) of this section.

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

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

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45 .....	Narasin 27 to 45 .....	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> .	Sec. 558.363(d)(1)(iii) .....	000986
	Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50.	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate by 046573.	000986

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
113.5 (0.0125 pct) ....	Narasin 27 to 45 and Lincomycin 2 to 4.	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Narasin and nicarbazin as provided by 000986, lincomycin by 000009.	000986
	.....	Chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	000986 060728 063271
	Bacitracin methylene disalicylate 30.	Broiler chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis; for increased rate of weight gain and improved feed efficiency.	.....do .....	060728 063271
	Lincomycin 2 (0.00044 pct).	Broiler chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> and <i>E. brunetti</i> ) coccidiosis; for increased rate of weight gain.	.....do .....	060728 063271
	Roxarsone 22.7 (0.0025)..	.....do .....	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; as sole source of organic arsenic; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 5 days before slaughter.	060728 063271
Roxarsone 22.7 (0.0025) plus lincomycin 2 (0.0004)..	.....do .....	.....do .....	060728 063271	

[42 FR 56729, Oct. 28, 1977; 43 FR 1942, Jan. 13, 1978, as amended at 44 FR 40887, July 13, 1979; 50 FR 13562, Apr. 5, 1985; 51 FR 7399, Mar. 3, 1986; 54 FR 1928, Jan. 18, 1989; 60 FR 29483, June 5, 1995; 61 FR 1832, Jan. 24, 1996; 61 FR 14021, Mar. 29, 1996; 61 FR 14483, Apr. 2, 1996; 62 FR 29011, May 29, 1997; 63 FR 13124, Mar. 18, 1998; 63 FR 57248, Oct. 27, 1998; 64 FR 4966, Feb. 2, 1999]

**§ 558.369 Nitarsone.**

- (a) *Approvals.* Type A medicated articles: 50 percent to 046573 in § 510.600(c) of this chapter.
- (b) *Related tolerances.* See § 556.60 of this chapter.
- (c) [Reserved]

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

- (1) *Chickens and turkeys.*—(i) *Amount.* Nitarsone, 0.01875 percent.
- (ii) *Indications for use.* As an aid in the prevention of blackhead.

(iii) *Limitations.* Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeder at all times. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 days. Discontinue use 5 days before slaughtering animals for human consumption to allow elimination of the drug from edible tissues. The drug is dangerous for ducks, geese, and dogs. Overdosage or lack of water may result in leg weakness or paralysis. Use as sole source of arsenic.

(2) *Turkeys*—(i) *Amount.* Nitarsone 0.01875 percent, plus bacitracin methylene disalicylate 4 to 50 grams per ton.

(ii) *Indications for use.* As an aid in the prevention of blackhead, and for increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For growing turkeys. Feed continuously as sole ration. Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeders at all times. Overdosage or lack of water may result in leg weakness or paralysis. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 days. Discontinue use 5 days before slaughtering animals for human consumption to allow elimination of the drug from edible tissues. The drug is dangerous for ducks, geese, and dogs. Use as sole source of arsenic.

[46 FR 47535, Sept. 29, 1981, as amended at 47 FR 14152, Apr. 2, 1982; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8460, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 63 FR 39028, July 21, 1998]

#### § 558.376 Nitromide and sulfantran.

(a) *Approvals.* Type A medicated articles: 25 percent nitromide, 30 percent sulfantran, with or without 5 percent roxarsone to 053501 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See §§ 556.220 and 556.680 of this chapter.

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

(1) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfantran (0.03 percent).

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

*Eimeria tenella*, *E. necatrix*, and *E. acervulina*.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide and 30 percent sulfantran.

(2) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfantran (0.03 percent), plus 45.4 grams per ton roxarsone (0.005 percent).

(i) *Indications for use.* Prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, and *E. acervulina*; growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide, 30 percent sulfantran, and 5 percent roxarsone; as sole source of organic arsenic.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8460, Mar. 8, 1990]

#### § 558.415 Novobiocin.

(a) *Approvals.* Type A medicated articles: 25 grams of activity per pound to 000009 in § 510.600(c) of this chapter. Type B medicated feeds: 17.5 grams per pound to 000009 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.460 of this chapter.

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

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than

350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount*. Novobiocin, 4–5 mgs. per lb. body weight per day.

(a) *Indications for use*. Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations*. Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount*. Novobiocin, 5–8 mgs. per lb. body weight per day.

(a) *Indications for use*. Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(b) *Limitations*. Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount*. Novobiocin, 7–8 mgs. per lb. body weight per day.

(a) *Indications for use*. Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(b) *Limitations*. Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount*. 20 mgs. per lb. body weight per day.

(ii) *Indications for use*. For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations*. Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

(4) *Ducks*—(i) *Amount*. Novobiocin, 350 grams per ton.

(ii) *Indications for use*. Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida*, susceptible to novobiocin.

(iii) *Limitations*. Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary, repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

[40 FR 13959, Mar. 27, 1975, as amended at 45 FR 42263, June 24, 1980; 51 FR 7399, Mar. 3, 1986; 52 FR 36402, Sept. 29, 1987]

**§ 558.430 Nystatin.**

(a) *Approvals*. Type A medicated articles: 20 grams of activity per pound to 046573 in §510.600(c) of this chapter.

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

(c) *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]

**§ 558.435 Oleandomycin.**

(a) *Approvals*. Type A medicated articles: 5 grams of activity per pound to 000069 in §510.600(c) of this chapter.

(b) *Related tolerances*. See §556.480 of this chapter.

(c) *Special considerations*. Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin. Oleandomycin refers to oleandomycin or feed-grade oleandomycin.

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

(1) *Chickens and turkeys*—(i) *Amount per ton*. Oleandomycin, 1 to 2 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feed

efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton.* Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987]

**§ 558.450 Oxytetracycline.**

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to 000069 in §510.600(c) of this chapter.

(2) 50 and 100 grams per pound to 053389 in §510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with §558.5 labeling shall bear the statement: "FOR USE IN DRY

ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C<sub>8</sub>-C<sub>18</sub>) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl (C<sub>8</sub>-C<sub>18</sub>) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

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

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

TABLE 1

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 20 grams per ton (g/ton)		Sheep; increased rate of weight gain and improved feed efficiency.	.....	000069, 053389
(ii) 10 to 50 g/ton		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	Do.
		2. Growing turkeys; increased rate of weight and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	Do.
		3. Swine; increased rate of weight and improved feed efficiency.	.....	Do.
(iii) 100 g/ton		Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 days (d); do not feed to turkeys producing eggs for human consumption.	Do.
(iv) 100 to 200 g/ton		Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> ; control of fowl cholera caused by <i>Pasteurella multocida</i> 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.	Do.
	Nequinatate 18.16 g/ton (0.002%)	Chickens; control of infectious synovitis caused by <i>M. synoviae</i> ; control of fowl cholera caused by <i>P. multocida</i> susceptible to oxytetracycline; as an aid in the control of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	.....do .....	000069

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/ton		Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> 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.	000069, 053389
(vi) 400 g/ton	Monensin 90 to 110 g/ton	Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	Do.
	Nequinatate 18.16 g/ton (0.002%)	Chickens; control of CRD and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to oxytetracycline; and as an aid in the prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	.....do .....	000069
		Chickens; control of CRD and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to oxytetracycline; as an aid in prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	.....do .....	Do.
(vii) 500 g/ton	Monensin 90 to 110 g/ton	Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.	000069, 053389
		Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline; as an aid in the prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	.....do .....	000069
	Salinomycin 40 to 60 g/ton	Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline; prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	.....do .....	000069, 012799

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(viii) 0.05 to 0.1 milligram/pound (mg/lb) of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	Feed continuously; in milk replacers or starter feed.	000069, 053389
(ix) 10 mg/lb of body weight daily.		1. Calves and beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; in feed or milk replacers; withdraw 5 d before slaughter.	Do.
		2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; in milk replacers or starter feed; withdraw 5 d before slaughter.	Do.
		3. Sheep; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	Do.
		4. Swine; treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> susceptible to oxytetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	Do.
		5. Breeding swine; control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	Do.
(x) 25 mg/lb of body weight		Turkeys; 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.	Do.
(xi) 25 mg/head/day		Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.	.....	Do.
(xii) 75 mg/head/day		Growing cattle (over 400 lb); increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	.....	Do.
(xiii) 0.5 to 2.0 g/head/day		Cattle; prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots.	Do.

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(xiv) 200 mg/colony		Honey bees; control of American foulbrood caused by <i>Bacillus larvae</i> and European foulbrood caused by <i>Streptococcus pluton</i> susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	Do.

(2) It is used in fish feed as follows:

TABLE 2

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 250 mg/kilogram of fish/d (11.35 g/100 lb of fish/d).		Pacific salmon for marking of skeletal tissue.	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in feed containing oxytetracycline hydrochloride or mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of medicated feed.	000069
(ii) 2.5 to 3.75 g/100 lb of fish/d.		1. Salmonids; control of ulcer disease caused by <i>Hemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> , and pseudomonas disease.  2. Catfish; control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and pseudomonas disease.	Administer as mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 ±C (48.2 ±F).	000069
(iii) 1 g/lb of medicated feed.		Lobsters; control of gaffkemia caused by <i>Aerococcus viridans</i> .	Administer as mono-alkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 ±C (62 ±F)	000069
			Administer as sole ration for 5 consecutive days in feed containing monoalkyl (C <sub>8</sub> –C <sub>18</sub> ) trimethyl ammonium oxytetracycline; withdraw medicated feed 30 d before harvesting lobsters.	

(3) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

- (i) Robenidine hydrochloride in accordance with §558.515.
- (ii) Lasalocid as in §558.311.

(iii) Melengestrol acetate as in § 558.342.

[61 FR 51590, Oct. 3, 1996, as amended at 63 FR 41192, Aug. 3, 1998]

**§ 558.460 Penicillin.**

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.

(b) *Sponsors.* Type A medicated articles: To 000069, 100 grams per pound. To 046573, 100 and 227 grams per pound.

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

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

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 2.4 to 50 .....	.....	Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency..	Do not feed to poultry producing eggs for human consumption..	000069, 046573.
(ii) 5 to 20 .....	.....	Quail; for increased rate of weight gain and improved feed efficiency..	Quail; not over 5 weeks of age.	Do.
(iii) 10 to 50 .....	.....	Swine; for increased rate of weight gain and improved feed efficiency..	.....	Do.

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii)-(v) [Reserved]

(vi) Hygromycin B in accordance with § 558.274.

(vii) Roxarsone and zoalene in accordance with § 558.680.

(viii) Zualene in accordance with § 558.680.

[41 FR 11004, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 36995, July 19, 1977; 47 FR 42103, Sept. 24, 1982; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 58 FR 30120, May 26, 1993; 60 FR 39847, Aug. 4, 1995; 63 FR 36179, July 2, 1998]

**§ 558.464 Poloxalene.**

(a) *Approvals.* (1) Dry Type A medicated articles: 53 percent to 000069 in § 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For 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 arti-

cle 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]

**§ 558.465 Poloxalene free-choice liquid Type C feed.**

(a) *Approvals.* Type A medicated articles: 99.5 percent to 000069 in § 510.600(c) of this chapter.

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

(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]

#### § 558.485 Pyrantel tartrate.

(a) *Approvals.* Type A medicated articles containing pyrantel tartrate to firms identified by drug labeler codes in § 510.600(c) of this chapter for the specific usage indicated in paragraph (e) of this section:

(1) To 000069: 9.6, 19.2, 48 and 80 grams per pound, paragraph (e)(1) of this section; 48 grams per pound, paragraph (e)(2) of this section.

(2) To 017800: 19.2 and 48 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(3) To 016968: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(4) [Reserved]

(5) To 017790: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) [Reserved]

(7) To 051359: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(8) To 011490: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(9) To 011749: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(10) To 043733: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(11) To 017519: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(12) To 046987: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(13) To 034936: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(14) [Reserved]

(15) To 049685: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(16)–(17) [Reserved]

(18) To 001800: 9.6 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(19) To 050568: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(20) To 050639: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(21) [Reserved]

(22) To 017473: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(23) To 021676: 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(24)–(26) [Reserved]

(27) To 010439: 9.6 and 19.2 grams per pound, paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(28) To 062240: 48 grams per pound, paragraph (e)(2) of this section.

(b) [Reserved]

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

(d) *Special considerations.* (1) Consult veterinarian before using in severely debilitated animals.

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

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

(1) *Swine*—(i) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Feed continuously as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(ii) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Feed for 3 days as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(iii) *Amount per ton.* 800 grams (0.0881 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* As sole ration for a single therapeutic treatment in Type C feed; feed at the rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over; withdraw 24 hours prior to slaughter.

(iv) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

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

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

(v) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin, 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* For prevention of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Use 100 grams tylosin per ton for at least 3 weeks followed by 40 grams tylosin per ton until market weight; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vi) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* Treatment and control of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Administer tylosin in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 grams per gallon in drinking water for 3 to 10 days, 40 to 100 grams tylosin per ton in feed for 2 to 6 weeks; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 40 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more

than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(viii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, then 40 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment and control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ix) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(x) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii),

or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(ii)(B) of this section.

(xi) *Amount per ton.* Pyrantel tartrate, 800 grams (0.0881 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(iii)(B) of this section.

(xii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 200 grams as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For the reduction in severity of swine mycoplasma pneumonia caused by *Mycoplasma hyopneumoniae*; aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter; consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

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

(2) *Horses—(i) Amount.* 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, *S. edentatus*, and *Triodontophorus* spp.), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 12,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal

parasites. Not for use in horses intended for food. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.485, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.515 Robenidine hydrochloride.**

(a) *Approvals.* Type A medicated articles: 30 grams per pound to 063238 in § 510.600(c) of this chapter.

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

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

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

(1) *For broiler and fryer chickens—(i) Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent).

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

(b) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter.

(ii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus roxarsone, 22.5–45.4 grams (.005 percent).

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

(b) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter; as sole source of organic arsenic. Roxarsone provided by No. 046573, § 510.600(c) of this chapter.

(iii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 to 200 grams.

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

control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(b) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(iv) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 to 400 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.

(b) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(v) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 500 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*; as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.

(b) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously up to 5 days.

(vi) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as zinc bacitracin).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*, and: in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as zinc bacitracin provided by Nos. 063238 and 046573 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as bacitracin methylene disalicylate).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*, and: in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus lincomycin, 2 grams.

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

(b) *Limitations.* Do not feed to laying hens; feed continuously as the sole ration; withdraw 5 days before slaughter; lincomycin as provided by No. 000009, § 510.600(c) of this chapter; approval for this combination granted to No. 000009 as identified in § 510.600(c) of this chapter.

(2) *For broiler chickens—(i) Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus oxytetracycline, 400 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*; control of CRD and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.

(iii) *Limitations.* Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; do not use in feeds containing bentonite; feed must be used within 50 days of manufacture; oxytetracycline

as provided by No. 000069 of this chapter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 33444, Aug. 8, 1975; 40 FR 39859, Aug. 29, 1975; 41 FR 1062, Jan. 6, 1976; 41 FR 28514, July 12, 1976; 41 FR 53002, Dec. 3, 1976; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 61 FR 18082, Apr. 24, 1996; 61 FR 35956, July 9, 1996; 61 FR 51593, Oct. 3, 1996; 62 FR 61626, Nov. 19, 1997; 62 FR 66986, Dec. 23, 1997; 63 FR 17948, Apr. 13, 1998; 63 FR 27845, May 21, 1998]

**§ 558.530 Roxarsone.**

(a) *Approvals.* Type A medicated articles: (1) 10, 20, and 50 percent to 046573 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

(2) 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

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

(c) [Reserved]

(d) *Conditions of use—(1) Growing chickens and growing turkeys—(i) Grams per ton.* Roxarsone 22.7 and 45.4 (0.0025 to 0.005 percent).

(ii) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(2) *Growing chickens—(i) Grams per ton.* Roxarsone, 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(ii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 100 to 200.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused

by *Mycoplasma synoviae* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 200 to 400.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 500.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(2)(i)(B) of this section except feed for 5 days.

(3) *Growing turkeys—(i) Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Do not feed to turkeys producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing season.

(ii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline 200.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iv) *Amount.* Roxarsone 22.7 to 45.4 grams per ton (0.0025 to 0.005 percent) plus chlortetracycline, 25 milligrams per pound of body weight daily.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(4) *Growing-finishing swine—(i) Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed for not more than 14 days.

(iii) *Grams per ton.* Roxarsone 181.5 (0.02 percent).

(A) *Indications for use.* For the treatment of swine dysentery.

(B) *Limitations.* Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source or organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.

(iv) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(v) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For the treatment of swine dysentery; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(5) *Permitted combinations.* It may be used in accordance with this section in combination as follows:

- (i) Aklomide as in § 558.35.
- (ii) Amprolium as in § 558.55.
- (iii) Amprolium and ethopabate as in § 558.58.
- (iv) Bacitracin methylene disalicylate as in § 558.76.
- (v) Bacitracin zinc as in § 558.78.
- (vi) Bambermycins and bambermycins plus certain anticoccidials as in § 558.95.
- (vii) [Reserved]
- (viii) Chlortetracycline as in § 558.128.
- (ix) Clopidol as in § 558.175.
- (x) Decoquinatone alone or in combination as in § 558.195.
- (xi) Monensin as in § 558.355.
- (xii) Nequinatone as in § 558.365.
- (xiii) Nicarbazine as in § 558.366.
- (xiv) Nitroimidazole and sulfanitran as in § 558.376.
- (xv) Robenidine hydrochloride as in § 558.515.
- (xvi) Sulfadimethoxine, ormetoprim as in § 558.575.
- (xvii) Zoalene as in § 558.680.

(xviii) Penicillin and zoalene as in § 558.680

(xix) Lasalocid as in § 558.311.

(xx) Lasalocid sodium and lincomycin as in § 558.311.

(xxi) Monensin and virginiamycin as in § 558.355.

(xxii) Monensin and bacitracin zinc as in § 558.355.

(xxiii) Narasin with bacitracin methylene disalicylate as in § 558.363.

(xxiv) Semduramicin with bacitracin methylene disalicylate as in § 558.555.

(6) *Additional combinations.* (i) Roxarsone may be used in combination "as an aid in the reduction of lesions due to *E. tenella*" as follows:

(A) Lasalocid as in § 558.311.

(B) Lasalocid plus bacitracin methylene disalicylate as in § 558.311.

(C) Lasalocid plus lincomycin as in § 558.311.

(D) Lasalocid and bacitracin zinc as in § 558.311.

(ii) Roxarsone may be used in combination with salinomycin as in § 558.550.

(iii) Roxarsone may be used in combination with salinomycin and bacitracin methylene disalicylate as in § 558.550.

(iv) Roxarsone may be used in combination with salinomycin and bacitracin zinc as in § 558.550.

(v) Roxarsone may be used in combination with halofuginone hydrobromide and bacitracin methylene disalicylate as in § 558.265.

(vi) Roxarsone may be used in combination with narasin as in § 558.363 of this part.

(vii) Roxarsone may be used in combination with salinomycin and chlortetracycline as in § 558.550.

[46 FR 52331, Oct. 27, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.530, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.550 Salinomycin.**

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

(1) To 063238 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) To 012799 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), and (d)(3)(i) through (d)(3)(iii) of this section.

(3) To 046573 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

(b)-(c) [Reserved]

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

(i)(a) *Amount per ton.* Salinomycin 40 to 60 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Do not feed to layers. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and roxarsone 45.4 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone.

(c) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 011526 or 046573 in § 510.600(c) of this chapter.

(iii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 30 grams.

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

(c) *Limitation.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iv)(a) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain.

(c) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

(v)(a) *Amount per ton.* Salinomycin 40 to 60 grams per ton with roxarsone 22.7 to 45.4 grams per ton.

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

(c) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(vi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 50 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin MD as provided by No. 046573 in § 510.600(c) of this chapter.

(vii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin zinc 10 to 50 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 063238 in § 510.600(c) of this chapter.

(viii)(a) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin zinc 4 to 50 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain and improved feed efficiency.

(c) *Limitations.* See paragraph (b)(1)(iv)(c) of this section.

(ix)(a) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 grams and bacitracin zinc 10 to 50 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 and bacitracin as provided by No. 063238 in § 510.600(c) of this chapter.

(x)(a) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers or to chickens over 16 weeks of age. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 053571 in § 510.600(c) of this chapter.

(xi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 to 15 grams.

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

(c) *Limitations.* See paragraph (b)(1)(x)(c) of this section.

(xii) (a) *Amount per ton.* Salinomycin 40 to 60 grams, virginiamycin 5 grams, and roxarsone 45.4 grams.

(b) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(c) *Limitations.* Feed continuously as sole ration. Withdraw 5 days prior to slaughter. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 053571 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xiii)(a) *Amount per ton.* Salinomycin 40 to 60 grams and lincomycin 2 to 4 grams.

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

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter.

(xiv)(a) *Amount per ton.* Salinomycin 40 to 60 grams, roxarsone 45.4 grams, and lincomycin 2 grams.

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

that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Drug overdose or lack of water may result in leg weakness. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Withdraw 5 days before slaughter. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xv)(a) *Amount per ton.* Salinomycin 40 to 60 grams, chlortetracycline 500 grams, and roxarsone 45.4 grams.

(b) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(c) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium, not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 5 days before slaughter. May be fatal if accidentally fed to adult turkeys or to horses. Chlortetracycline as provided by Nos. 046573 and 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xvi)(a) *Amount per ton.* Salinomycin 40 to 60 grams and chlortetracycline 500 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(c) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium. Not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlor-

tetracycline as provided by No. 063238 in § 510.600(c) of this chapter.

(xvii)(A) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 or 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain. Use of 34.1 or 45.4 grams per ton roxarsone is indicated to meet the *E. tenella* challenge which varies with environmental and management conditions.

(C) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to laying chickens. May be fatal if accidentally fed to adult turkeys or horses. Poultry should have access to drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Salinomycin as provided by No. 000004 in § 510.600(c) of this chapter. Roxarsone and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

(2) *Quail*—(i)(a) *Amount per ton.* Salinomycin 50 grams.

(b) *Indications for use.* For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*.

(c) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii) [Reserved]

(3) *Roaster and replacement (breeder and layer) chickens:* It is used as follows:

(i) *Amount per ton.* Salinomycin 40 to 60 grams.

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

(iii) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to horses or adult turkeys.

(4) *Permitted combinations.* Salinomycin may be used as in this section in combinations as follows:

(i) Bambermycins and roxarsone as in § 558.95.

(ii) Bambermycins as in § 558.95.

(iii) Oxytetracycline as in § 558.450.

[48 FR 30616, July 5, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.550, see the List of CFR Sections Affected in the Finding Aids section of this volume.

EDITORIAL NOTE: At 62 FR 29014, May 29, 1997, in § 558.550, paragraph (b) was redesignated as paragraph (d). At 62 FR 60781, Nov. 13, 1997, paragraph (b)(1)(vii)(c) was amended by removing "No. 000004" and adding in its place "Nos. 000004 and 046573" and at 62 FR 66985, Dec. 23, 1997, paragraph (b)(1)(ix)(c) was amended by removing "No. 000004" and adding in its place "Nos. 000004 and 046573". Since § 558.550(b) does not exist, these amendments could not be incorporated.

**§ 558.555 Semduramicin.**

(a) *Approvals.* Type A medicated article containing 5.13 percent semduramicin sodium (equivalent to 50 grams semduramicin per kilogram or 22.7 grams per pound) to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) Broilers:

(i) *Amount.* Semduramicin: 25 parts per million.

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

(iii) *Limitations.* Do not feed to laying hens.

(2) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams and roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone, and for improved feed efficiency.

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking

water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Semduramicin as provided by 000069 in § 510.600(c) of this chapter, bacitracin methylene disalicylate and roxarsone as provided by 046573.

(3) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, and for improved feed efficiency in broiler chickens.

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Semduramicin as provided by 000069, bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(4) *Amount.* Semduramicin 22.7 grams with roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.

(ii) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Roxarsone as provided by 046573, semduramicin as provided by 000069 in § 510.600(c) of this chapter.

[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]

**§ 558.575 Sulfadimethoxine, ormetoprim.**

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

(1) 25 percent sulfadimethoxine and 15 percent ormetoprim to 063238 for use for poultry as in paragraphs (c)(1), (2), (3), and (4) of this section.

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim to 063238 for use

for fish as in paragraphs (c)(5) and (6) of this section.

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

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

(1) *Broiler chickens—(i) Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(b) *Limitations.* Feed as sole ration; withdraw 5 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli*, (colibacillosis); and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) *Replacement chickens—(i) Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. galmaxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.

(3) *Turkeys—(i) Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides*, *E. gallopavonis*, and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(iii) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

(4) *Ducks—(i) Amount per ton.* Sulfadimethoxine, 227 grams (0.025 percent) plus ormetoprim, 136.2 grams (0.015 percent).

(a) *Indications for use.* As an aid in the control of bacterial infections due to *P. multocida* (fowl cholera) in ducks, including breeding ducks.

(b) *Limitations.* Feed as sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; do not feed to ducks producing eggs for food.

(ii) *Amount per ton.* Sulfadimethoxine, 454 grams (0.05 percent) plus ormetoprim, 272.4 grams (0.03 percent).

(a) *Indications for use.* As an aid in the control of bacterial infections due to *E. coli*, *P. anatipestifer*, and severe challenge of *P. multocida* (fowl cholera) in ducks.

(b) *Limitations.* Feed as a sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; not for breeding ducks; do not feed to ducks producing eggs for food.

(5) *Salmonids—(i) Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications of use.* For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 42 days before release as stocker fish or slaughter.

(6) *Catfish—(i) Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications for use.* For control of enteric septicemia of catfish caused by

*Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 3 days before slaughter or release as stocker fish.

[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]

#### § 558.579 Sulfaethoxypyridazine.

(a) *Approvals.* Type A medicated articles: 5.5 percent for swine, and 5.5 and 11 percent for cattle to 010042 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.650 of this chapter.

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

(1) *Swine*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of bacterial scours, pneumonia, enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Administer 1,000 grams per ton (0.11 percent) for not less than 4 days nor more than 10 days; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer as a top dressing or in mixed feed for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use by or on the order of a licensed veterinarian.

[41 FR 11005, Mar. 15, 1976, as amended at 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987]

#### § 558.582 Sulfamerazine.

(a) *Approvals.* Type A medicated articles: 99 percent to 063238 in § 510.600(c) of this chapter.

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

(c) *Conditions of use.* It is used in fish feed for rainbow trout, brook trout, and brown trout as follows:

(1) *Amount.* 10 grams of sulfamerazine per 100 pounds of fish per day.

(2) *Indications for use.* Control of furunculosis.

(3) *Limitations.* Treat for not more than 14 days; do not treat within 3 weeks of marketing or stocking in stream open to fishing.

[41 FR 11005, Mar. 15, 1976, as amended at 51 FR 7400, Mar. 3, 1986; 61 FR 18082, Apr. 24, 1996; 63 FR 27846, May 21, 1998]

#### § 558.586 Sulfaquinoxoline.

(a) *Approvals.* Type A medicated articles: 40 percent to 050749 in § 510.600(c) of this chapter.

(b)–(c) [Reserved]

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Special considerations.* (1) For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, and rabbits must actually consume enough medicated feed which provides a recommended dose of approximately 3.5 to 60 milligrams per pound per day in chickens, 2.5 to 100 milligrams per pound per day in turkeys, and 2.8 to 68 milligrams per pound per day in rabbits depending upon age and class of animal, ambient temperature, and other factors. Consult a veterinarian or poultry pathologist for diagnosis.

(2) [Reserved]

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

(1) *Chickens*—(i) *Amount.* 0.015 percent.

(a) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti* under average conditions of exposure.

(b) *Limitations.* Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(ii) *Amount.* 0.0175 percent.

(a) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti* where excessive exposure to coccidia is increased due to overcrowding or other management factors.

(b) *Limitations.* Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(iii) *Amount.* 0.1 to 0.05 percent.

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

(b) *Limitations.* Feed at 0.1 percent level for first 48 to 72 hours. Skip 3 days; 0.05 percent for 2 days, skip 3 days; 0.05 percent for 2 days. If bloody droppings recur, give 0.05 percent for another 2 days. Do not treat chickens

within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(2) *Turkeys*—(i) *Amount.* 0.0175 percent.

(a) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria meleagritidis* and *E. adenoides*.

(b) *Limitations.* Feed 0.0175 percent continuously during time birds are closely confined. May be continued for week to 10 days after flock is transferred to range to reduce danger of an outbreak following moving of the flock. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(ii) *Amount.* 0.05 percent.

(a) *Indications for use.* As an aid in controlling outbreaks of coccidiosis caused by *Eimeria meleagritidis*, and *E. adenoides*.

(b) *Limitations.* Feed 0.05 percent for 2 days. Follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Again follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Continue this schedule if necessary till all signs of the outbreaks have subsided. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(3) *Chickens and turkeys*—(i) *Amount.* 0.05 or 0.1 percent.

(a) *Indications for use.* As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(b) *Limitations.* Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption.

(ii) [Reserved]

(4) *Rabbits*—(i) *Amount.* 0.025 percent.

(a) *Indications for use.* As an aid in preventing coccidiosis caused by *Eimeria stiedae*.

(b) *Limitations.* Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2 days out of every week until marketing. Do not treat within 10 days of slaughter.

(ii) *Amount.* 0.1 percent.

(a) *Indications for use.* As an aid in controlling outbreaks of coccidiosis caused by *Eimeria stiedae*.

(b) *Limitations.* Feed for 2 weeks. Do not treat within 10 days of slaughter.

[48 FR 3965, Jan. 28, 1983, as amended at 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

**§ 558.600 Tiamulin.**

(a) *Approvals.* Type A article containing 5, 10, or 113.4 grams of tiamulin (as tiamulin hydrogen fumarate) per pound to 000010 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.738 of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* 35 grams of tiamulin per ton.

(i) *Indications for use.* For control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) *Limitations.* Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter. Not for use in swine over 250 pounds body weight. Use as only source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, or salinomycin) as adverse reactions may occur.

(2) *Amount.* 10 grams of tiamulin per ton.

(i) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds. Use as sole source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, or salinomycin) as adverse reactions may occur.

(3) *Amount.* 200 grams of tiamulin per ton.

(i) *Indications for use.* Treatment of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) *Limitations.* Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter. Not for use in swine over 113.40 kilograms (250 pounds) body weight. Use as the only source of tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, semduramicin, or salinomycin) as adverse reactions may occur.

(4) *Amount per ton.* 35 grams of tiamulin (as tiamulin hydrogen fumarate), plus the equivalent of approximately 400 grams of chlortetracycline hydrochloride varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline per pound of body weight daily.

(i) *Indications for use.* Treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) *Limitations.* Feed continuously as sole ration for 14 days. Not for use in swine weighing over 250 pounds. Use as only source of chlortetracycline and tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., monensin, salinomycin, narasin, semduramicin, and lasalocid) as adverse reactions may occur. If signs of toxicity occur, discontinue use. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 046573, 053389, and 063238 in § 510.600(c) of this chapter.

[52 FR 26956, July 17, 1987, as amended at 53 FR 39257, Oct. 6, 1988; 59 FR 41975, Aug. 16, 1994; 62 FR 12086, Mar. 14, 1997; 62 FR 35077, June 30, 1997; 63 FR 27846, May 21, 1998; 63 FR 52969, Oct. 2, 1998]

**§ 558.615 Thiabendazole.**

(a) *Approvals.* Dry Type A medicated articles: 22, 44.1, 66.1, and 88.2 percent to 050604 in § 510.600(c) of this chapter. The 66.1 percent Type A is solely for the manufacture of cane molasses liquid Type B feed which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

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

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

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

(1) *Cattle*—(i) *Amount.* 3 grams per 100 lb. body weight.

(a) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Nematodirus spp.*, *Oesophagostomum radiatum*).

(b) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(a) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Nematodirus spp.*, *Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(b) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount.* 3 grams per 100 lb. body weight.

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

*Bunostomum spp.*, *Strongyloides spp.*, *Chabertia spp.*, and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*, *Cooperia spp.*; *Nematodirus spp.*, *Bunostomum spp.*, *Strongyloides spp.*, *Chabertia spp.*, and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axeii*, *Ostertagia spp.*, *Nematodirus spp.*, *Strongyloides spp.*; less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount.* 45.4-908 grams per ton (0.005-0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations.* Administer continuously feed containing 0.05-0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005-0.02 percent thiabendazole per ton for 8-14 weeks; do not treat animals within 30 days of slaughter.

(5) *Pheasants*—(i) *Amount.* 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) *Indications for use.* For the treatment of gapeworms (*Syngamus trachea*) in pheasants.

(iii) *Limitations.* Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data

are not available on use in breeding animals.

[40 FR 13959, Mar. 27, 1975, as amended at 47 FR 49641, Nov. 2, 1982; 49 FR 29958, July 25, 1984; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 62 FR 63271, Nov. 28, 1997]

#### § 558.618 Tilmicosin.

(a) *Approvals.* Type A medicated articles: 90.7 grams of tilmicosin (as tilmicosin phosphate) per pound (200 grams per kilogram) to 000986 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in any feed containing bentonite.

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

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

(1) *Amount per ton.* 181 grams to 363 grams tilmicosin.

(2) *Indications for use.* For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

(3) *Limitations.* For use in swine feed only. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Do not allow horses or other equine access to feeds containing tilmicosin. Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Withdraw 7 days before slaughter. Federal law restricts this drug to use under the professional supervision of a licensed veterinarian. Any animal feed bearing or containing this drug shall be fed to animals only by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice. VFD's for tilmicosin phosphate shall not be refilled.

(4) *VFD Requirements.* This drug and any article or feed manufactured from it shall bear the following cautionary statements: "Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice." A VFD shall contain

the following information: The name, address, and phone number of the veterinarian and the client; identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals; date of treatment and, if different, date of prescribing the VFD drug; the condition or disease being diagnosed or treated; name of the animal drug; level of animal drug in feed and amount of feed; feeding instructions with withdrawal time; any special instructions and cautionary statements necessary for use of the drug in conformance with the approval; expiration date of VFD; number of refills, if permitted by approval; signature of the veterinarian; veterinarian's license number and name of the State issuing the license.

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999]

#### § 558.625 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2) To 051359: 1, 2, 4, 5, 8, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)–(7) [Reserved]

(8) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(9) To 043727: 4 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(10) To 017519: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

(11) [Reserved]

(12) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15) [Reserved]

(16) To 049768: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(17) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(18) [Reserved]

(19) To 033999: 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(20)–(21) [Reserved]

(22) To 026282: 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(23)–(24) [Reserved]

(25) To 000069: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)–(30) [Reserved]

(31) To 029341: 5 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(35) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(36)–(37) [Reserved]

(38) To 053740: 1 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(39) To 050604: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(40) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(41) [Reserved]

(42) To 010439: 0.4, 0.5, and 2 grams per pound, paragraph (f)(1)(vi) (a) of this section; 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

(43)–(44) [Reserved]

(45) To 017139: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(46)–(47) [Reserved]

(48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(49)–(51) [Reserved]

(52) To 017519: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(53) [Reserved]

(54) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(55)–(56) [Reserved]

(57) To 028459: 0.4 and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(58)–(62) [Reserved]

(63) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(64)–(65) [Reserved]

(66) To 024174: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(67) To 027190: 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(68) To 017473: 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(69)–(72) [Reserved]

(73) To 035098: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi)(a) of this section; 0.8, 1, 2, and 10 grams per pound, paragraphs (f)(1) (i) and (vi) (a), (b) and (d) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(74)–(76) [Reserved]

(77) To 050639: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (a), (b), and (d) of this section.

(79) To 012286: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(80) To 049685: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(81)–(82) [Reserved]

(83) To 046573: 5-, 10-, 20-, and 40-grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(84) [Reserved]

(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(86)–(88) [Reserved]

(89) To 053389: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

(c)–(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle—(a) Amount per ton.* 8–10 grams.

(b) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(c) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens—(a) Amount per ton.* Tylosin, 800–1000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.

(iii) *Chickens—(a) Amount per ton.* Tylosin, 4–50 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate.

(iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20–50 grams.

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

(c) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine—(a) Amount per ton.* Tylosin, 10–100 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(b) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibrionic).

(2) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(c) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(2) *Limitations.* Administer in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3–10 days, 40–100 grams per ton in feed for 2–6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) *Limitations.* As tylosin phosphate.

(2) Tylosin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Hygromycin B as in § 558.274.

(ii) Melengestrol acetate alone or in combination with certain ionophores in accordance with § 558.342.

(iii) [Reserved]

(iv) Monensin in accordance with § 558.355.

(v) Pyrantel tartrate in accordance with § 558.485.

(e) *Amount per ton.* Tylosin 100 grams. (1) *Indications for use.* Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

(2) *Limitations.* As tylosin phosphate, administer for 21 days.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.630 Tylosin and sulfamethazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated article levels, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section.

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i).

(2) To 000986: 10 grams per pound each, paragraph (f)(2)(i).

(3) To 017519: 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(4) To 021780: 2 grams per pound each, paragraph (f)(2)(ii) of this section.

(5) To 017800: 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(6) To 017139: 4, 10, or 20 grams per pound each, paragraph (f)(2)(ii) of this section.

(7) To 021930: 2 grams per pound each, paragraph (f)(2)(i) of this section; 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(8) To 017519, 026186: 5 or 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(9) [Reserved]

(10) To 010439, 011749, 016968, 017473, 017519, 017790, 021780, 024174, 030841, 034936, 035098, 043727, 043733, 046573, 046987, 050568, 050639, and 051359, 053389: 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(c)–(d) [Reserved]

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

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

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibriotic); control of swine pneumonias caused by bacterial pathogens (*P. multocida* and/or *C. pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibriotic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(3) *Limitations.* As tylosin phosphate; withdraw 15 days before slaughter.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.630, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.635 Virginiamycin.**

(a) [Reserved]

(b) *Approvals.* Type A medicated articles. (1) 1.1 percent activity (5 grams per pound), 2.2 percent activity (10 grams per pound), 4.4 percent activity (20 grams per pound), 11 percent activity (50 grams per pound), and 50 percent activity (227 grams per pound) used as in paragraph (f) of this section; and 30 percent activity (136.2 grams per pound) for the manufacture of Type C medicated feed for cattle used as in paragraph (f)(3); to 000069 in § 510.600(c) of this chapter.

(2) 2.2 percent activity (10 grams per pound) to 046573, 016968, and 017790 in § 510.600(c) of this chapter for use as in paragraphs (f)(1)(iv) and (f)(1)(v) of this section.

(c) [Reserved]

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

(e) *Special considerations.* (1) Not for use in breeding swine over 120 pounds.

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

(3)–(4) [Reserved]

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

(i) 100 grams per ton for 2 weeks, for treatment of swine dysentery in non-breeding swine over 120 pounds.

(ii) 100 grams per ton for 2 weeks, 50 grams per ton thereafter, for treatment and control of swine dysentery in swine up to 120 pounds.

(iii) 25 grams per ton, as an aid in control of dysentery in swine up to 120 pounds. For use in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.

(iv) 10 grams per ton from weaning up to 120 pounds for increased rate of weight gain and improved feed efficiency, followed by 5 grams per ton to market weight for increased rate of weight gain and improved feed efficiency. For continuous use from weaning to market weight.

(v) 10 grams per ton from weaning up to 120 pounds for increased rate of weight gain and improved feed efficiency, followed by 5 to 10 grams per ton to market weight for increased

rate of weight gain. For continuous use from weaning to market weight.

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

(i) 5 to 15 grams per ton for increased rate of weight gain, for use in broiler chickens, not for use in layers.

(ii) 5 grams per ton for increased rate of weight gain and improved feed efficiency in broiler chickens, not for use in layers.

(iii) 20 grams per ton for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin in broiler chickens; not for use in layers.

(iv) 10 to 20 grams per ton for increased rate of weight gain and improved feed efficiency in growing turkeys.

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

(i) 16.0 to 22.5 grams per ton to provide 100 to 340 milligrams per head per day for increased rate of weight gain.

(ii) 13.5 to 16.0 grams per ton to provide 85 to 240 milligrams per head per day for reduction of incidence of liver abscesses.

(iii) 11.0 to 16.0 grams per ton to provide 70 to 240 milligrams per head per day for improved feed efficiency.

(iv) Feed continuously as sole ration to cattle fed in confinement for slaughter. Not for use in animals intended for breeding.

(4) Virginiamycin may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Monensin sodium in accordance with § 558.355.

(ii) Lasalocid sodium in accordance with § 558.311.

(iii) Monensin and roxarsone as in § 558.355.

(iv) Amprolium and ethopabate as in § 558.58.

(v) Halofuginone as in § 558.265.

(vi) Salinomycin alone or with roxarsone as in § 558.550.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.635, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 558.680 Zoalene.**

(a) *Approvals.* Type A medicated articles: 25 percent to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.770 of this chapter. (c) *Conditions of use—(1) Chickens and turkeys:*

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) 36.3–113.5 (0.004–0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Grower ration not to be fed to birds over 14 weeks of age; as follows:

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/ton	Indications for use	Limitations
	Arsanilate sodium 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days (d) before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.  2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).  Feed for 7 to 14 d; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Bacitracin 100 to 500.	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.	As bacitracin zinc; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 200 to 400.	Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 92.5.	1. Replacement chickens, as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis.  2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis.	Feed for 2 d before stress and 3 to 6 after stress; withdraw 24 hours (h) before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).  Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Hygromycin B 8 to 12.	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms ( <i>Ascaris galli</i> ) cecal worms ( <i>Heterakis gallinae</i> ) and capillary worms ( <i>Capillaria obsignate</i> ).	Grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Roxarsone 22.7 to 45.5 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
(ii) 113.5 (0.0125%).		Broiler chickens; prevention and control of coccidiosis.	

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Arsanilate sodium 90 (0.01%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens; growth prevention and control of coccidiosis; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis. 2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Do.  Do.
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As procaine penicillin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus bacitracin 4 to 50.	Broiler chickens; prevention and control of coccidiosis; improving pigmentation; growth promotion and feed efficiency.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate.
	Bacitracin 4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As bacitracin methylene disalicylate or zinc bacitracin.
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As bacitracin methylene disalicylate or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Bacitracin 100 to 500.	Broiler chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); prevention and control of coccidiosis.	As zinc bacitracin.
	Chlortetracycline 100 to 200	Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
	Chlortetracycline 200 to 400	Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(iii) 113.5 to 170.3 (0.0125 to 0.01875%).	Erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As erythromycin thiocyanate.
	Erythromycin 92.5.	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis. 2. Broiler chicken; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate. Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate.
	Erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.
	Hygromycin B 8 to 12.	Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms ( <i>Ascaris galli</i> ) cecal worms ( <i>Heterakis gallinae</i> ) and capillary worms ( <i>Capillaria obsignate</i> ).	
	Lincomycin 2.	Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis.	Do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in § 510.600(c) of this chapter.
	Penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As procaine penicillin.
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as procaine penicillin.
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilate sodium 90 (0.01%).	Turkeys; prevention and control of coccidiosis. Turkeys; growth promotion and feed efficiency; improving pigmentation.	For turkeys grown for meat purposes only. For turkeys grown for meat purposes only; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90(0.01%). Bacitracin methylene disalicylate 4–50.	do. Turkeys; prevention and control of coccidiosis, and increased rate of weight gain and improved feed efficiency.	Do. For turkeys grown for meat purposes only, not to be fed to laying birds, feed continuously as sole ration until 14 to 16 weeks of age.
	Carbarsone (not U.S.P.) 277 to 340.5 (0.025% to 0.0375%).	Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead.	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.
Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	

(2) *Permitted combinations.* It may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Bambermycins in accordance with § 558.95.

(ii) Roxarsone in accordance with § 558.530.

[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]

## PART 564 [RESERVED]

### PART 570—FOOD ADDITIVES

#### Subpart A—General Provisions

Sec.

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#### Subpart B—Food Additive Safety

570.20 General principles for evaluating the safety of food additives.

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570.35 Affirmation of generally recognized as safe (GRAS) status.

570.38 Determination of food additive status.

AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

#### Subpart A—General Provisions

##### § 570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301–392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals in the United States.

(g) The word *substance* in the definition of the term *food additive* includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) *Scientific procedures* include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of