PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 23. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 24. In § 529.1660, add paragraph (d)(3) to read as follows:

§ 529.1660 Oxytetracycline.

* * * * *

(d) * * *

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

Dated: December 20, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016–31084 Filed 12–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs for Use in Animal Feed; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of 71 supplemental new animal drug applications (NADAs) and 35 supplemental abbreviated new animal drug applications (ANADAs) for revised labeling reflecting a change in marketing status from over-the-counter (OTC) use to use by veterinary feed directive (VFD) for antimicrobial drugs of importance to human medicine administered to food-producing animals in medicated feed. Where applicable, FDA is also withdrawing approval of those parts of the NADAs that pertain to use of these antimicrobial drugs for growth promotion indications. These actions are being taken at the sponsors' requests because these particular medicated feeds will no longer be manufactured or marketed. These applications were submitted in voluntary compliance with the goals of FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative. In addition, the animal drug regulations are being amended to reflect the voluntary withdrawal of approval of certain entire NADAs and ANADAs that were affected by this initiative. The animal drug regulations are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

DATES: This rule is effective December 30, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Supplemental Approval of Revised Labeling and Withdrawal of Approval of Portions of NADAs Pertaining to Production Indications

FDA is amending the animal drug regulations to reflect approval of 71 supplemental NADAs and 35 supplemental ANADAs for revised labeling reflecting a change in marketing status from OTC use to use by VFD for antimicrobial drugs of importance to human medicine administered to food-producing animals in medicated feed. Where applicable, FDA is also withdrawing approval of those parts of the NADAs that pertain to use of these antimicrobial drugs for growth promotion indications. These actions are being taken at the sponsors' requests because these particular medicated feeds will no longer be manufactured or marketed.

These applications were identified as being affected by guidance for industry (GFI) #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'', December 2013 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*). Their change to VFD marketing status is consistent with FDA CVM's initiative for the Judicious Use of Antimicrobials.

The animal drug regulations for medicated feeds are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

The affected applications for Type A medicated articles for which supplemental applications with revised labeling were approved follow:

File No.	Animal drug product	Sponsor
006–391	S.Q. 40% (sulfaquinoxaline) Type A Medicated Article	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
008–804	TM–50 or TM–100 (oxytetracycline) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.).
010–092	GALLIMYCIN–100P (erythromycin) Type A Medicated Article	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland (Cross Vetpharm Group Ltd.).
010–918	HYGROMIX 8 (hygromycin B) Type A Medicated Article	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (Elanco US Inc.).
012–491	TYLAN (tylosin) Type A Medicated Article	Elanco US Inc.
033–950	Sulfamerazine In Fish Grade	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
035–688	AUREOMIX S 40/40 (chlortetracycline and sulfamethazine) Granular Type A Medicated Article.	Zoetis Inc.
035–805	AUREO S 700 (chlortetracycline and sulfamethazine) Granular Type A Medicated Article.	Zoetis Inc.
038–439	TERRAMYCIN 200 (oxytetracycline) for Fish Type A Medicated Article.	Phibro Animal Health Corp.
040–209	ROFENAID 40 (sulfadimethoxine and ormetoprim) Type A Medicated Article.	Zoetis Inc.

File No.	Animal drug product	Sponsor
041–275	TYLAN 40 Sulfa-G (tylosin and sulfamethazine) Type A Medicated Article.	Elanco US Inc.
041–647	AUREOMIX S 700–A (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–648	AUREOMIX S 700–D (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–649	AUREOMIX S 700–G (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–650	AUREOMIX S 700–E (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–651	AUREOMIX S 700–F (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–652	AUREOMIX S 700–C–2 (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–653	AUREOMIX S 700–B (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
041–654	AUREOMIX S 700–H (chlortetracycline and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
046–415	Tylosin Type A Medicated Article	Zoetis Inc.
046–699	CHLORMAX (chlortetracycline) Type A Medicated Article	Zoetis Inc.
048–480	CHLORATET (chlortetracycline) Type A Medicated Article	Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405 (Pharmgate LLC).
048–761	AUREOMYCIN (chlortetracycline) Type A Medicated Article	Zoetis Inc.
049–287	CHLORACHEL (chlortetracycline)Type A Medicated Article	Zoetis Inc.
091–749	TYLAN 40 Plus Sulfa-G (tylosin and sulfamethazine) Type A Medicated Article.	Zoetis Inc.
092–286	CLTC–50 MR (chlortetracycline) Type A Medicated Article	Phibro Animal Health Corp.
092–287	CLTC 100 MR (chlortetracycline) Type A Medicated Article	Phibro Animal Health Corp.
094–975	NEO-TERRAMYCIN 100/100 (oxytetracycline and neomycin) Type A Medicated Article.	Phibro Animal Health Corp.
095–143	TERRAMYCIN 10, 30, 50, 100, or 200 (oxytetracycline) Type A Medicated Article.	Phibro Animal Health Corp.
097–505	LINCOMIX 20 (lincomycin) Type A Medicated Article	Zoetis Inc.
098–431	TYLAN 10 (tylosin) Premix Type A Medicated Article	Phibro Animal Health Corp.
100–901	PFICHLOR 100S (chlortetracycline) Milk Replacer Type A Medicated Article.	Zoetis Inc.
125–933	ROMET–30 (ormetoprim and sulfadimethoxine) Type A Medicated Article.	Pharmaq AS.
126–050	APRALAN 75 (apramycin) Type A Medicated Article	Elanco US Inc.
138–934	PENNCHLOR S 40/40 (chlortetracycline and sulfamethazine) Type A medicated article.	Pharmgate LLC.
138–935	PENNCHLOR 100 MR (chlortetracycline) Type A Medicated Article.	Pharmgate LLC.
138–938	PENNOX 50, 100, or 200 Hi-Flo, or 100–MR (oxytetracycline) Type A Medicated Article.	Pharmgate LLC.
138–939	NEO-OXY 100/100 MR (oxytetracycline and neomycin) Type A Medicated Article.	Pharmgate LLC.
140–976	NEOMIX 325 Milk Replacer (neomycin) Type A Medicated Article.	Zoetis Inc.
200–314	PENNCHLOR S (chlortetracycline and sulfamethazine) Type A Medicated Article.	Pharmgate LLC.
200–484	TYLOVET 100 (tylosin) Type A Medicated Article	Huvepharma.
200–510	DERACIN 100 (chlortetracycline) Type A Medicated Article	Pharmgate LLC.

The affected applications for manufacturing combination drug medicated feeds follow:

File No.	Animal drug product	Sponsor
036–361	CTC Sodium Sulfate (chlortetracycline and sodium sulfate)/AMPROL PLUS (amprolium and ethopabate).	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
045–444	CHLORMAX (chlortetracycline)/DECCOX (decoquinate)	Zoetis Inc.
046–209	CTC (chlortetracycline)/COYDEN (clopidol)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
092–507	AUREOMYCIN (chlortetracycline)/ROBENZ (robenidine)	Zoetis Inc.
099–006	TERRAMYCIN (oxytetracycline)/COBAN (monensin)	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.).
101–666	TERRAMYCIN (oxytetracycline)/ROBENZ (robenidine)	Phibro Animal Health Corp.

File No.	Animal drug product	Sponsor
104–646	TYLAN (tylosin)/RUMENSIN (monensin)	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (Elanco US Inc.).
110–047	TYLAN (tylosin)/BANMINTH (pyrantel)	Phibro Animal Health Corp.
116–044	LINCOMIX (lincomycin)/BANMINTH (pyrantel)	Phibro Animal Health Corp.
121–553	AUREOMYCIN (chlortetracycline)/COBAN (monensin)	Zoetis Inc.
138–870	TYLAN (tylosin)/RUMENSIN (monensin)/MGA (melengestrol)	Zoetis Inc.
138–941	LINCOMIX (lincomycin)/BANMINTH (pyrantel)	Zoetis Inc.
138–992	TYLAN (tylosin)/BOVATEC (lasalocid)/MGA (melengestrol)	Zoetis Inc.
138–995	TYLAN (tylosin)/MGA (melengestrol)	Zoetis Inc.
139–192	TYLAN (tylosin)/MGA (melengestrol)	Zoetis Inc.
140–448	TERRAMYCIN (oxytetracycline)/BIO–COX (salinomycin)	Phibro Animal Health Corp.
140–859	AUREOMYCIN (chlortetracycline)/BIO–COX (salinomycin)	Zoetis Inc.
140–954	LINCOMIX (lincomycin)/SAFE–GUARD (fenbendazole)	Intervet, Inc.
141–011	CTC (chlortetracycline)/DENAGARD (tiamulin)	Elanco US Inc.
141–054	LINCOMIX (lincomycin)/IVOMEC (ivermectin)	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.
141–059	CHLORMAX (chlortetracycline)/BMD (bacitracin)	Zoetis Inc.
141–147	CHLORMAX (chlortetracycline)/DECCOX (decoquinate)	Zoetis Inc.
141–149	TYLAN (tylosin)/RUMENSIN (monensin)/DECCOX (decoquinate).	Zoetis Inc.
141–172	TYLAN (tylosin)/PAYLEAN (ractopamine)	Elanco US Inc.
141–185	AUREOMYCIN (chlortetracycline)/DECCOX (decoquinate)	Zoetis Inc.
141–201	AUREOMYCIN (chlortetracycline)/CATTLYST (laidlomycin)	Zoetis Inc.
141–211	TERRAMYCIN (oxytetracycline)/(carbadox)	Phibro Animal Health Corp.
141–224	TYLAN (tylosin)/RUMENSIN (monensin)/OPTAFLEXX (ractopamine).	Elanco US Inc.
141–233	TYLAN (tylosin)/RUMENSIN (monensin)/OPTAFLEXX (ractopamine)/MGA (melengestrol).	Elanco US Inc.
141–250	AUREOMYCIN (chlortetracycline)/BOVATEC (lasalocid)	Zoetis Inc.
141–276	TYLAN (tylosin)/RUMENSIN (monensin)/ZILMAX (zilpaterol)	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940 (Intervet, Inc.).
141–280	TYLAN (tylosin)/RUMENSIN (monensin)/ZILMAX (zilpaterol)/MGA (melengestrol).	Intervet, Inc.
200–095	AUREOMYCIN (chlortetracycline)/SACOX (salinomycin)	Huvepharma EOOD.
200–096	TERRAMYCIN (oxytetracycline)/SACOX (salinomycin)	Huvepharma EOOD.
200–242	AUREOMYCIN (chlortetracycline)/BMD (bacitracin)	Zoetis Inc.
200–261	CHLORMAX (chlortetracycline)/BIO–COX (salinomycin)	Zoetis Inc.
200–262	CHLORMAX (chlortetracycline)/SACOX (salinomycin)	Zoetis Inc.
200–263	CHLORMAX (chlortetracycline)/COBAN (monensin)	Zoetis Inc.
200–354	PENNCHLOR (chlortetracycline)/COBAN (monensin)	Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405 (Pharmgate LLC).
200–356	PENNCHLOR (chlortetracycline)/DENAGARD (tiamulin)	Pharmgate LLC.
200–357	PENNCHLOR (chlortetracycline)/BIO–COX (salinomycin)	Pharmgate LLC.
200–358	PENNCHLOR (chlortetracycline)/BMD (bacitracin)	Pharmgate LLC.
200–359	PENNCHLOR (chlortetracycline)/DECCOX (decoquinate)	Pharmgate LLC.
200–375	TYLAN (tylosin)/RUMENSIN (monensin)/HEIFERMAX (melengestrol).	Elanco US Inc.
200–424	TYLAN (tylosin)/RUMENSIN (monensin)/OPTAFLEXX (ractopamine)/HEIFERMAX (melengestrol).	Elanco US Inc.
200–427	TYLAN (tylosin)/HEIFERMAX 500 (melengestrol) Liquid	Elanco US Inc.
200–430	TYLAN (tylosin)/BOVATEC (lasalocid)/HEIFERMAX 500 (melengestrol) Liquid.	Elanco US Inc.
200–480	TYLAN (tylosin)/RUMENSIN (monensin)/ZILMAX (zilpaterol)/HEIFERMAX 500 (melengestrol).	Elanco US Inc.
200–530	TYLOVET (tylosin)/PAYLEAN (ractopamine)	Huvepharma EOOD.
200–531	TYLOVET (tylosin)/RUMENSIN (monensin)	Huvepharma EOOD.
200–532	TYLOVET (tylosin)/MGA (melengestrol)	Huvepharma EOOD.
200–533	TYLOVET (tylosin)/RUMENSIN (monensin)/DECCOX (decoquinate).	Huvepharma EOOD.
200–534	TYLOVET (tylosin)/RUMENSIN (monensin)/MGA (melengestrol).	Huvepharma EOOD.
200–535	TYLOVET (tylosin)/BOVATEC (lasalocid)/MGA (melengestrol).	Huvepharma EOOD.
200–544	TYLOVET (tylosin)/RUMENSIN (monensin)/ZILMAX (zilpaterol)/MGA (melengestrol).	Huvepharma EOOD.
200–547	TYLOVET (tylosin)/RUMENSIN (monensin)/ZILMAX (zilpaterol).	Huvepharma EOOD.
200–558	TYLAN (tylosin)/ENGAIN (ractopamine)	Zoetis Inc.
200–561	TYLAN (tylosin)/RUMENSIN (monensin)/ACTOGAIN (ractopamine).	Zoetis Inc.
200–562	TYLAN (tylosin)/RUMENSIN (monensin)/ACTOGAIN (ractopamine).	Zoetis Inc.
200–566	TYLOVET (tylosin)/RUMENSIN (monensin)	Huvepharma EOOD.
200–567	TYLOVET (tylosin)/RUMENSIN (monensin)	Huvepharma EOOD.

File No.	Animal drug product	Sponsor
200–583	TYLOVET (tylosin)/RUMENSIN (monensin)/ACTOGAIN (ractopamine)/MGA (melengestrol).	Zoetis Inc.
200–584	TYLOVET (tylosin)/ENGAIN (ractopamine)	Zoetis Inc.
200–585	TYLOVET (tylosin)/RUMENSIN (monensin)/ACTOGAIN (ractopamine).	Zoetis Inc.

The animal drug regulations are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect approval of similar supplemental NADAs and ANADAs changing the marketing status of antimicrobial drugs administered to food-producing animals in medicated water.

II. Changes of Sponsorship

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–110, providing for the manufacture of combination drug medicated turkey feeds containing STAFAC (virginiamycin) and COBAN (monensin) to Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this change of sponsorship.

III. Withdrawals of Approval

In addition, approval of the following applications for medicated feeds containing antimicrobial drugs of importance to human medicine administered to food-producing animals is being withdrawn at the sponsors' requests because the products are no longer manufactured or marketed:

File No.	Product name	Sponsor
034–085	LINCOMIX (lincomycin hydrochloride monohydrate) Type A Medicated Article.	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
035–287	OM–5 Premix (oleandomycin) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.).
046–668	Penicillin G Procaine 50% Type A Medicated Article	Phibro Animal Health Corp.
091–668	CHLORMAX–SP 500 (chlortetracycline, sulfamethazine, penicillin G procaine) Type A Medicated Article.	Zoetis Inc.
108–116	LINCOMIX (lincomycin)/NICARB (nicarbazin)	Phibro Animal Health Corp.
133–334	Virginiamycin Type A Medicated Article	Zoetis Inc.
139–473	STAFAC (virginiamycin)/STENEROL (halofuginone hydrobromide).	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
140–340	LINCOMIX (lincomycin)/STENOROL (halofuginone hydrobromide).	Huvepharma EOOD.
140–443	HYGROMIX 1.6 (hygromycin B) Type A Medicated Article	Zoetis Inc.
140–947	LINCOMIX (lincomycin)/MAXIBAN (narasin and nicarbazin)	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (Elanco US Inc.).
141–090	STAFAC (virginiamycin)/CLINICOX (diclazuril)	Huvepharma EOOD.
200–171	LINCOMIX (lincomycin)/NICARMIX (nicarbazin)	Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil.
200–569	TYLAN (tylosin)/SACOX (salinomycin)	Huvepharma EOOD.
200–570	TYLOVET 100 (tylosin)/BIO–COX (salinomycin)	Huvepharma EOOD.
200–580	TYLOVET 100 (tylosin)/SACOX (salinomycin)	Huvepharma EOOD.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 034–085, 035–287, 046–668, 091–668, 108–116, 133–334, 139–473, 140–340, 140–443, 140–947, and 141–090, and ANADAs 200–171, 200–569, 200–570, and 200–580, and all supplements and amendments thereto, is withdrawn, effective January 6, 2017. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.480 [Removed]

■ 2. Remove § 556.480.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 4. In § 558.4, in paragraph (d), in the Category I table, in the column headings for ''Assay limits [1] percent type A'' and ''Assay limits percent [1] type B/C [2]'', remove ''type'' and in its place add ''Type'', and remove the row entries for ''Erythromycin (thiocyanate salt)'' and ''Oleandomycin''; and in the Category II table, alphabetically add an entry for ''Erythromycin'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent [1] Type A	Type B maximum (100×)	Assay limits percent [1] Type B/C [2]
*	*	*	*	*	*	*
Erythromycin	85–115	4.625 g/lb (1.02%)	75–125
*	*	*	*	*	*	*

* * * * *

■ 5. In § 558.58, remove and reserve paragraphs (e)(2), (7), and (8); remove paragraphs (e)(10) and (11); and add paragraph (f) to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

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

(1) [Reserved]

(2) [Reserved]

(3) Chlortetracycline as in § 558.128.

(4) Lincomycin as in § 558.325.

(5) Virginiamycin as in § 558.635.

■ 6. Revise § 558.59 to read as follows:

§ 558.59 Apramycin.

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

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

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

(d) *Conditions of use in swine*—

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

■ 7. In § 558.76, redesignate paragraphs (e)(2)(iii) through (xvi) as paragraphs (e)(2)(iv) through (xvii); and add new paragraph (e)(2)(iii) to read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

* * * * *

(e) * * *

(2) * * *

(iii) Chlortetracycline as in § 558.128.

* * * * *

■ 8. Revise § 558.128 to read as follows:

§ 558.128 Chlortetracycline.

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

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

(1) *Nos. 054771:* 50, 65, or 100 grams per pound (g/lb) Type A medicated article.

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

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

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

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

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

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

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

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

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 100 to 200 g/ton	.....	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption.	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 100 to 200 g/ton	Clopidol, 113.5	Broiler and replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti;* and for control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as the sole ration from the time chicks are placed in floor pens for 7 to 14 days. Do not feed to chickens over 16 weeks of age. Do not feed to chickens producing eggs for human consumption. Chlortetracycline as provided by No. 054771; clopidol as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(iii) 100 to 200 g/ton	Decoquinate, 27.2 ..	Chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* and for control of infectious synovitis caused by *M, synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption. Chlortetracycline and decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 100 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration. Do not use this product in feeds conta. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 200 to 400 g/ton	.....	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption.	054771 066104 069254
(vi) 200 g/ton	Amprolium, 227 and ethopabate, 3.6.	For chickens where immunity to coccidiosis is not desired: For prevention of coccidiosis; and for treatment of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline.	Use in low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption. Chlortetracycline as provided by No. 054771; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter.	054771
(vii) 200 g/ton	Decoquinate, 27.2 ..	Broilers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* and for the treatment of chronic respiratory disease (air sac infection) and the prevention of synovitis.	Feed continuously as the sole ration for no more than 8 weeks. Use in low calcium feed containing 0.8% dietary calcium. Bentonite should not be used in decoquinate feeds. Do not feed to chickens producing eggs for human consumption. Chlortetracycline and decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 200 g/ton	Robenidine 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline; and as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 500 g/ton	.....	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 days. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	054771 069254
			2. Feed for 5 days; withdraw 24 hours prior to slaughter. Do not feed to chickens producing eggs for human consumption.	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(x) 500 g/ton	Monensin, 90 to 110.	Chickens: As an aid in the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline; and as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed for 5 days as the sole ration. Do not feed to laying chickens. Not to be fed continuously for more than 5 days. Do not feed to chickens over 16 weeks of age. Withdraw 24 hours before slaughter. See § 558.355(d) of this chapter. Chlortetracycline as provided by No. 054771; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	054771 069254
(xi) 500 g/ton	Robenidine, 30	Broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.	Feed continuously as sole ration for up to 5 days. Do not use this product in feeds containing bentonite. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. Chlortetracycline and robenidine as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xii) 500 g/ton	Salinomycin, 40 to 60.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.	For use in low calcium feeds containing 0.8% calcium. Not approved for use with pellet binders. Not to be fed continuously for more than 5 days. Do not feed to laying chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by Nos. 054771 or 069254; salinomycin as provided by Nos. 054771 or 016592 in § 510.600(c) of this chapter.	016592 054771 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 200 g/ton	.....	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254
(ii) 400 g/ton	.....	1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254
.....	.....	2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.	.....	054771 066104 069254
(iii) 25 mg/lb of body weight.	.....	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.	054771 066104 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 50 to 100 g/ton ..	.....	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline.	.....	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 400 g/ton	.....	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 days.	054771 066104 069254
(iii) 10 mg/lb of body weight.	.....	Swine: For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254 in § 510.600(c) of this chapter.	054771 066104 069254
(iv) 10 mg/lb of body weight.	Bacitracin methylenedisalicylate, 10 to 30.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 days.	054771
(v) 10 mg/lb of body weight.	Bacitracin methylenedisalicylate, 10 to 30.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide 10 mg/lb of body weight. Feed for not more than 14 days. Withdraw 5 d prior to slaughter for sponsor No. 069254. Bacitracin methylenedisalicylate provided by No. 054771; chlortetracycline provided by Nos. 054771 and 069254 in § 510.600(c) of this chapter.	069254
(vi) 500 to 4,000 to provide 10 mg/lb of body weight daily.	Tiamulin hydrogen fumarate, 35.	For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin and for treatment of swine bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* sensitive to chlortetracycline and treatment of bacterial pneumonia caused by *P. multocida* sensitive to chlortetracycline.	Feed continuously as the sole ration for 14 days. Withdraw medicated feed 2 days before slaughter. Tiamulin as provided by Nos. 058198 or 069254in § 510.600(c) of this chapter.	058198 069254

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

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.5 mg/lb of body weight daily.	.....	Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 25 to 1,100 to provide 0.5 mg/lb of body weight daily.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) over 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis 0.5 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 0.5 to 2.0 mg/lb of body weight daily.	.....	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplsmosis caused by *A. marginale* susceptible to chlortetracycline.	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771
(iv) 10 mg/lb of body weight daily.	.....	1. Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor No. 069254: zero withdrawal time. See paragraph (d)(3) of this section.	054771 066104 069254
		2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	See paragraph (d)(3) of this section	054771 066104 069254
(v) 10 mg/lb of body weight daily.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vi) 10 mg/lb of body weight daily.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) 500 to 2,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(viii) 500 to 1,200 to provide 10 mg/lb of body weight daily.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 500 to 4,000 to provide 10 mg/lb of body weight daily.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(x) 500 to 4,000 g/ton.	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046–699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal period.	054771 069254
(xi) 500 to 4,000	Decoquinate, 12.9 to 90.8.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xii) 4,000 to 20,000 g/ton.	.....	Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(3) of this section.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xiii) 4,000 to 20,000 g/ton.	Decoquinate, 90.8 to 535.7.	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *E. bovis* and *E. zuernii*.	Administer as a top dress supplement or mix into the daily ration to provide 22.7 mg decoquinate per 100 lb of body weight per day and 1 g chlortetracycline per 100 lb body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xiv) 70 mg/head/day.	.....	Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	See paragraph (d)(3) of this section	054771 066104 069254
(xv) 350 mg/head/day.	.....	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-hour withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal period.	054771 066104 069254
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-hour withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	054771 066104 069254
(xvi) 350 mg/head/day.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xvii) 350 mg/head/day.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xviii) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xix) 25 to 42.2 g/ton to provide 350 mg/head/day.	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xx) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxi) 25 to 100 g/ton to provide 350 mg/head/day.	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxii) 25 to 700 to provide 350 mg/head/day.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For control of bacterial pneumonia associated with shipping fever complex caused by *P. multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxiii) 25 to 700 to provide 350 mg/head/day.	Lasalocid, 30 to 600.	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) under 700 pounds: For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline; and for increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxiv) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8.	Beef cattle weighing up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for the control of coccidiosis caused by *E. bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxv) 500 to 4,000 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8.	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline; and for the control of coccidiosis caused by *E. bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

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

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

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

(i) *Specifications.*

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

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

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

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

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

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

■ 9. In § 558.140, redesignate paragraph (d) as paragraph (e) and add new paragraph (d) to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

* * * * *

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

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

* * * * *

§ 558.145 [Removed]

■ 10. Remove § 558.145.

■ 11. In § 558.175, in paragraph (b), remove ''*Approvals*'' and in its place add ''*Sponsor*''; add paragraph (c); remove and reserve paragraphs (d)(5) and (6); and add paragraph (e) to read as follows:

§ 558.175 Clopidol.

* * * * *

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

* * * * *

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

(1) [Reserved]

(2) [Reserved]

(3) Chlortetracycline as in § 558.128.

(4) Lincomycin as in § 558.325.

■ 12. In § 558.195, remove and reserve paragraphs (e)(1)(iv) through (vi), (e)(2)(ii), (e)(2)(iv), and (e)(2)(vii); and add paragraph (e)(4) to read as follows:

§ 558.195 Decoquinate.

* * * * *

(e) * * *

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

(i) [Reserved]

(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

■ 13. In § 558.198, remove and reserve paragraphs (d)(1)(iv) and (v); and add paragraph (d)(3) to read as follows:

§ 558.198 Diclazuril.

* * * * *

(d) * * *

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

■ 14. In § 558.248, revise paragraph (a); redesignate paragraph (d) as paragraph (e); add new paragraph (d); and revise redesignated paragraph (e) to read as follows:

§ 558.248 Erythromycin.

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

* * * * *

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

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

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

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

(2) *Turkeys*—

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

■ 15. In § 558.258, remove and reserve paragraphs (e)(2)(ii) through (v); and add paragraph (e)(6) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

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

(i) [Reserved]

(ii) Lincomycin as in § 558.325.

■ 16. In § 558.265, remove and reserve paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(1)(vii); and add paragraph (d)(4) to read as follows:

§ 558.265 Halofuginone.

* * * * *

(d) * * *

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

(i) [Reserved]

(ii) Lincomycin as in § 558.325.

(iii) Virginiamycin as in § 558.635.

■ 17. Revise § 558.274 to read as follows:

§ 558.274 Hygromycin B.

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

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

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

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

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

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

(1) *Chickens*—

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

(2) Swine—

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

■ 18. In § 558.300, remove and reserve paragraphs (e)(4) through (7); and add paragraph (f) to read as follows:

§ 558.300 Ivermectin.

* * * * *

(f) Ivermectin may also be used in combination with:

(1) [Reserved]

(2) Lincomycin as in § 558.325.

■ 19. In § 558.305, remove paragraphs (e)(2), (e)(3), (e)(5), and (e)(6); redesignate paragraph (e)(4) as new paragraph (e)(2); and add paragraph (f) to read as follows:

§ 558.305 Laidlomycin.

* * * * *

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

■ 20. In § 558.311, in paragraph (e)(1)(i), in the row entry for ''Bambermycins 1 to 2'', in the ''Lasalocid sodium in grams per ton'' column, add ''(ii) 68 (0.0075 pct) to 113 (0.0125 pct).''; in paragraphs (e)(1)(vi) and (vii), remove the row entries for ''Oxytetracycline 7.5''; in paragraph (e)(1)(xv), remove the row entry for ''Virginiamycin 10 to 20''; remove and reserve paragraphs (e)(1)(iii), (e)(1)(v), and (e)(1)(xx) through (e)(1)(xxviii); redesignate paragraph (e)(5)(i) as paragraph (e)(5)(ii); and add new paragraphs (e)(5)(i) and (e)(5)(iii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(5) * * *

(i) Chlortetracycline as in § 558.128.

* * * * *

(iii) Virginiamycin as in § 558.635.

■ 21. Revise § 558.325 to read as follows:

§ 558.325 Lincomycin.

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

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

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

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

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

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

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

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

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

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

(e) Conditions of use—(1) Chickens—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 2	.....	Broilers: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin.	Feed as the sole ration. Not for use in layers, breeders, or turkeys.	054771
(ii) [Reserved]				

(2) *Swine*—

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 40	.....	For control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.	Feed as sole ration. For use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis).	054771
(ii) 40	Fenbendazole, 10 to 80.	For control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(iii) 40	Ivermectin, 1.8	Weaned, growing and finishing swine: For control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred; and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidney worms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(iv) 40	Pyrantel, 96	For control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(v) 40	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(vi) 40 or 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	For treatment of swine dysentery, feed 100 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed for 3 weeks or until clinical signs of the disease disappear, following with 40 grams of lincomycin and 96 grams of pyrantel tartrate per ton of complete feed as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(vii) 100		For treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear.	054771
(viii) 100	Fenbendazole, 10 to 80.	For the treatment of swine dysentery; and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(ix) 100	Ivermectin, 1.8	Weaned, growing and finishing swine: For the treatment of swine dysentery; and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 100 g/ton lincomycin may be continued to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(x) 100	Pyrantel, 96	For the treatment of swine dysentery; as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration for 3 weeks or until clinical signs of the disease disappear. Not to be fed to swine that weigh more than 250 pounds. Withdraw 6 days prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xi) 100	Pyrantel, 96	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.	Feed for 3 days as the sole ration. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xii) 100	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.	Feed as a single therapeutic treatment. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xiii) 200		For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.	Feed as sole ration for 21 days	054771
(xiv) 200	Fenbendazole, 10 to 80.	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and for the removal of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration to provide a total dose of 9 mg fenbendazole/kg of body weight within 3 to 12 days. Do not feed to swine that weigh more than 250 pounds. Do not use within 6 days of slaughter. Lincomycin as provided by No. 054771; fenbendazole as provided by No. 000061 in § 510.600(c) of this chapter.	000061

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(xv) 200	Ivermectin, 1.8	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and for treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg ivermectin/kg of body weight per day. A separate feed containing 200 g/ton lincomycin may be continued for an additional 14 days to complete the lincomycin treatment. Not to be fed to swine that weigh more than 250 lbs. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; ivermectin as provided by No. 050604 in § 510.600(c) of this chapter.	050604
(xvi) 200	Pyrantel, 96	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae;* and as an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.	Feed as the sole ration for 21 days. Not for use in swine that weigh more than 250 pounds. Withdraw 6 days before slaughter. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	054771

■ 22. In § 558.342, remove and reserve paragraphs (e)(1)(iii), (e)(1)(iv), (e)(1)(viii), (e)(1)(ix), and (e)(1)(xi); and revise paragraph (e)(2) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

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

(i) Ractopamine as in § 558.500.

(ii) Tylosin as in § 558.625.

(iii) Zilpaterol as in § 558.665.

■ 23. In § 558.355, revise paragraphs (a) and (b); remove and reserve paragraphs (f)(1)(viii), (f)(1)(ix), (f)(1)(xiii), (f)(1)(xiv), (f)(1)(xxi), (f)(1)(xxii), (f)(1)(xxxi), (f)(2)(iv), (f)(3)(ii), and (f)(3)(xii); and revise paragraph (f)(8) to read as follows:

§ 558.355 Monensin.

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

(b) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for conditions of use as in paragraph (f) of this section:

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

(2) No. 054771 for use as in paragraphs (f)(1)(xxiv) and (xxv) of this section.

(3) No. 058198 for use as in paragraphs (f)(1)(i), (iii), (iv), and (v) of this section.

* * * * *

(f) * * *

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

(i) Chlortetracycline as in § 558.128.

(ii) Decoquinate as in § 558.195.

(iii) Lincomycin as in § 558.325.

(iv) Melengestrol acetate as in § 558.342.

(v) Oxytetracycline as in § 558.128.

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

(vii) Tilmicosin as in § 558.618.

(viii) Tylosin as in § 558.625.

(ix) Virginiamycin as in § 558.635.

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

■ 24. In § 558.364, redesignate paragraph (d) as paragraph (e) and revise paragraphs (a) through (d) to read as follows:

§ 558.364 Neomycin sulfate.

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

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

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

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

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

* * * * *

■ 25. In § 558.366, in the table in paragraph (d), remove the row entries under ''Nicarbazin in grams per ton'' ''27 to 45'' for ''Narasin 27 to 45 and Lincomycin 2 to 4''; and under ''Nicarbazin in grams per ton'' ''113.5 (0.0125 pct)'' for ''Lincomycin 2 (0.00044 pct)''; and add paragraph (e) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(e) * * *

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

(i) [Reserved]

(ii) Lincomycin as in § 558.325.

§ 558.435 [Removed]

■ 26. Remove § 556.435.

■ 27. Revise § 558.450 to read as follows:

§ 558.450 Oxytetracycline.

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

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

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

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

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

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

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

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

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

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

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

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

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vii) 500 g/ton	Salinomycin, 40 to 60.	Chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and as an aid in the reduction of mortality due to air-sacculitis (air sac infection) caused by *E. coli* sensitive to oxytetracycline.	Feed for 5 days as the sole ration. Treat at first clinical signs of the disease. Do not feed to laying chickens. Do not use in feed containing less than 0.55% dietary calcium. Use in such low calcium feeds may result in violative residues. Withdraw 24 hours before slaughter. Oxytetracycline as provided by No. 066104; salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	066104 016592

(2) *Turkeys*—

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

(3) *Swine*—

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

(4) *Cattle*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	.....	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
		2. Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days in milk replacer or starter feed. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(ii) 75 mg/head/day	.....	Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	Feed continuously	066104 069254
(iii) 0.5 to 2.0 g/head/day.	.....	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 days before and after arrival in feedlots.	066104 069254

(5) *Minor species*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter.	066104 069254
(ii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	066104 069254
(iii) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day).	Pacific salmon: For marking of skeletal tissue	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 days following the last administration of medicated feed.	066104
(iv) 2.5 to 3.75 g/100 lb of fish/day.	1. Salmonids: For control of ulcer disease caused by *Haemophilus piscium,* furunculosis caused by *Aeromonas salmonicida,* bacterial hemorrhagic septicemia caused by *A. liquefaciens,* and pseudomonas disease.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F).	066104
(v) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Freshwater-reared *Oncorhynchus mykiss:* For control of mortality due to columnaris disease associated with *Flavobacterium columnare*.	Administer in mixed ration for 10 days; do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
(vi) 1 g/lb of medicated feed.	Lobsters: For control of gaffkemia caused by *Aerococcus viridans*.	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 days before harvesting lobsters.	066104

■ 28. In § 558.455, revise paragraph (d); remove and reserve paragraphs (e)(1)(i), (e)(2)(i), (e)(3)(i), (e)(4)(i), (e)(4)(ii), and (e)(4)(iv); and in paragraph (e)(4)(v), remove ''increased rate of weight gain; improved feed efficiency, and'' to read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

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

(2) The expiration date of VFDs for oxytetracycline and neomycin

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

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

* * * * *

§ 558.460 [Removed]

■ 29. Remove § 558.460.

■ 30. In § 558.485, remove paragraphs (e)(1)(v) through (xii); and add paragraph (e)(3) to read as follows:

§ 558.485 Pyrantel.

* * * * *

(e) * * *

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

(i) Lincomycin as in § 558.325.

(ii) Tylosin as in § 558.325.

■ 31. In § 558.500, remove and reserve paragraphs (e)(1)(ii), (iii), and (iv), (e)(2)(iv), (e)(2)(ix) and (x); remove paragraph (e)(2)(xiii); and add paragraph (e)(4) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

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

■ 32. In § 558.515, in the table in paragraph (d), remove the row entries for ''Chlortetracycline 100 to 200'', ''Chlortetracycline 200 to 400'', ''Chlortetracycline 500'', ''Lincomycin 2'', and ''Oxytetracycline 400'' in the ''Combination in grams/ton'' column; and add paragraph (e) to read as follows:

§ 558.515 Robenidine.

* * * * *

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

(1) Chlortetracycline as in § 558.128.

(2) Lincomycin as in § 558.325.

(3) Oxytetracycline as in § 558.450.

■ 33. In § 558.550, remove and reserve paragraphs (d)(1)(x), (d)(1)(xi), (d)(1)(xiii), and (d)(1)(xvi); and revise paragraph (d)(4) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(d) * * *

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

(i) [Reserved]

(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

(v) Oxytetracycline as in § 558.450.

(vi) Virginiamycin as in § 558.635.

■ 34. In § 558.555, remove paragraphs (d)(3) through (5); (e)(3) and (e)(4); remove and reserve paragraph (e)(2); and add paragraph (f) to read as follows:

§ 558.555 Semduramycin.

* * * * *

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

■ 35. In § 558.575, revise the section heading; redesignate paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e); revise paragraph (a); and add new paragraphs (b) and (d) to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

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

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

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim.

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

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraphs (e)(1), (e)(2), (e)(3), (e)(4), and (e)(7) of this section.

(2) No. 015331 for use of the product described in paragraph (a)(2) as in paragraphs (e)(5) and (e)(6) of this section.

* * * * *

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

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

* * * * *

■ 36. Revise § 558.582 to read as follows:

§ 558.582 Sulfamerazine.

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

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

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

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

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

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

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

■ 37. Revise § 558.586 to read as follows:

§ 558.586 Sulfaquinoxaline.

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

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

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

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

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

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

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

(2) *Turkeys*—

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

(3) *Rabbits*—

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

■ 38. In § 558.612, remove paragraphs (e)(1)(i) and (e)(1)(iii); redesignate paragraphs (e)(1)(ii) and (e)(1)(iv) as new paragraphs (e)(1)(i) and (ii); and add paragraph (e)(2) to read as follows:

§ 558.612 Tiamulin.

* * * * *

(e) * * *

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

■ 39. Amend § 558.625 as follows:

■ a. Remove paragraph (d);

■ b. Redesignate paragraphs (c), (e), and (f) as paragraphs (d), (c) and (e); and

■ c. Revise paragraph (b) and redesignated paragraphs (d) and (e).

The revisions read as follows:

§ 558.625 Tylosin.

* * * * *

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

(1) No. 016592: Type medicated article containing 100 grams per pound.

(2) No. 054771: Type medicated article containing 40 grams per pound.

(3) No. 058198: Type medicated article containing 10, 40, or 100 grams per pound.

(4) No. 066104: Type medicated article containing 20 or 40 grams per pound.

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

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

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

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

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

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

the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Conditions of use*—(1) *Swine*—

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

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

(2) Cattle—

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

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(ii) 90 to 360	Lasalocid, 100 to 1440 plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Feed to heifers at the rate of 0.5 to 2.0 pound(s) per head per day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate per head per day (specify one level), 100 to 360 mg lasalocid per head per day (specify one level), and 90 mg tylosin per head per day. This Type C product may be top dressed onto or mixed into a complete feed prior to feeding. Tylosin as provided by Nos. 058198 and 016592; lasalocid as provided by No. 054771; melengestrol as provided by Nos. 054771 and 058198 in § 510.600(c) of this chapter.	054771 016592
(iii) 90 to 360	Melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Each pound contains 0.125 to 1.0 mg melengestrol acetate and 45 to 180 mg of tylosin. Feed to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg melengestrol acetate and 60 to 90 mg tylosin per head per day. Prior to feeding, this Type C product must be top-dressed onto a complete feed or mixed into the amount of complete feed consumed by an animal per day. Tylosin provided by No. 058198; melengestrol provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 8 to 10	Monensin, 5 to 40 ..	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for improved feed efficiency.	Feed continuously as sole ration to provide 50 to 480 monensin mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	016592 058198
(v) 8 to 10	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and for prevention of coccidiosis caused by *Eimeria bovis* and *E zuernii*.	Feed continuously as sole ration to provide 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	016592 058198
(vi) 8 to 10	Monensin, 5 to 30 plus decoquinate, 13.6 to 22.7.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for improved feed efficiency.	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin/head/day, and 60 to 90 mg of tylosin/head/day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by Nos. 016592 and 058198; monensin as provided by No. 058198; decoquinate as provided by No. 058198 in § 510.600(c) of this chapter.	016592 054771

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(vii) 8 to 10	Monensin, 10 to 40 plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; melengestrol provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(viii) 8 to 10	Monensin, 10 to 40 plus ractopamine, 8.2 to 24.6.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed continuously as sole ration to provide 70 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter.	054771 058198
(ix) 8 to 10	Monensin, 10 to 40 plus ractopamine, not to exceed 800.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.	Feed a minimum of 1.0 lb/head/day ractopamine Type C top dress feed continuously to cattle fed in confinement for slaughter, to provide 70 to 400 mg/head/day ractopamine for the last 28 to 42 days on feed. Feed on top of a ration containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin phosphate, to provide 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin provided by Nos. 016592 or 058198; monensin as provided by No. 058198; ractopamine provided by Nos. 054771 or 058198 in § 510.600(c) of this chapter.	054771 058198

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

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

■ 40. Revise § 558.630 to read as follows:

§ 558.630 Tylosin and sulfamethazine.

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

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

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

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

(c) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

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

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

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

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

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

■ 41. Revise § 558.635 to read as follows:

§ 558.635 Virginiamycin.

(a) *Specifications.* Type A medicated articles containing 5, 10, 20, 50, 136.2, or 227 grams per pound virginiamycin.

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

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

(d) *Special considerations*—(1) [Reserved]

(2) [Reserved]

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

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

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

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 5		Broiler chickens: For increased rate of weight gain and improved feed efficiency.	Not for use in layers	066104
(ii) 5	Monensin, 90 to 110.	Broiler chickens: 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. maxima,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying chickens. Virginiamycin as provided by No. 066104; monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(iii) 5	Salinomycin, 40 to 60.	Broiler chickens: For increased rate of weight gain and improved feed efficiency; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to layers or to chickens over 16 weeks of age. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 066104; salinomycin as provided by No. 054771 in § 510.600(c) of this chapter.	066104 016592
(iv) 5	Semduramicin, 22.7	Broiler chickens: For increased rate of weight gain and improved feed efficiency; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(v) 5	Semduramicin (biomass), 22.7.	Broiler chickens: For increased rate of weight gain and improved feed efficiency; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Virginiamycin and semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(vi) 5 to 15		Broiler chickens: For increased rate of weight gain.	Not for use in layers	066104

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(vii) 5 to 15	Amprolium, 113.5 and ethopabate, 36.3.	Broiler chickens: For increased rate of weight gain; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Feed continuously as the sole ration and as the sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter.	066104
(viii) 5 to 15	Monensin, 90 to 110.	Broiler chickens: For increased rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying chickens. Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	066104
(ix) 5 to 15	Salinomycin, 40 to 60.	Broiler chickens: For increased rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to layers or to chickens over 16 weeks of age. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 066104; salinomycin as provided by Nos. 016592 or 054771 in § 510.600(c) of this chapter.	016592 066104
(x) 5 to 15	Semduramicin, 22.7	Broiler chickens: For increased rate of weight gain; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xi) 5 to 15	Semduramicin (biomass), 22.7.	Broiler chickens: For increased rate of weight gain; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Virginiamycin as provided by No. 066104; semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xii) 15	Amprolium, 113.5 and ethopabate, 36.3.	Broiler chickens: For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Feed continuously as the sole ration and as the sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter.	066104
(xiii) 20		Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin.	Not for use in layers	066104
(xiv) 20	Lasalocid, 68 to 113.	Broiler chickens: For increased rate of weight gain and improved feed efficiency; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed continuously as the sole ration. Do not feed to laying chickens. Lasalocid sodium as provided by No. 054771 in § 510.600(c) of this chapter.	066104
(xv) 20	Monensin, 90 to 110.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying chickens. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(xvi) 20	Semduramicin, 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(xvii) 20	Semduramicin (biomass), 22.7.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104

(2) *Turkeys*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 10 to 20		Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Not for use in layers	066104
(ii) 10 to 20	Lasalocid, 68 to 113.	Growing turkeys: For increased rate of weight gain and improved feed efficiency; and for the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides*.	Lasalocid sodium as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 10 to 20	Monensin, 90 to 110.	Growing turkeys: For increased rate of weight gain and improved feed efficiency; and for the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides*.	Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104

(3) *Swine*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 5 or 10		Growing-finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously from weaning to market weight. Feed 10 grams per ton from weaning up to 120 pounds, followed by 5 grams per ton to market weight.	066104
(ii) 5 to 10		Growing-finishing swine: For increased rate of weight gain.	Feed continuously from weaning to market weight. Feed 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.	066104
(iii) 25		Growing-finishing swine: As an aid in control of dysentery in swine up to 120 pounds in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.		066104
(iv) 50 or 100		Growing-finishing swine: For treatment and control of swine dysentery in swine up to 120 pounds.	Feed 100 grams per ton for 2 weeks, 50 grams per ton thereafter.	066104
(v) 100		Growing-finishing swine: For treatment of swine dysentery in nonbreeding swine over 120 pounds.	Feed for 2 weeks	066104

(4) *Cattle*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 11.0 to 16.0		Cattle fed in confinement for slaughter: For improved feed efficiency.	Feed continuously as the sole ration to provide 70 to 240 milligrams per head per day. Not for use in animals intended for breeding.	066104
(ii) 13.5 to 16.0		Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses.	Feed continuously as the sole ration to provide 85 to 240 milligrams per head per day. Not for use in animals intended for breeding.	066104
(iii) 16.0 to 22.5		Cattle fed in confinement for slaughter: For increased rate of weight gain.	Feed continuously as the sole ration to provide 100 to 340 milligrams per head per day. Not for use in animals intended for breeding.	066104

■ 42. In § 558.665, remove and reserve paragraphs (e)(5) and (6); remove paragraphs (e)(11) and (12); and add paragraph (f) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

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

■ 43. In § 558.680, remove paragraph (d)(1)(x); and add paragraph (e)(3) to read as follows:

§ 558.680 Zoalene.

* * * * *

(e) * * *

(3) Zoalene may also be used in combination with lincomycin as in § 558.325.

Dated: December 20, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016–31083 Filed 12–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 11 new animal drug applications (NADAs) and 4 abbreviated new animal drug applications (ANADAs). These withdrawals of approval of NADAs and ANADAs for antimicrobial drugs of importance to human medicine that are administered to food-producing animals in medicated feed are being made because the products are no longer being manufactured or marketed. These actions are consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

DATES: Withdrawal of approval is effective December 30, 2016.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is withdrawing approval of 11 NADAs and 4 ANADAs. These applications were identified as being affected by guidance for industry (GFI) #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209,'' December 2013 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*). Their withdrawal of approval is consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors' requests because these products are no longer manufactured or marketed:

File No.	Product name	Sponsor
034–085	LINCOMIX (lincomycin hydrochloride monohydrate) Type A Medicated Article.	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
035–287	OM–5 Premix (oleandomycin) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.
046–668	Penicillin G Procaine 50% Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.
091–668	CHLORMAX–SP 500 (chlortetracycline, sulfamethazine, penicillin G procaine) Type A Medicated Article.	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
108–116	LINCOMIX (lincomycin)/NICARB (nicarbazin)	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.
133–334	Virginiamycin Type A Medicated Article	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
139–473	STAFAC (virginiamycin)/STENEROL (halofuginone hydrobromide).	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.
140–340	LINCOMIX (lincomycin)/STENOROL (halofuginone hydrobromide).	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.
140–443	HYGROMIX 1.6 (hygromycin B) Type A Medicated Article	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.
140–947	LINCOMIX (lincomycin)/MAXIBAN (narasin and nicarbazin)	Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140.
141–090	STAFAC (virginiamycin)/CLINICOX (diclazuril)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.
200–171	LINCOMIX (lincomycin)/NICARMIX (nicarbazin)	Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil.
200–569	TYLAN (tylosin)/SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.
200–570	TYLOVET 100 (tylosin)/BIO–COX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.
200–580	TYLOVET 100 (tylosin)/SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 034–085, 035–287, 046–668, 091–668, 108–116, 133–334, 139–473,