was less than $500,000, adjusted for inflation.

* * * * *

■ 4. In § 112.161, revise paragraph (b) to read as follows:

§ 112.161 What general requirements apply to records required under this part?

* * * * *

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROS FOR HUMAN FOOD

■ 5. The authority citation for part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. In § 117.126, revise paragraph (b)(5) to read as follows:

§ 117.126 Food safety plan.

* * * * *

(b) * * *

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a);

* * * * *

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

■ 7. The authority citation for part 507 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 8. In § 507.31, revise paragraph (c)(5) to read as follows:

§ 507.31 Food safety plan.

* * * * *

(c) * * *

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a);

* * * * *

■ 9. In § 507.130, revise paragraph (c)(2)(ii) to read as follows:

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.

* * * * *

(c) * * *

(2) * * *

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

* * * * *

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06141 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, 556, and 558

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2018. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the readability of the regulations.

DATES: This rule is effective April 2, 2019.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2018, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2018

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 1, 2018	200–490	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.	Carprofen, Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2018—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 15, 2018	141–485	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	Lincomycin and clopidol, Type C medicated feeds.	Chickens ...	Original approval for use of LINCOMIX (lincomycin) and COYDEN (clopidol) Type A medicated articles in the manufacture of Type C medicated broiler chicken feeds for the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E maxima, E. brunetti,* and *E. mivati*.	FOI Summary.
November 1, 2018.	200–627	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.	Cyclosporine Capsules, USP MODIFIED.	Dogs	Original approval as a generic copy of NADA 141–218.	FOI Summary.
November 6, 2018.	141–508	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	EXPERIOR (lubabegron) Type A medicated article to be used in the manufacture of Type B and Type C medicated feeds.	Cattle	Original approval for reduction of ammonia gas emissions per pound of live weight and hot carcass weight in beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed.	FOI Summary EA/FONSI.[1]
November 9, 2018.	141–502	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	REVOLUTION PLUS (selamectin and sarolaner topical solution).	Cats	Original approval for the prevention of heartworm disease caused by *Dirofilaria immitis*. Kills adult fleas *(Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations; the treatment and control of tick infestations with *Ixodes scapularis* (black-legged or deer tick), *Amblyomma maculatum* (Gulf Coast tick), and *Dermacentor variabilis* (American dog tick); the treatment and control of ear mite *(Otodectes cynotis)* infestations; and the treatment and control of roundworm *(Toxocara cati)* and intestinal hookworm *(Ancylostoma tubaeforme)* infections in cats and kittens 8 weeks of age and older, and weighing 2.8 pounds or greater.	FOI Summary.
November 21, 2018.	038–439	Phibro Animal Health, Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	TERRAMYCIN (oxytetracycline), Type A medicated article.	Salmonids	Supplemental approval for marking the skeletal tissue of freshwater-reared salmonids.	FOI Summary.
December 4, 2018.	141–509	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.	PEXION (imepitoin tablets).	Dogs	Original approval for the treatment of noise aversion in dogs.	FOI Summary.
December 19, 2018.	200–629	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	MILBEGUARD (milbemycin oxime), Flavored Tablets.	Dogs and cats.	Original approval as a generic copy of NADA 140–915.	FOI Summary.
December 27, 2018.	141–511	LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702.	Bc2371 rDNA construct in R69 New Zealand white rabbits.	R69 New Zealand white rabbits.	Original approval for expression of a gene for recombinant human Factor VII (rhFVIIa) in R69 New Zealand white rabbits.	FOI Summary EA/FONSI.[1]

[1] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

II. Change of Sponsorship

Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria, has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.

File No.	Product name	21 CFR section
140–951	CLINACOX (diclazuril) Type A Medicated Article	558.198
141–153	CLINACOX (diclazuril)/BMD (bacitracin methylenedisalicylate)	558.198
141–158	CLINACOX (diclazuril)/FLAVOMYCIN (bambermycins)	558.198
141–194	CLINACOX (diclazuril)/BMD (bacitracin methylenedisalicylate)	558.198

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Technical Amendments

We are reformatting the regulations in subpart B of part 558 for certain medicated feeds to present their approved conditions of use in the current tabular format. In addition, we are removing cross-referencing citations for indications for use of combination drug medicated feeds wherever they have been used and in their place are adding the full text of the indications. These actions are being taken to improve the consistency and readability of the regulations.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 528

Animal drugs.

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, 21 CFR parts 510, 520, 522, 524, 528, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), revise the entry for ''AquaBounty Technologies, Inc.'' and alphabetically add an entry for ''Dragon Fire Holding Co., Inc.''; and in the table in paragraph (c)(2), numerically add an entry for ''076033'' and revise the entry for ''086053'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754	086053
* * * * * * *	
Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052	076033
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
076033	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.
* * * * * * *	
086053	AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

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

§ 520.304 [Amended]

■ 4. In § 520.304, in paragraph (b)(1), remove ''054771, 026637, 055529, and 062250'' and in its place add ''026637, 054771, 055529, 062250, and 076033''.

■ 5. In § 520.522, revise paragraph (b) to read as follows:

§ 520.522 Cyclosporine.

* * * * *

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

(1) No. 058198 for use of products described in paragraph (a) as in paragraph (d) of this section.

(2) No. 026637 for use of product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

* * * * *

■ 6. Add § 520.1150 to read as follows:

§ 520.1150 Imepitoin.

(a) *Specifications.* Each tablet contains 100 or 400 milligrams (mg) imepitoin.

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

(c) *Conditions of use*—(1) *Amount.* Administer orally twice daily, approximately 12 hours apart, at a dose of 13.6 mg per pound (30 mg/kg) of body weight. Initiate therapy starting 2 days prior to the day of the expected noise event and continuing through the noise event.

(2) *Indications for use.* For the treatment of noise aversion in dogs.

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

■ 7. Revise § 520.1441 to read as follows:

§ 520.1441 Milbemycin.

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

(b) *Sponsors.* See Nos. 013744 and 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* For hookworm, roundworm, and whipworm, administer 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)). For heartworm, administer 0.05 mg/lb of body weight (0.1 mg/kg). Administer once a month.

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

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

(2) *Cats*—(i) *Amount.* Administer 0.91 mg/lb of body weight (2.0 mg/kg) once a month.

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

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

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for part 522 continues to read as follows:

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

■ 9. Amend § 522.1662a by adding two sentences at the end of paragraph (h)(3)(iii) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(h) * * *

(3) * * *

(iii) * * * A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for part 524 continues to read as follows:

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

■ 11. Add § 524.2099 to read as follows:

§ 524.2099 Selamectin and sarolaner.

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) selamectin and 10 mg sarolaner. The drug is provided in single dose tubes containing 0.25, 0.5, or 1 mL of solution.

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

(c) *Conditions of use in cats*—(1) *Amount.* Administer 2.7 mg selamectin per pound (/lb) (6 mg per kilogram (/kg)) of body weight and 0.45 mg/lb sarolaner (1 mg/kg) by emptying the contents of the tube on the back of the animal at the base of the neck in front of the shoulder blades.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis.* Kills adult fleas *(Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations; the treatment and control of tick infestations with *Ixodes scapularis* (black-legged or deer tick), *Amblyomma maculatum* (Gulf Coast tick), and *Dermacentor variabilis* (American dog tick); the treatment and control of ear mite *(Otodectes cynotis)* infestations; and the treatment and control of roundworm *(Toxocara cati)* and intestinal hookworm *(Ancylostoma tubaeforme)* infections in cats and kittens 8 weeks of age and older, and weighing 2.8 pounds or greater.

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

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

■ 12. The authority citation for part 528 continues to read as follows:

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

■ 13. Add § 528.1080 to read as follows:

§ 528.1080 Bc2371 recombinant deoxyribonucleic acid construct.

(a) *Specifications and intended use.* A single copy of Bc2371, a human Factor VII recombinant deoxyribonucleic acid (rDNA) gene construct, located on chromosome 3p1.1–2 in a diploid line (R69) of hemizygous and homozygous New Zealand white rabbits (*Oryctolagus cuniculus*).

(b) *Sponsor.* See No. 086047 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Intended use.* The construct directs gene expression of recombinant human Factor VII (hFVII) in the mammary gland such that recombinant hFVII zymogen is present in the rabbit milk, enabling purification and activation of recombinant hFVIIa intended for the treatment of hemophilia A or B in humans with inhibitors to Factors VIII and IX.

(2) *Limitations.* Food or feed from R69 rabbits is not permitted in the food or feed supply.

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

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

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

■ 15. Add § 556.370 to subpart B to read as follows:

§ 556.370 Lubabegron.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lubabegron is 3 micrograms per kilogram of body weight per day.

(b) *Tolerance in cattle.* The tolerance for lubabegron (marker residue) is:

(1) *Cattle—Liver (target tissue):* 10 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.330 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 17. In § 558.4, in paragraph (d), in the ''Category I'' table, alphabetically add an entry for ''Lubabegron'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent [1] Type A	Type B maximum (200x)	Assay limits percent [1] Type B/C [2]
* * *	* * *	* * *	
Lubabegron	87–107	908 g/ton	85–115/80–120
* * *	* * *	* * *	

* * * * *

■ 18. In § 558.140, revise paragraphs (e)(1) and (2) to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

* * * * *

(e) * * *

(1) *Cattle*—

Chlortetracycline and sulfamethazine amount	Indications for use	Limitations	Sponsors
(i) To provide 350 milligrams per head per day each, chlortetracycline and sulfamethazine.	Beef cattle: For aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.	Feed for 28 days; withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 069254
(ii) [Reserved]			

(2) *Swine*—

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

* * * * *

■ 19. In § 558.175, revise paragraph (d) to read as follows:

§ 558.175 Clopidol.

* * * * *

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

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 113.5		Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Do not feed to chickens over 16 weeks of age	016592
(ii) 113.5	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(iii) 113.5	Bacitracin zinc, 5 to 25	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771 016592
(iv) 113.5	Bambermycins, 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age.	016592

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(v) 227		Broiler and replacement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	016592
(vi) 227	Bambermycins, 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age.	016592

(2) *Turkeys*—

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

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

(i)–(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

■ 20. In § 558.195, revise paragraphs (e)(1) through (3) to read as follows:

§ 558.195 Decoquinate.

* * * * *

(e) * * *

(1) *Chickens*—

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2		Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*	Do not feed to laying hens producing eggs for human consumption.	054771
(ii) 27.2	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 27.2	Bacitracin zinc, 10 to 50	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(2) *Cattle*—

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for human consumption. See paragraph (d)(3) of this section.	054771
(ii) 12.9 to 90.8	Monensin, 5 to 30	Cattle fed in confinement for slaughter: For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for improved feed efficiency.	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb of body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and § 558.355(d)(9)(i). Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	054771

Decoquinate in grams/ton	Combination in grams/ ton	Indications for use	Limitations	Sponsor
(iii) 90.9 to 535.7 ...		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section.	054771

(3) *Minor species—*

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

* * * * *

§§ 558.198 and 558.205 [Redesignated as §§ 558.205 and 558.198]

■ 21. Redesignate §§ 558.198 and 558.205 as §§ 558.205 and 558.198, respectively.

■ 22. Revise newly redesignated § 558.198 to read as follows:

§ 558.198 Dichlorvos.

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

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

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

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

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

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

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

Dichlorvos grams/ton	Combination in grams/ ton	Indications for use	Limitations	Sponsor
(i) 348		Swine up to 70 pounds body weight: For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum* sp.), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.	Feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.	054628

Dichlorvos grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 479		Boars, open or bred gilts, and sows: For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum* sp.), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.	Feed as sole ration at the rate of 6 pounds per head for one feeding.	054628
(iii) 334 to 500		Pregnant swine: An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum spp.*) large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.	Mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.	054628

■ 23. In newly redesignated § 558.205, revise paragraphs (b) and (d)(1) and (2) to read as follows:

§ 558.205 Diclazuril.

* * * * *

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

* * * * *

(d) * * *

(1) *Chickens.* For chickens it is used as follows:

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

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

Diclazuril grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91		Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis.*	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption.	058198
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91	Bambermycins, 1 to 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis,* and for improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

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

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■ 24. In § 558.258, revise paragraph (e)(2) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(2) *Swine.*

Fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period..		For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as the sole ration	000061
(ii) 10 to 300 (to provide 9 mg/kg of body weight)..	Bacitracin methylenedisalicylate, 10 to 30.	Growing/finishing swine: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter	054771
(iii) 10 to 300 (to provide 9 mg/kg of body weight)..	Bacitracin methylenedisalicylate, 250.	1. Growing/finishing swine: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter	054771
		2. Pregnant sows: For the removal and control of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*); for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens.*	2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	

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■ 25. In § 558.300, revise paragraph (e) to read as follows:

§ 558.300 Ivermectin.

* * * * *

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

Ivermectin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 1.8		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 milligrams per kilograms (mg/kg) of body weight per day. Withdraw 5 days before slaughter.	050604
(2) 1.8	Bacitracin methylenedisalicylate, 10 to 30.	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for increased rate of weight gain and improved feed efficiency.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(3) 1.8	Bacitracin methylenedisalicylate, 250.	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(4) 1.8 to 11.8		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(5) 1.8 to 11.8	Bacitracin methylenedisalicylate, 250.	Pregnant sows: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter. Feed bacitracin methylenedisalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604

Ivermectin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(6) 18.2 to 120		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum,* adults and fourth-stage larvae; *Ascarops strongylina,* adults; *Hyostrongylus rubidus,* adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus,* adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi,* adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Top dress on daily ration for individual treatment for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604

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■ 26. In § 558.325, add paragraph (e)(1)(iii) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(1) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	*	*
(iii) 2	Clopidol, 113.5	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid in the prevention of cecal and intestinal coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed as the sole ration to broiler chickens. Do not feed to chickens over 16 weeks of age. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Clopidol as provided by No. 016592 in § 510.600 of this chapter.	054771
*	*	*	*	*

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■ 27. Add § 558.330 to read as follows:

§ 558.330 Lubabegron.

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

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

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

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

Lubabegron grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(1) 1.25 to 4.54		Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed.	Feed 1.25 to 4.54 g/ton (1.39 to 5 ppm) of complete feed (90% dry matter basis) to provide 13 to 90 milligrams lubabegron/head/day continuously. Do not allow horses or other equines access to feed containing lubabegron. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals.	058198
(ii) [Reserved]				

■ 28. In § 558.415, revise paragraph (d) to read as follows:

§ 558.415 Novobiocin.

* * * * *

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

(1) *Chickens*—

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

(2) *Turkeys*—

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

(3) *Minor species*—

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) 350 grams per ton.	Ducks: For the control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida,* susceptible to novobiocin.	Administer as the sole ration for 5 to 7 days. Continue medication for 14 days if necessary. Repeat if reinfection occurs. Discontinue use at least 3 days before slaughter. Not for use in laying ducks.	054771
(ii) To provide 20 mg/lb of body weight per day.	Mink: For the treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 7 days.	054771

■ 29. In § 558.450, redesignate paragraphs (e)(5)(iii), (iv), and (v) as paragraphs (e)(v), (iii), and (iv) respectively; and revise newly redesignated paragraphs (e)(5)(iv) and (v) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(5) * * *

Oxytetracycline amount	Indications for use	Limitations	Sponsor
*	* * *	* * *	
(iv) 3.75 g/100 lb of fish/day.	* * *	* * *	066104
	3. Freshwater-reared salmonids weighing up to 55 grams: For marking the skeletal tissue.	Feed for 10 days. Immediate release is permitted following the last feeding of medicated feed.	
(v) 11.35 g/100 lb of fish/day.	Pacific salmon not over 30 grams body weight: For marking of skeletal tissue.	Administer medicated feed as the sole ration for 4 consecutive days. Do not liberate for at least 7 days following last feeding of medicated feed.	066104
*	* * *	* * *	

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■ 30. In § 558.575, revise paragraphs (b) and (e) to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

* * * * *

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

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

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

* * * * *

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

(1) *Chickens*—

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

(2) *Turkeys*—

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

(3) *Minor species*—

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

■ 30. Revise § 558.600 to read as follows:

§ 558.600 Thiabendazole.

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

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

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

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

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

(1) *Cattle*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) To provide 3 grams per 100 lb of body weight.	Cattle: For control of infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Nematodirus* spp., *Oesophagostomum radiatum*).	Use 3 grams per 100 lb of body weight as a single dose. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604

Thiabendazole amount	Indications for use	Limitations	Sponsor
(ii) To provide 5 grams per 100 lb of body weight.	Cattle: For control of severe infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Nematodirus* spp., *Oesophagostomum radiatum*); control of infections of *Cooperia* spp.	Administer 5 grams per 100 lb of body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604

(2) *Swine*—

Thiabendazole in grams/ton	Indications for use	Limitations	Sponsor
(i) 45.4 to 908	Swine: As an aid in the prevention of infections of large roundworms (genus *Ascaris*).	Administer continuously feed containing 0.05 to 0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005 to 0.02 percent thiabendazole per ton for 8 to 14 weeks. Do not treat animals within 30 days of slaughter.	050604
(ii) [Reserved]			

(3) *Minor species*—

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

■ 31. In § 558.633, revise paragraph (e) to read as follows:

§ 558.633 Tylvalosin.

* * * * *

(e) *Conditions of use.*

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

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06136 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P