humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–05877 Filed 3–18–21; 8:45 am]

BILLING CODE 9112–FP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA–2020–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, Department of Health and Human Services (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 July, August, and September 2020. 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 improve the accuracy and readability of the regulations.

DATES: This rule is effective March 19, 2021.

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. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2020, 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, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book*.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 9, 2020	141–532	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO 1-MONTH (furalaner) Chews for Dogs.	Dogs	Original approval for the treatment and prevention of flea infestations, and the treatment and control of tick infestations for 1 month in dogs and puppies.	FOI Summary.
July 27, 2020	141–538	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	CARDALIS (spironolactone and benazepril hydrochloride chewable tablets).	Dogs	Original approval with concurrent therapy (*e.g.,* furosemide, etc.) for the management of clinical signs of mild, moderate, or severe congestive heart failure in dogs due to atrioventricular valvular insufficiency (AVVI).	FOI Summary.
July 29, 2020	200–687	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	Carprofen Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.
August 4, 2020	200–681	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.	Carprofen Tablets	Dogs	Original approval as a generic copy of NADA 140–035.	FOI Summary.
September 9, 2020	141–529	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.	MAXIBAN (naracin and nicarbazin) plus PENNITRACIN MD (bacitracin methylenedisalicylate) Type C medicated feeds.	Chickens	Original approval for increased rate of weight gain, improved feed efficiency, and for the prevention of coccidiosis in broiler chickens.	FOI Summary.
September 18, 2020.	200–690	Pharmasone LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.	ZOASHIELD 25% (zoalene Type A medicated article).	Chickens, turkeys.	Original approval as a generic copy of NADA 141–218.	FOI Summary.
September 28, 2020.	200–069	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	OVACYST (gonadorelin) Injectable Solution.	Cattle	Supplemental approval for fixed-time artificial insemination (FTAI) in beef cows and lactating dairy cows.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND—Continued SEPTEMBER 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
September 29, 2020.	200–528	Pharmgate, Inc, 1800 Sir Tyler Dr., Wilmington, NC 28405.	SAVALAN 60 (salinomycin sodium) Type A medicated article.	Chickens, quail	Original approval as a generic copy of NADA 011–116.	FOI Summary.

II. Changes of Sponsor

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 141–437 for OSNURIA (betamethasone acetate, florfenicol, terbinafine) Otic Gel to Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.

Pharmasone LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–690 for ZOASHIELD 25% (zoalene Type A medicated article) to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.

Also, Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interest in, the 39 NADAs and 17 ANADAs listed below to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140:

File No.	Product name
034–641	TIGUVON (fenthion) Pour-On Cattle Insecticide.
040–001	MELDANE 2 (coumaphos) Type A Medicated Article.
045–416	TEVCODYNE (phenylbutazone) Injectable.
047–138	SPOTTON (fenthion) 20% Ready-to-Use Cattle Insecticide.
047–955	ROMPUN (xylazine hydrochloride) Injectable (20 mg).
047–956	ROMPUN (xylazine hydrochloride) Injectable (100 mg).
091–818	Phenylbutazone Tablets, USP 1 gram.
093–329	HAVASPAN (sulfamethazine) Prolonged Release Bolus; SULFASPAN (sulfamethazine) Prolonged Release Bolus.
093–483	SPECTAM (spectinomycin hydrochloride) Injectable Solution.
107–345	RINTAL (febantel) Paste.
107–346	RINTAL (febantel) Suspension.
111–529	EQUIMATE (fluprostenol sodium).
111–607	DRONCIT (praziquantel) 5.68% Injectable Solution.
111–798	DRONCIT (praziquantel) Canine Cestocide Tablets; DRONCIT (praziquantel) Feline Cestocide Tablets.
116–089	VELTRIM (clotrimazole) 1% Dermatologic Cream.
132–336	PROBAN (cythioate) Oral Liquid.
132–337	PROBAN (cythioate) Tablets.
132–533	STYQUIN (butamisole hydrochloride) Parenteral 1.1%.
132–789	PRO–SPOT (fenthion) Solution.
133–953	VERCOM (febantel and praziquantel) Paste Anthelmintic.
140–441	BAYTRIL (enrofloxacin) Antibacterial Tablets; BAYTRIL TASTE TABS (enrofloxacin) Antibacterial Tablets.
140–912	RINTAL (febantel) Tabs Anthelmintic Tablets.
140–913	BAYTRIL (enrofloxacin) Antibacterial Injectable Solution.
141–007	DRONTAL Plus (febantel, praziquantel, pyrantel pamoate) Taste Tablets.
141–008	DRONTAL (praziquantel and pyrantel pamoate) Tablets.
141–068	BAYTRIL 100 (enrofloxacin) Injectable Solution.
141–099	CYDECTIN (moxidectin) Pour-On for Beef and Dairy Cattle.
141–176	BAYTRIL (enrofloxacin and silver sulfadiazine) Otic Emulsion.
141–208	ADVANTAGE DUO (imidacloprid and ivermectin) Topical Solution.
141–220	CYDECTIN (moxidectin) Injectable Solution.
141–247	CYDECTIN (moxidectin) Oral Drench for Sheep.
141–251	ADVANTAGE MULTI (imidacloprid and moxidectin) Topical Solution for Dogs.
141–254	ADVANTAGE MULTI (imidacloprid and moxidectin) Topical Solution for Cats.
141–275	PROFENDER (emodepside and praziquantel) Topical Solution.
141–344	VERAFLOX (pradofloxacin) Oral Suspension for Cats.
141–417	CORAXIS (moxidectin) Topical Solution.
141–435	ADVANTUS (imidacloprid) Tablets.
141–440	CLARO (florfenicol, mometasone furoate, terbinafine) Otic Solution.
141–527	BAYTRIL 100 (enrofloxacin) CA1.
200–042	Ketamine Hydrochloride Injection, USP.
200–124	Flunixin Meglumine Injection.
200–126	Phenylbutazone 20% Injection.
200–137	GENTAMAX 100 (gentamicin sulfate) Solution.
200–181	AMIMAX E (amikacin sulfate) Solution.
200–202	PHOENECTIN (ivermectin) Liquid for Horses.
200–230	Guaifenesin Injection.
200–246	ANTHELBAN V (pyrantel pamoate) Equine Anthelmintic Suspension.
200–286	PHOENECTIN (ivermectin) Paste 1.87%.
200–293	Furosemide Injection 5%.
200–319	Acepromazine Maleate Injection.

File No.	Product name
200–322	Butorphanol Tartrate Injection.
200–360	TIAGARD (tiamulin) Liquid Concentrate.
200–408	Butorphanol Tartrate Injection.
200–555	QUELLIN (carprofen) Tablets.
200–582	LONCOR 300 (florfenicol) Injectable Solution.
200–608	BAYTRIL (enrofloxacin) Soft Chewable Tablets.

Following these changes of sponsorship, neither Bayer HealthCare LLC nor Pharmasone LLC are the sponsor of an approved application. Accordingly, they will be removed from the list of sponsors of approved applications in 21 CFR 510.600(c). As provided in the regulatory text, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Technical Amendments

FDA is making the following amendments to improve the accuracy, consistency, and readability of the animal drug regulations:

- 21 CFR 520.905a is amended to reflect the approved conditions of use for fenbendazole suspension in laying hens.
- 21 CFR 522.1182 is amended to reflect the 2016 change of sponsorship of an injectable ferric hydroxide product in young piglets.
- 21 CFR 522.1193 is amended to reflect the approved withdrawal period for a clorsulon injectable solution product.
- 21 CFR 522.1696a is amended to reflect an associated limitation for a penicillin G benzathine and penicillin G procaine injectable suspension product.
- 21 CFR 522.1890 is amended to reflect the current format for titling regulations for injectable dosage form new animal drugs.
- Entries in parts 556 and 558 (21 CFR parts 556 and 558) for a coumaphos Type A medicated article are being added. These sections were withdrawn in error (85 FR 18114, April 1, 2020).
- Part 558 is amended to reflect current naming and organization for specifications and application sponsors.
- 21 CFR 558.261 is amended to reflect an approved incorporation level of florfenicol in medicated feed for fish.
- 21 CFR 558.311 for lasalocid in medicated feed is amended to reflect a current tabular organization by species.
- 21 CFR 558.355 is amended to provide accurate cross references for approved uses to special considerations and label statements for monensin medicated feeds.
- 21 CFR 558.450 is amended to add two indications for use of oxytetracycline in medicated feed for fish that were removed during the recent codification of a supplemental approval (84 FR 12491 at 12502, April 2, 2019).
- Part 558 is amended by removing 21 CFR 558.465, which is redundant with 21 CFR 558.464. The cross reference for poloxalene in part 556 is amended to reflect this action.
- Part 558 is amended by adding 21 CFR 558.470 to reflect the approved conditions of use of a polyoxyethylene medicated feed block, which previously had been removed from 21 CFR part 520 without being added to part 558.
- Typographical errors are being corrected wherever they have been found.

IV. Legal Authority

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. This 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 the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug's sponsor in a ''notice, which upon publication shall be effective as a regulation.'' A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* See section 512(i) of the FD&C Act; 21 CFR 10.40(e)(3); S. Rep. 90–1308, at 5 (1968).

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 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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, 529, 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.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''Bayer HealthCare LLC'' and in the table in paragraph (c)(2), remove the entry for ''000859''.

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.

■ 4. In § 520.304, add paragraph (a)(3), revise paragraphs (b)(1) and (2), and add paragraph (b)(3) to read as follows:

§ 520.304 Carprofen.

(a) * * *

(3) Each chewable tablet contains 25, 37.5, 50, 75, or 100 mg carprofen.

(b) * * *

(1) Nos. 017033, 054771, 055529, and 062250 for use of product described in paragraphs (a)(1) and (2) of this section as in paragraph (c) of this section.

(2) No. 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (c) of this section.

(3) No. 069043 for use of product described in paragraph (a)(3) of this section as in paragraph (c) of this section.

* * * * *

■ 5. In § 520.530, revise paragraph (b) to read as follows:

§ 520.530 Cythioate oral liquid.

* * * * *

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

* * * * *

■ 6. In § 520.531, revise paragraph (b)(1) to read as follows:

§ 520.531 Cythioate tablets.

* * * * *

(b) * * *

(1) No. 058198 for use of 30- and 90-mg tablets.

* * * * *

■ 7. In § 520.812, revise paragraph (b)(1) to read as follows:

§ 520.812 Enrofloxacin.

* * * * *

(b) * * *

(1) No. 058198 for use of products described in paragraphs (a)(1)(i) and (a)(2) and (3) of this section.

* * * * *

■ 8. In § 520.903a, revise paragraph (b) to read as follows:

§ 520.903a Febantel paste.

* * * * *

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

* * * * *

■ 9. In § 520.903b, revise paragraph (b) to read as follows:

§ 520.903b Febantel suspension.

* * * * *

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

* * * * *

■ 10. In § 520.903c, revise paragraph (b) to read as follows:

§ 520.903c Febantel and praziquantel paste.

* * * * *

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

* * * * *

■ 11. In § 520.903d, revise paragraph (b) to read as follows:

§ 520.903d Febantel tablets.

* * * * *

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

* * * * *

■ 12. In § 520.905a, revise paragraph (e)(5)(ii), remove paragraph (e)(5)(iii), and revise paragraph (e)(6)(ii) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(5) * * *

(ii) *Indications for use.* For the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens, and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens and laying hens.

(6) * * *

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult *Metastrongylus apri,* Adult *Metastrongylus pudendotectus;* Gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (*Ascaris suum*), Adult nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*), Adult small stomach worms (*Hyostrongylus rubidus*), Adult and larvae (L2, L3, L4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and Kidney worms: Adult and larvae *Stephanurus dentatus.*

* * * * *

■ 13. Revise § 520.998 to read as follows:

§ 520.998 Fluralaner.

(a) *Specifications.* (1) Each chewable tablet contains 112.5, 250, 500, 1,000, or 1,400 milligrams (mg) fluralaner.

(2) Each chewable tablet contains 45, 100, 200, 400, or 560 mg fluralaner.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose with food:

(i) *Chewable tablets described in paragraph (a)(1) of this section.* Administer every 12 weeks, an appropriate combination of tablets to provide a minimum dose of 11.4 mg per pound (lb) (25 mg per kilogram (kg)) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(ii) *Chewable tablets described in paragraph (a)(2) of this section.* Administer monthly, an appropriate combination of tablets to provide a minimum dose of 4.5 mg/lb (10 mg/kg) body weight.

(2) *Indications for use*—(i) *Chewable tablets described in paragraph (a)(1) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick)*, Dermacentor variabilis* (American dog tick)*,* and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater.

(ii) *Chewable tablets described in paragraph (a)(2) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*), and the treatment and control of tick infestations [*I. scapularis* (black-legged tick)*, D. variabilis* (American dog tick)*,* and *R. sanguineus* (brown dog tick)] for 1 month in dogs and puppies 8 weeks of age and older, and weighing 4.4 lbs or greater; and for the treatment and control of *A. americanum* (lone star tick) infestations for 1 month in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater.

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

■ 14. In § 520.1156, revise paragraph (b) to read as follows:

§ 520.1156 Imidacloprid.

* * * * *

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

* * * * *

■ 15. In § 520.1192, revise paragraph (b)(2) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(2) Nos. 051311, 054925, 058198, and 061133 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

* * * * *

■ 16. In § 520.1195, revise paragraph (b)(1) to read as follows:

§ 520.1195 Ivermectin liquid.

* * * * *

(b) * * *

(1) Nos. 000010, 054925, 058005, and 058198 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

* * * * *

■ 17. In § 520.1454, revise paragraph (b) to read as follows:

§ 520.1454 Moxidectin solution.

* * * * *

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

* * * * *

■ 18. In § 520.1720a, add paragraph (b)(5) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

* * * * *

(b) * * *

(5) No. 058198 for use of 1-g tablets in horses.

* * * * *

■ 19. In § 520.1860, revise paragraph (b) to read as follows:

§ 520.1860 Pradofloxacin.

* * * * *

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

* * * * *

■ 20. In § 520.1870, revise paragraph (b) to read as follows:

§ 520.1870 Praziquantel tablets.

* * * * *

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

(1) No. 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (c)(1) of this section and for use of product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

(2) No. 069043 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1) of this section.

* * * * *

■ 21. In § 520.1871, revise paragraph (b)(1) to read as follows:

§ 520.1871 Praziquantel and pyrantel.

* * * * *

(b) * * *

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

* * * * *

■ 22. In § 520.1872, revise paragraph (b) to read as follows:

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

* * * * *

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

* * * * *

■ 23. In § 520.2043, revise paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) Nos. 054771, 058198, and 058829 for use of the products described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

■ 24. Add § 520.2138 to read as follows:

§ 520.2138 Spironolactone and benazepril.

(a) *Specifications.* Each chewable tablet contains 20 milligrams (mg) spironolactone and 2.5 mg benazepril hydrochloride, 40 mg spironolactone and 5 mg benazepril hydrochloride, or 80 mg spironolactone and 10 mg benazepril hydrochloride.

(b) *Sponsor.* See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once daily, with food, at a dose of 0.9 mg per pound (lb) (2 mg per kilogram (kg)) spironolactone and 0.11 mg/lb (0.25 mg/kg) benazepril hydrochloride, according to dog body weight using a suitable combination of whole and/or half tablets.

(2) *Indications for use.* With concurrent therapy (*e.g.,* furosemide, etc.) for the management of clinical signs of mild, moderate, or severe congestive heart failure in dogs due to atrioventricular valvular insufficiency (AVVI).

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

■ 25. In § 520.2260b, add a heading for paragraph (b), revise paragraph (b)(1), add a heading for paragraph (e), and revise paragraph (e)(1) to read as follows:

§ 520.2260b Sulfamethazine sustained-release boluses.

* * * * *

(b) *22.5-gram bolus*—(1) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine prolonged-release bolus.

* * * * *

(e) *22.5-gram bolus*—(1) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine sustained release bolus.

* * * * *

■ 26. In § 520.2455, revise paragraphs (b)(1) and (2) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(1) No. 058198 for products described in paragraphs (a)(1) and (3) of this section.

(2) No. 066104 for the product described in paragraph (a)(1) of this section.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 28. In § 522.23, revise paragraph (b) to read as follows:

§ 522.23 Acepromazine.

* * * * *

(b) *Sponsors.* See Nos. 000010 and 058198 in § 510.600(c) of this chapter.

* * * * *

■ 29. In § 522.234, revise paragraph (b) to read as follows:

§ 522.234 Butamisole.

* * * * *

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

* * * * *

■ 30. In § 522.246, revise paragraphs (b)(2) and (3) to read as follows:

§ 522.246 Butorphanol.

* * * * *

(b) * * *

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

(3) Nos. 000061, 058198, and 059399 for use of the product described in paragraph (a)(3) of this section as in paragraph (d)(3) of this section.

* * * * *

■ 31. In § 522.812, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 017033, 055529, and 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and

(2) Nos. 055529, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraphs (e)(2) and (3) of this section.

* * * * *

■ 32. In § 522.955, revise paragraph (b)(2) to read as follows:

§ 522.955 Florfenicol.

* * * * *

(b) * * *

(2) Nos. 000061 and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

* * * * *

■ 33. In § 522.970, revise paragraph (b)(1) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See Nos. 000061, 016592, 055529, 058198, and 061133 for use as in paragraph (e) of this section.

* * * * *

■ 34. In § 522.995, revise paragraph (b) to read as follows:

§ 522.995 Fluprostenol.

* * * * *

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

* * * * *

■ 35. In § 522.1010, revise paragraph (b)(3) to read as follows:

§ 522.1010 Furosemide.

* * * * *

(b) * * *

(3) No. 058198 as described in paragraph (a)(2) of this section for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

* * * * *

■ 36. In § 522.1077:

■ a. Revise paragraph (b)(3);

■ b. Remove paragraph (b)(4); and

■ c. Redesignate paragraph (b)(5) as paragraph (b)(4).

The revision reads as follows:

§ 522.1077 Gonadorelin.

* * * * *

(b) * * *

(3) Nos. 000010 and 061133 for use of the 50-µg/mL product described in paragraph (a)(3) of this section as in paragraphs (e)(1)(i) and (v) of this section.

* * * * *

■ 37. In § 522.1086, revise paragraph (b) to read as follows:

§ 522.1086 Guaifenesin solution.

* * * * *

(b) *Sponsors.* See Nos. 037990 and 058198 in § 510.600(c) of this chapter.

* * * * *

■ 38. In § 522.1182, revise paragraph (b)(1) introductory text to read as follows:

§ 522.1182 Iron injection.

* * * * *

(b) * * *

(1) Nos. 016592 and 042552 for use of product described in paragraph (a)(1)(i) of this section as follows:

* * * * *

■ 39. In § 522.1193, revise paragraph (e)(3)(i) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(e) * * *

(3) * * *

(i) Nos. 000010, 055529, and 061133: Do not treat cattle within 21 days of slaughter. No. 058005: Do not treat cattle within 49 days of slaughter.

* * * * *

■ 40. In § 522.1222, revise paragraph (b) to read as follows:

§ 522.1222 Ketamine.

* * * * *

(b) *Sponsors.* See Nos. 017033, 054771, 058198, 059399, 063286, and 069043 in § 510.600(c) of this chapter.

* * * * *

■ 41. In § 522.1450, revise paragraph (b) to read as follows:

§ 522.1450 Moxidectin solution.

* * * * *

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

* * * * *

■ 42. In § 522.1696a, revise paragraph (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For Nos. 000859 and 016592: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

■ 43. In § 522.1720, revise paragraph (b)(2) to read as follows:

§ 522.1720 Phenylbutazone.

* * * * *

(b) * * *

(2) Nos. 000061, 054771, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraph (c) of this section.

* * * * *

■ 44. In § 522.1870, revise paragraph (b) to read as follows:

§ 522.1870 Praziquantel.

* * * * *

(b) *Sponsors.* See Nos. 058198 and 061133 in § 510.600(c) of this chapter.

* * * * *

■ 45. In § 522.1890, revise the section heading to read as follows:

§ 522.1890 Prednisone suspension.

■ 46. Revise § 522.2120 to read as follows:

§ 522.2120 Spectinomycin hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) spectinomycin hydrochloride (as spectinomycin dihydrochloride pentahydrate).

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

(1) Nos. 016592 and 054771 for use as in paragraph (d)(1) of this section; and

(2) No. 058198 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.600 of this chapter.

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

(1) *Turkeys (1- to 3-day-old poults) and chickens (newly hatched chicks)*—(i) *Amounts and indications for use.* (A) Administer 5 mg per poult subcutaneously as an aid in the control of chronic respiratory disease (CRD) associated with *Escherichia coli* in 1- to 3-day-old turkey poults.

(B) Administer 10 mg per poult as a single subcutaneous injection in the nape of the neck as an aid in the control of airsacculitis associated with *Mycoplasma meleagridis* sensitive to spectinomycin in 1- to 3-day-old turkey poults.

(C) Administer 2.5 to 5 mg per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae, Salmonella typhimurium, S. infantis,* and *E. coli.*

(ii) *Limitations.* For use only in 1- to 3-day-old turkey poults and newly hatched chicks.

(2) *Dogs*—(i) *Amount.* Administer 2.5 to 5.0 mg per pound of body weight by intramuscular injection twice daily. Treatment may be continued for 4 days.

(ii) *Indications for use.* For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

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

■ 47. In § 522.2662, revise paragraph (b)(3) to read as follows:

§ 522.2662 Xylazine.

* * * * *

(b) * * *

(3) Nos. 058198 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 49. In § 524.450, revise paragraph (b) to read as follows:

§ 524.450 Clotrimazole.

* * * * *

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

* * * * *

■ 50. In § 524.775, revise paragraph (b) to read as follows:

§ 524.775 Emodepside and praziquantel.

* * * * *

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

* * * * *

■ 51. In § 524.802, revise paragraph (b) to read as follows:

§ 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.

* * * * *

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

* * * * *

■ 52. In § 524.920, revise paragraphs (b)(1) through (3) to read as follows:

§ 524.920 Fenthion.

* * * * *

(b) * * *

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

(2) No. 058198 for use of product described in paragraph (a)(1)(ii) of this section as in paragraph (d)(2) of this section.

(3) No. 058198 for use of products described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.

* * * * *

■ 53. In § 524.955, revise paragraph (b) to read as follows:

§ 524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.

* * * * *

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

* * * * *

■ 54. In § 524.957, revise paragraph (b) to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

* * * * *

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

* * * * *

■ 55. In § 524.1140, revise paragraph (b) to read as follows:

§ 524.1140 Imidacloprid and ivermectin.

* * * * *

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

* * * * *

■ 56. In § 524.1146, revise paragraphs (b)(1) through (3) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(1) Nos. 017030 and 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030 and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) No. 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.

* * * * *

■ 57. In § 524.1450, revise paragraphs (b)(1) and (2) to read as follows:

§ 524.1450 Moxidectin.

* * * * *

(b) * * *

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

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

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 59. In § 529.56, revise paragraph (b) to read as follows:

§ 529.56 Amikacin.

* * * * *

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

* * * * *

■ 60. In § 529.1044a, revise paragraph (b) to read as follows:

§ 529.1044a Gentamicin solution for infusion.

* * * * *

(b) *Sponsors.* See Nos. 000061, 016592, 054628, 054771, 058005, 058198, and 061133 in § 510.600(c) of this chapter.

* * * * *

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

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

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

■ 62. Add § 556.168 to read as follows:

§ 556.168 Coumaphos.

(a) [Reserved]

(b) *Tolerances.* The tolerances for coumaphos (measured as coumaphos and its oxygen analog, O,O-diethyl O-3-chloro-4-methyl-2-oxo-2 H-1-benzopyran-7-yl phosphate) are:

(1) *Chickens.* (i) Edible tissues (excluding eggs): 1 ppm.

(ii) Eggs: 0.1 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.185 of this chapter.

■ 63. In § 556.517, revise paragraph (c) to read as follows:

§ 556.517 Poloxalene.

* * * * *

(c) *Related conditions of use.* See §§ 520.1840 and 558.464 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 65. In § 558.55:

■ a. Revise paragraph (a);

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

■ c. Add new paragraph (b).

The revision and addition read as follows:

§ 558.55 Amprolium.

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

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

* * * * *

■ 66. In § 558.58:

■ a. Revise paragraph (b); and

■ b. Redesignate paragraphs (c) and (d) as paragraphs (d) and (c).

The revision reads as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

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

* * * * *

■ 67. In § 558.68, revise paragraph (a) to read as follows:

§ 558.68 Avilamycin.

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

* * * * *

■ 68. In § 558.76:

■ a. Revise paragraph (b);

■ b. Remove paragraph (c); and

■ c. Redesignate paragraphs (d) and (e) as paragraphs (c) and (d).

The revision reads as follows:

§ 558.76 Bacitracin methylenedisalicylate.

* * * * *

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

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

(2) No. 069254 for use of product in paragraph (a)(2) of this section as in paragraph (d) of this section.

* * * * *

■ 69. In § 558.78, revise paragraph (b) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

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

* * * * *

■ 70. In § 558.95:

■ a. Revise paragraph (a);

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

■ c. Add new paragraph (b);

■ d. Add a heading for newly redesignated paragraph (e)(5); and

■ e. Revise newly redesignated paragraph (e)(5)(iii).

The revisions and additions read as follows:

§ 558.95 Bambermycins.

(a) *Specifications.* Type A medicated articles containing 2, 4, or 10 grams bambermycins per pound.

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

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

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

* * * * *

(e) * * *

(5) *Combinations.* * * *

(iii) Clopidol as in § 558.175.

* * * * *

■ 71. In § 558.128, revise paragraph (b) introductory text to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

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

* * * * *

■ 72. In § 558.140, revise paragraph (b) introductory text to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

* * * * *

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

* * * * *

■ 73. In § 558.175:

■ a. Revise paragraph (d)(3); and

■ b. Remove paragraph (e).

The revision reads as follows:

§ 558.175 Clopidol.

* * * * *

(d) * * *

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

(i) Chlortetracycline as in § 558.128.

(ii) Lincomycin as in § 558.325.

■ 74. Add § 558.185 to read as follows:

§ 558.185 Coumaphos.

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

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

(c) *Related tolerances.* See § 556.168 of this chapter.

(d) *Special considerations.* (1) Labeling shall bear the following warning: The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals.

(2) See § 500.25 of this chapter.

(e) *Conditions of use in laying chickens.*

Coumaphos in grams per ton	Indications for use	Limitations	Sponsor
(1) 27.2 (0.003 percent).	Laying chickens: For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).	Feed continuously as the sole ration for 14 days. If reinfection occurs, treatment may be repeated, but not sooner than 3 weeks after the end of the previous treatment. Do not feed to chickens within 10 days of vaccination or other conditions of stress..	058198
(2) 36.3 (0.004 percent).	Replacement pullets: For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).	Feed continuously as the sole ration for from 10 to 14 days. Do not feed to chickens under 8 weeks of age or within 10 days of vaccination or other conditions of stress. If birds are maintained on contaminated litter or exposed to infected birds, a second 10- to 14-day treatment is recommended, but not sooner than 3 weeks after the end of the previous treatment. If reinfection occurs after production begins, repeat treatment as recommended for laying flocks..	058198

■ 75. In § 558.195, revise paragraph (b) to read as follows:

§ 558.195 Decoquinate.

* * * * *

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

* * * * *

■ 76. In § 558.258, revise paragraph (b) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

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

* * * * *

■ 77. In § 558.261, revise paragraph (e)(2)(ii) to read as follows:

§ 558.261 Florfenicol.

* * * * *

(e) * * *

(2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
*	*	*
(ii) 182 to 2,724	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
*	*	*

■ 78. In § 558.295, revise paragraph (a) to read as follows:

§ 558.295 Iodinated casein.

(a) *Specifications.* Type A medicated article containing iodinated casein.

* * * * *

■ 79. In § 558.305, revise paragraph (b) to read as follows:

§ 558.305 Laidlomycin.

* * * * *

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

* * * * *

■ 80. In § 558.311:

■ a. Revise paragraphs (a), (b), and (d)(7);

■ b. Add a heading and introductory text for paragraph (e);

■ c. Revise paragraph (e)(1);

■ d. Redesignate paragraphs (e)(2) through (5) as paragraphs (e)(5) through (8);

■ e. Add new paragraphs (e)(2) through (4); and

■ f. In the table in newly redesignated paragraph (e)(6)(i), revise the last row.

The revisions and additions read as follows:

§ 558.311 Lasalocid.

(a) *Specifications.* Each pound of Type A medicated article contains 68 grams (15 percent), 90.7 grams (20 percent), or 150 grams (33.1 percent) lasalocid as lasalocid sodium activity. A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

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

* * * * *

(d) * * *

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(3)(vi) through (e)(3)(viii) of this section must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.

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

(1) The conditions of use for chickens are:

Lasalocid in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 68 to 113	.....	Broiler or fryer chickens: 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	054771
(ii) 68	Bacitracin methylenedisalicylate, 10 to 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as the sole ration. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 68 to 113	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for improved feed efficiency..	Feed continuously as the sole ration. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 68 to 113	Bacitracin zinc, 4 to 50	Broiler chickens. For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as the sole ration. Bacitracin zinc provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 68 to 113	Bambermycins, 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592

(2) The conditions of use for turkeys are:

Lasalocid in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 68 to 113	.....	Growing turkeys; For prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides*..	Feed continuously as sole ration	054771
(ii) 68 to 113	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides;* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as the sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.	054771
(iii) 68 to 113	Bacitracin zinc, 4 to 50	Growing turkeys: For prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides;* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as the sole ration. Bacitracin zinc as provided by No. 054771 in § 510.600(c) in this chapter.	054771

(3) The conditions of use for cattle are—

Lasalocid amount	Indications for use	Limitations	Sponsor
(i) 10 to 30 grams/ton of feed	Cattle fed in confinement for slaughter: For improved feed efficiency..	Feed continuously in complete feed to provide not less than 100 milligrams (mg) nor more than 360 mg of lasalocid sodium activity per head per day.	054771
(ii) 25 to 30 grams/ton of feed	Cattle fed in confinement for slaughter: For improved feed efficiency and increased rate of weight gain..	Feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	054771
(iii) Not less than 60 mg or more than 300 mg of lasalocid per head per day.	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture. The drug must be contained in at least 1 pound of feed. Daily intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	054771
(iv) 1 mg lasalocid per 2.2 pounds (lb) body weight per day.	Cattle up to 800 lb: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*..	Hand feed continuously at a rate of 1 mg of lasalocid per 2.2 lb body weight per day to provide not more than 360 mg of lasalocid per head per day.	054771
(v) 1 mg lasalocid per 2.2 lb body weight per day.	Replacement calves: For control of coccidiosis caused by *E. bovis* and *E. zuernii*..	In milk replacer powder, hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day. A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal.	054771
(vi) 1,440 grams/ton	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	As a free-choice Type C medicated loose mineral, feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	012286
(vii) 1,440 grams/ton	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	As a free-choice Type C medicated mineral block, feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	017800
(viii) 300 grams/ton	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain..	As a free-choice Type C medicated protein block, feed continuously at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	067949

(4) The conditions of use for minor species are:

Lasalocid in grams/ton	Indications for use	Limitations	Sponsor
(i) 20 to 30	Sheep maintained in confinement: For prevention of coccidiosis caused by *Eimeria ovina, E. crandallis, E. ovinoidalis (E. ninakohlyakimovae), E. parva,* and *E. intricata*..	Feed continuously in complete feed to provide not less than 15 milligrams (mg) nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	054771
(ii) 113	Chukar partridges: For prevention of coccidiosis caused by *E. legionensis*..	Feed continuously as sole ration up to 8 weeks of age	054771
(iii) 113	Rabbits: For prevention of coccidiosis caused by *E. stiedae*..	Feed continuously as sole ration up to 6 1/2 weeks of age	054771

* * * * *

(6) * * *

(i) * * *

Ingredient	Percent	International feed No.
* * * * * * *		
Lasalocid liquid Type A medicated article (90.7 g/lb)[2]	0.083	

* * * * *

■ 81. In § 558.325, revise paragraphs (b) and (e)(1)(ix) to read as follows:

§ 558.325 Lincomycin.

* * * * *

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

* * * * *

(e) * * *

(1) * * *

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

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

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	* * * *	
(ix) 2	Salinomycin, 40 to 60.	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E maxima, E. brunetti,* and *E. mivati.*	Feed as the sole ration to broiler chickens. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Salinomycin as provided by No. 054771 in § 510.600 of this chapter.	05477
*	*	*	* * * *	

* * * * *

■ 82. In § 558.342, revise paragraph (b) to read as follows:

§ 558.342 Melengestrol.

* * * * *

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

* * * * *

■ 83. In § 558.355, revise paragraphs (b) introductory text, (d)(9)(i) and (ii), and (d)(10)(i) and (ii) to read as follows:

§ 558.355 Monensin.

* * * * *

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

* * * * *

(d) * * *

(9) * * *

(i) *Cattle (as described in paragraphs (f)(3)(i) through (iii), (vi), and (vii) and (f)(4)(i) through (vi) of this section).* See paragraphs (d)(6) and (d)(7)(i) through (v), (vii), and (viii) of this section.

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

* * * * *

(10) * * *

(i) *Cattle (as described in paragraphs (f)(3)(i) through (iii), (vi), and (vii) and (f)(4)(i) through (vi) of this section).* See paragraphs (d)(6) and (d)(7)(i), (v), (vii), and (viii) of this section. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

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

* * * * *

■ 84. In § 558.363, revise paragraph (a) to read as follows:

§ 558.363 Narasin.

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

* * * * *

■ 85. In § 558.364, revise paragraph (d)(1)(ii) to read as follows:

§ 558.364 Naracin and nicarbazin.

* * * * *

(d) * * *

(1) * * *

Narasin and nicarbazin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * * *	
(ii) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. For No. 054771: Withdraw 5 days before slaughter. For No. 069254: Zero withdrawal period. Bacitracin methylenedisalicylate as provided by Nos. 054771 and 069254 in § 510.600(c) of this chapter.	058198 069254
*	*	*	* * * *	

* * * * *

■ 86. In § 558.366, revise paragraph (b) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(b) *Sponsors.* See Nos. 058198, 060728, and 066104 in § 510.600(c) of this chapter.

* * * * *

■ 87. In § 558.450, revise paragraph (e)(5)(iv) 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.	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

Oxytetracycline amount	Indications for use	Limitations	Sponsor
	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
	3. Freshwater-reared salmonids weighing up to 55 grams: For marking the skeletal tissue.	Feed for 10 days. Immediate release is permitted following last feeding of medicated feed..	066104

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§ 558.465 [Removed]

■ 88. Remove § 558.465.

■ 89. Add § 558.470 to read as follows:

§ 558.470 Polyoxyethylene.

(a) *Specifications.* Each molasses-based block contains 2.2 percent polyoxyethylene (23) lauryl ether.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 2 grams of polyoxyethylene (23) lauryl ether per 100 kilograms of body weight per day (1 pound of block per 500 kilogram (1,100 pound) animal per day). Initially, provide one block per five head of cattle. Start treatment 10 to 14 days before exposure to bloat-producing pastures.

(2) *Indications for use.* For reduction of the incidence of bloat (alfalfa and clover) in pastured cattle.

(3) *Limitations.* Administer free-choice to beef cattle and nonlactating dairy cattle only. Do not allow cattle access to other sources of salt while being fed this product. Do not feed this product to animals without adequate forage/roughage consumption.

■ 90. In § 558.485, revise paragraph (b) introductory text to read as follows:

§ 558.485 Pyrantel.

* * * * *

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

* * * * *

■ 91. In § 558.500, revise paragraph (b) to read as follows:

§ 558.500 Ractopamine.

* * * * *

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

* * * * *

■ 92. In § 558.515:

■ a. Revise paragraph (a);

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

■ c. Add new paragraph (b).

The revision and addition read as follows:

§ 558.515 Robenidine.

(a) *Specifications.* Type A medicated articles containing 30 grams per pound.

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

* * * * *

■ 93. In § 558.550:

■ a. Revise paragraphs (a), (b), (e)(1)(i), and (e)(2)(i);

■ b. Add a heading for paragraph (e)(3);

■ c. Redesignate paragraphs (e)(3)(i) through (iv) as paragraphs (e)(3)(ii) through (v); and

■ d. Add new paragraph (e)(3)(i).

The revisions and additions read as follows:

§ 558.550 Salinomycin.

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

(1) 30 grams of salinomycin sodium activity per pound; or

(2) 60 grams of salinomycin sodium activity per pound.

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

(1) No. 016592 for product described in paragraph (a)(1) of this section.

(2) Nos. 016592 and 069254 for product described in paragraph (a)(2) of this section.

* * * * *

(e) * * *

(1) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40 to 60		Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses..	016592 069254

* * * * * * *

(2) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 50		Quail: For the prevention of coccidiosis caused by *Eimeria. dispersa* and *E. lettyae.*	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses..	016592 069254

* * * * * * *

(3) *Combinations.* * * *

(i) Avilamycin as in § 558.68.

* * * * *

■ 94. In § 558.555, revise paragraph (b) to read as follows:

§ 558.555 Semduramicin.

* * * * *

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

* * * * *

■ 95. In § 558.575, revise paragraph (b) introductory text to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

* * * * *

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

* * * * *

■ 96. In § 558.600, revise paragraphs (a) and (d) to read as follows:

§ 558.600 Thiabendazole.

(a) *Specifications.* Dry Type A medicated articles containing 22, 44.1, 66.1, or 88.2 percent thiabendazole.

* * * * *

(d) *Special considerations.* (1) The 66.1 percent Type A medicated article is solely for the manufacture of cane molasses liquid Type B feed, which is mixed in dry feeds.

(2) The 88.2 percent Type A medicated article is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(3) Do not use in Type B or Type C medicated feed containing bentonite.

* * * * *

■ 97. In § 558.612, revise paragraph (b) to read as follows:

§ 558.612 Tiamulin.

* * * * *

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

* * * * *

■ 98. In § 558.618, revise paragraph (b) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

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

* * * * *

■ 99. In § 558.680, revise paragraphs (b), (d)(1)(i) and (v), and (d)(2)(i) to read as follows:

§ 558.680 Zoalene.

* * * * *

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

* * * * *

(d) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	.....	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously as sole ration. Grower ration not to be fed to birds over 14 weeks of age. Starter ration not to be fed to laying birds.	054771 058198

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

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(v) 113.5	.....	Broiler chickens: For prevention and control of coccidiosis.	Feed continuously as sole ration. Not to be fed to laying birds	054771 058198
*	*	*	*	*

(2) * * *

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3 ..	.....	Growing turkeys: For prevention and control of coccidiosis.	Feed continuously as sole ration. For turkeys grown for meat purposes only. Not to be fed to laying birds..	054771 058198
*	*	*	*	*

* * * * *

Dated: March 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2016–0321; FRL–10021–50–Region 5]

Air Plan Approval; Michigan; Partial Approval and Partial Disapproval of the Detroit SO*2* Nonattainment Area Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is partially approving and partially disapproving a revision to the Michigan State Implementation Plan (SIP) for attaining the 2010 1-hour primary sulfur dioxide (SO_2) national ambient air quality standard (NAAQS or ''standard'') for the Detroit SO_2 nonattainment area (NAA). This SIP revision (hereinafter called the ''Detroit SO_2 plan'' or ''plan'') includes Michigan's attainment demonstration and other elements required under the