

**PART 232—REGULATION S—
GENERAL RULES AND REGULATIONS
FOR ELECTRONIC FILINGS**

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78n–1, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: “General Information,” Version 43 (effective March 16, 2026). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 77 (March 16, 2026). All EDGAR material referenced in this paragraph is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for inspection at the Commission and at the National Archives and Records Administration (NARA). The EDGAR

Filer Manual is available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549; (202) 551–3900; *Library@sec.gov*, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission’s Public Reference Room. The EDGAR Filer Manual may also be obtained from <https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual>. For information on the availability of the EDGAR Filer Manual at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

By the Commission.
Dated: March 16, 2026.
Vanessa A. Countryman,
Secretary.
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

**21 CFR Parts 510, 516, 520, 522, 524,
and 558**

[Docket No. FDA–2025–N–0002]

**New Animal Drugs; Approval of New
Animal Drug Applications; Withdrawal
of Approval of New Animal Drug
Application; Change of Sponsor;
Change of Sponsor Address**

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), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during October, November, and December 2025. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective April 16, 2026.

FOR FURTHER INFORMATION CONTACT: James Delaney, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. james.delaney@fda.hhs.gov, 240–402–5677.

SUPPLEMENTARY INFORMATION:

I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during October, November, and December 2025, as listed in table 1. Documentation of environmental review required under the National Environmental Policy Act, summaries of the basis of approval under the Freedom of Information Act (FOIA summaries), and marketing exclusivity and patent information are available at Animal Drugs @FDA: <https://animaldrugsatfda.fda.gov/adafda/views/#/search>.

TABLE 1—ORIGINAL, CONDITIONAL, AND SUPPLEMENTAL APPLICATIONS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2025

Date of approval	Application No.	Sponsor (drug labeler code ¹)	Product name	Effect of the action	21 CFR sections
October 20, 2025	141–581	Elanco US Inc. (058198)	CREDELIO QUATTRO (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets).	Supplemental Approval	520.1287
October 21, 2025	200–825	Felix Pharmaceuticals Pvt. Ltd. (086101).	Clomipramine Hydrochloride Tablets.	Original approval as a generic copy of NADA 141–120.	520.455
October 21, 2025	141–574	Pharmgate Inc. (069254)	PENNITRACIN MD 50G (bacitracin methylenedisalicylate Type A medicated article) and MONTEBAN (narasin Type A medicated article).	Original approval	558.363
October 24, 2025	141–494	Elanco US Inc. (058198)	CREDELIO (lotilaner)	Supplemental approval	520.1286
December 5, 2025	200–710	Dechra Veterinary Products LLC (017033).	Maropitant Citrate (maropitant citrate) injectable solution.	Original approval as a generic copy of NADA 141–263.	522.1315
December 17, 2025	141–619	Elanco US Inc. (058198)	CREDELIO QUATTRO CA1 (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets).	Conditional approval	516.1287
December 18, 2025	141–614	Anivive Lifesciences, Inc. (086121)	LAVERDIA (verdinexor tablets)	Original approval from conditional approval.	520.2700 516.2980
December 19, 2025	141–576	Dechra, Ltd. (043264)	COSACTHEN (cosyntropin injection).	Original approval	522.500
December 19, 2025	141–273	Boehringer Ingelheim Animal Health USA, Inc. (000010).	VETMEDIN (pimobendan)	Supplemental approval	520.1780

TABLE 1—ORIGINAL, CONDITIONAL, AND SUPPLEMENTAL APPLICATIONS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2025—Continued

Date of approval	Application No.	Sponsor (drug labeler code ¹)	Product name	Effect of the action	21 CFR sections
December 19, 2025	200–823	Dechra Veterinary Products LLC (017033).	Zygolide (pergolide tablets)	Original approval as a generic copy of NADA 141–331.	520.1705
December 22, 2025	200–832	ZyVet Animal Health, Inc. (086117)	Robenacoxib (robenacoxib)	Original approval as a generic copy of NADA 141–320.	520.2075
December 22, 2025	200–834	Felix Pharmaceuticals Pvt. Ltd. (086101).	Praziquantel Tablets (praziquantel tablets).	Original approval as a generic copy of NADA 111–798.	520.1870
December 22, 2025	200–829	Aurora Pharmaceutical, Inc. (051072).	Klentz (florfenicol, terbinafine, mometasone furoate) otic solution.	Original approval as a generic copy of NADA 141–440.	524.957

¹ See 21 CFR 510.600(c) for sponsor addresses.

II. Changes of Sponsor

The sponsors of the approved applications listed in table 2 have

informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another

sponsor. The regulations cited in table 3 are amended to reflect these actions.

TABLE 2—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING OCTOBER, NOVEMBER, AND DECEMBER 2025

Application No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
039–417	DECCOX ((decoquinatate Type A medicated article).	Zoetis (054771)	Phibro (066104)	558.195
040–209	ROFENAID 40 (sulfadimethoxine and ormetoprim Type A medicated article).	Do	Do	558.575
045–348	DECCOX and ALBAC (decoquinatate Type A medicated article and bacitracin zinc Type A medicated article).	Do	Do	558.195
097–505	LINCOMIX 20 and LINCOMIX 50 (lincomycin Type A medicated article).	Do	Do	558.325
111–636	LINCOMIX Soluble Powder (lincomycin hydrochloride soluble powder).	Do	Do	520.1263b
138–941	LINCOMIX and BANMINTH (lincomycin Type A medicated article and pyrantel tartrate Type A medicated article).	Do	Do	558.325
140.853	BMD and MONTEBAN (bacitracin methylenedisalicylate Type A medicated article and narasin Type A medicated article).	Do	Do	558.363
140–865	MONTEBAN and BACIFERM or MONTEBAN and ALBAC (narasin Type A medicated article and bacitracin zinc Type A medicated article).	Do	Do	558.363
141–025	CATTLYST (laidlomycin propionate potassium Type A medicated article).	Do	Do	558.305
141–102	DECCOX and BMD (decoquinatate Type A medicated article and bacitracin methylenedisalicylate Type A medicated article).	Do	Do	558.1951
141–148	DECCOX and Rumensin (decoquinatate Type A medicated article and monensin Type A medicated article).	Do	Do	558.1951
141–149	DECCOX and RUMENSIN and TYLAN (decoquinatate Type A medicated article and monensin Type A medicated article and tylosin phosphate Type A medicated article).	Do	Do	558.625
141–191	COBAN and LINCOMIX (monensin Type A medicated article and lincomycin Type A medicated article).	Do	Do	558.325
141–483	DECCOX and LINCOMIX decoquinatate Type A medicated article and lincomycin Type A medicated articles to be used in the manufacture of Type C medicated feeds.	Do	Do	558.325
141–484	BIO–COX and LINCOMIX (salinomycin sodium Type A medicated article and lincomycin Type A medicated article).	Do	Do	558.325
141–485	COYDEN and LINCOMIX (clopidol Type A medicated article and lincomycin Type A medicated article).	Do	Do	558.325

TABLE 2—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING OCTOBER, NOVEMBER, AND DECEMBER 2025—Continued

Application No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
141–489	ZOAMIX and LINCOMIX (zoalene Type A medicated article and lincomycin Type A medicated article).	Do	Do	558.325
200–218	COYDEN and ALBAC (clopidol Type A medicated article and bacitracin zinc Type A medicated article).	Do	Do	558.175
200–548	Actogain (ractopamine hydrochloride)	Do	Do	558.500
200–579	Altrenogest Solution (altrenogest)	Ceva Sante Animale (013744).	Diamond Animal Health, Inc. (053701).	520.48

III. Change of Sponsor Address

Ivaoes Animal Health (drug labeler code 086064 in 21 CFR 510.600(c)), Kinetic Technologies, LLC, (drug labeler code 051031 in 21 CFR 510.600(c)), and Qbiotics Group Ltd., (drug labeler code 086132 in 21 CFR 510.600(c)) have informed FDA that they have changed their address. The entries in § 510.600(c) are amended to reflect these actions.

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy and readability of the animal drug regulations.

- 21 CFR 510.600(c) is amended to remove the entries for Agri Laboratories, Ltd., as the firm is no longer the sponsor of approved applications, and to add an entry for TriviumVet.
- 21 CFR 520.1660d is amended to reflect a 2016 and 2018 change of sponsorship for oxytetracycline powder that did not get recorded in the CFR.
- 21 CFR 520.2345d is amended to reflect a 2018 change of sponsorship for tetracycline powder.
- 21 CFR 522.2100 is revised to clarify the dosage is in pounds of body weight for all species listed.
- 21 CFR 524.1055h is amended to add clarity to the dosage directions for dogs.
- 21 CFR 558.78 is amended to remove inadvertent text.

• 21 CFR 558.500 is amended to present additional language for labeling and to add clarity to indications for use and limitations.

V. 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)). Although deemed a rule under 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” and 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.

List of Subjects

21 CFR Part 510

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

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

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, 516, 520, 522, 524, 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:

- a. In the table in paragraph (c)(1):
 - i. Revise the entries for Ivaoes Animal Health, Kinetic Technologies, LLC, and Qbiotics Group Ltd.,
 - ii Add in alphabetical order an entry for TriviumVet, and
 - iii. Remove the entry for Agri Laboratories, Ltd.
- b. In the table in paragraph (c)(2), add an entry in numerical order for 086169; remove the entry for 057561, and revise the entries for 051031, 086064, and 086132.

The revisions and additions 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
Ivaoes Animal Health, 1200 NW 78th, Suite 200–D, Doral, FL 33126	086064
Kinetic Technologies, LLC, 1700 Albany PI SE, Orange City, IA 51041	051031
Qbiotics Group Ltd., Level 14, 15 Lakes Street, Cairns, Queensland, QLD4870, Australia	086132
TriviumVet, Unit 3A, Cleaboy Business Park, Old Kilmeaden Road, Waterford, Waterford, X91 H5FE, Ireland	086169

Firm name and address						Drug labeler code
*	*	*	*	*	*	*
(2) * * *						
Drug labeler code	Firm name and address					
*	*	*	*	*	*	*
051031	Kinetic Technologies, LLC, 1700 Albany Pl SE, Orange City, IA 51041.					
*	*	*	*	*	*	*
086064	Ivaoes Animal Health, 1200 NW 78th, Suite 200-D, Doral, FL 33126.					
*	*	*	*	*	*	*
086132	Qbiotics Group Ltd., Level 14, 15 Lakes Street, Cairns, Queensland, QLD4870, Australia.					
*	*	*	*	*	*	*
086169	TriviumVet, Unit 3A, Cleaboy Business Park, Old Kilmeaden Road, Waterford, Waterford, X91 H5FE, Ireland.					
*	*	*	*	*	*	*

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

■ 4. Add § 516.1287 to read as follows:

§ 516.1287 Lotilaner, moxidectin, praziquantel, and pyrantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 56.25 milligrams (mg) lotilaner, 0.056 mg moxidectin, 14.25 mg praziquantel, and 14.25 mg pyrantel (as pamoate salt);

(2) 112.5 mg lotilaner, 0.113 mg moxidectin, 28.5 mg praziquantel, and 28.5 mg pyrantel (as pamoate salt);

(3) 225 mg lotilaner, 0.225 mg moxidectin, 57 mg praziquantel, and 57 mg pyrantel (as pamoate salt);

(4) 450 mg lotilaner, 0.45 mg moxidectin, 114 mg praziquantel, and 114 mg pyrantel (as pamoate salt); or

(5) 900 mg lotilaner, 0.9 mg moxidectin, 228 mg praziquantel, and 228 mg pyrantel (as pamoate salt).

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

(c) *Conditions of use—*

(1) *Amount.* Administer orally at the minimum dosage of 9 mg/pound (mg/lb) (20 mg/kilogram (mg/kg)) lotilaner, 0.009 mg/lb (0.02 mg/kg) moxidectin, 2.28 mg/lb (5 mg/kg) praziquantel, and 2.28 mg/lb (5 mg/kg) pyrantel (as pamoate salt).

(2) *Indications for use.* For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs

and puppies 8 weeks of age and older and weighing 3.3 pounds or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

§ 516.2980 [Removed]

■ 5. Remove § 516.2980.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.48 [Amended]

■ 7. In § 520.48, in paragraph (b)(3), remove the text “No. 013744” and in its place add the text “No. 053701”.

§ 520.455 [Amended]

■ 8. In § 520.455, in paragraph (a), remove the text “Specifications” and in its place add the text “*Specifications*”, and in paragraph (b), remove the text “Nos. 051311 and 086039” and in its place add the text “Nos. 051311, 086039, and 086101”.

■ 9. In § 520.1263b,

■ a. Retitle the section,

■ b. In paragraph (b)(1), remove the text “Nos. 054771 and 061133” and in its place add the text “Nos. 061133 and 066104”, and

■ c. Revise paragraph (d), to read as follows:

§ 520.1263b Lincomycin hydrochloride soluble powder.

* * * * *

(b) * * *

(1) Nos. 061133 and 066104 for use as in paragraph (d) of this section.

* * * * *

(d) * * *

(1) *Swine—*

(i) *Amount.* Administer at a dose rate of 250 milligrams (mg) of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day. The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin Type A medicated article at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lb of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioner to deliver 1 ounce of stock solution per gallon of drinking water. NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin Type A

medicated article at 40 grams lincomycin per ton of complete feed as the sole ration.

(ii) *Indications for use.* For the treatment of swine dysentery (bloody scours) in swine. Not for use in pregnant swine or swine intended for breeding.

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Fresh stock should be prepared daily. Do not use the water treatment and the feed treatment simultaneously. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. If clinical signs of bloody scours (watery, mucoid, or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. On rare occasions, some pigs may show reddening of the skin, swelling of the anus, and irritable behavior. These conditions have been self-correcting within five to seven days without discontinuing the lincomycin treatment. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Broiler Chickens—*

(i) *Amount.* Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water. Start medication as soon as the diagnosis of necrotic enteritis is determined. The drug should be administered for 7 consecutive days. NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin Type A medicated article at 2 grams lincomycin per ton of complete feed.

(ii) * * *

(iii) *Limitations.* Not for use in laying hens or breeder chickens. Discard medicated drinking water if not used within 2 days. Fresh stock should be prepared daily. Do not use the water treatment and the feed treatment simultaneously. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Honey bees—*

(i) *Amount.* Administer 100 mg lincomycin per hive once weekly for 3 weeks. Mix 250 mg LINCOMIX Soluble Powder (100 mg lincomycin) with 20 g confectioners' powder sugar and dust over the top bars of the brood chamber.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*) in honey bees.

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■ 10. In § 520.1286, revise paragraph (c)(1)(ii) to read as follow:

§ 520.1286 **Lotilaner.**

* * * * *

(c) * * *

(1) * * *

(i) * * *

(ii) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick)) for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

■ 11. In § 520.1287, revise paragraph (c)(2) to read as follows:

§ 520.1287 **Lotilaner, moxidectin, praziquantel, and pyrantel.**

* * * * *

(c) * * *

(1) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*), hookworm (fourth stage larvae, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick)) for one month in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

■ 12. In § 520.1660d,

■ a. Revise paragraph (d)(1)(ii)(A)(3), and

■ b. Revise paragraph (d)(1)(ii)(B)(3) to read as follows:

§ 520.1660d **Oxytetracycline powder.**

* * * * *

(d) * * *

(1) * * *

(ii) *Turkeys—*

(A) * * *

(3) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061133 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 016592. Zero-day withdrawal for those products sponsored by Nos. 016592 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) * * *

(3) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061133 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 016592. Zero-day withdrawal for those products sponsored by Nos. 016592 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 520.1705 [Amended]

■ 13. In § 520.1705, in paragraph (a), remove the text “peroglide (as pergolide mesylate)” and in its place add the text “pergolide (as pergolide mesylate)”, and in paragraph (b), remove the text “No. 000010” and in its place add the text “Nos. 000010 and 017033”.

■ 14. In § 520.1780, revise paragraph (c)(2) to read as follows:

§ 520.1780 **Pimobendan tablets.**

* * * * *

(c) * * *

(2) *Indications for use.* For the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease. Stage B2 preclinical myxomatous mitral valve disease (MMVD) refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly. For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical MMVD or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (e.g.,

furosemide, etc.) as appropriate on a case-by-case basis.

* * * * *

■ 15. In § 520.1870:

- a. Revise paragraphs (a) introductory text, revise paragraphs (a)(1) and (2), and add paragraph (a)(3); and
- b. Add paragraph (b)(3).

The revisions and additions read as follows:

§ 520.1870 Praziquantel tablets.

(a) *Specifications.*

(1) Each tablet contains 34 milligrams (mg) praziquantel.

(2) Each tablet contains 11.5 or 23 mg praziquantel.

(3) Each chewable tablet contains 23 mg praziquantel.

(b) * * *

(3) No. 086101 for use of product as described in paragraph (a)(3) of this section as in paragraph (c)(2) of this section.

* * * * *

- 16. In § 520.2075, revise paragraphs (a) and (b) to read as follows:

§ 520.2075 Robenacoxib.

(a) *Specifications.* Each tablet contains:

(1) 10, 20, or 40 milligrams (mg) robenacoxib for use in dogs; or

(2) 6 mg robenacoxib for use in cats.

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

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

(2) No. 086117 for use of product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

* * * * *

§ 520.2345d [Amended]

- 17. In § 520.2345d, in paragraph (d)(1)(iii), remove the text “for Nos. 016592, 054771, 054925, 057561, and 061133” and in its place add the text “for Nos. 016592, 054771, 054925, and 061133”, and in paragraph (d)(2)(iii), remove the text “for Nos. 016592, 054771, 054925, 057561, and 061133” and in its place add the text “for Nos. 016592, 054771, 054925, and 061133”.
- 18. Add § 520.2700 to read as follows:

§ 520.2700 Verdinexor tablets.

(a) *Specifications.* Each tablet contains 2.5, 10, 22.5, or 50 milligrams (mg) verdinexor.

(b) *Sponsor.* See No. 086121 in § 510.600(c) of this chapter.

(c) *Conditions of use—*

(1) *Amount.* Administer verdinexor tablets orally at an initial dose of 1.25 mg per kilogram (mg/kg) of body weight twice per week with at least 72 hours between doses. If tolerated after 2 weeks, increase the dose to 1.5 mg/kg twice per week with at least 72 hours between doses.

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

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 19. The authority citation for part 522 continues to read as follows:

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

- 20. Add § 522.500 to read as follows:

§ 522.500 Cosyntropin injection.

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

(b) *Specifications.* Each milliliter (mL) contains 0.25 milligrams (mg) cosyntropin, 1 mg glacial acetic acid, 0.82 mg sodium acetate trihydrate, 8.1 mg sodium chloride, and water for injection (to 100%).

(c) *Conditions of use—*

(1) *Amount.* Administer 0.25 mg (1 mL) per dog weighing 10–110 pounds (4.5–50 kilograms) by intravenous or intramuscular injection.

(2) *Indications for use.* For the evaluation of adrenal function in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

§ 522.1315 [Amended]

- 21. In § 522.1315, in paragraph (b), remove the text “No. 054771” and in its place add the text “Nos. 054771 and 017033”.
- 22. In § 522.2100, revise paragraph (c)(3)(i) to read as follows:

§ 522.2100 Selenium and vitamin E.

* * * * *

(c) * * *

(3) * * *

(i) *Dosage.* Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age and older: 1 milliliter per 40 pounds of body weight, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds of body weight. Sows: 1 milliliter per 40 pounds of body weight. Weanling pigs: 1 milliliter per 40 pounds of body weight, minimum 1 milliliter.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

- 23. The authority citation for part 524 continues to read as follows:

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

§ 524.957 [Amended]

- 24. In § 524.957, in paragraph (b), remove the text “Nos. 017030 and 058198” and in its place add the text “Nos. 017030, 051072, and 058198”.

- 25. In § 524.1044h, revise paragraph (c)(1) to read as follows:

§ 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

* * * * *

(c) * * *

(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5 gram (g), 15 g, or 30 g bottles (2 drops from the 215 g bottle) once daily into the ear canal. For dogs weighing 30 lb or more, instill 8 drops from the 7.5 g, 15 g, or 30 g bottles (4 drops from the 215 g bottle) once daily into the ear canal. Therapy should continue for 7 consecutive days.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 26. The authority citation for part 558 continues to read as follows:

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

- 27. In § 558.78, revise paragraph (d)(1)(vii) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(1) * * *

Bacitracin zinc in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
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(vii) 20 to 40		Growing-finishing swine; improved feed efficiency.		054771
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Bacitracin zinc in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
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* * * * *

§ 558.175 [Amended]
 ■ 28. In § 558.175, in the table in paragraph (d)(1)(iii), in the Sponsors column, replace the text “054771” and in its place add the text “066104”.
 ■ 29. In § 558.195,

■ a. In the tables in (e)(1), (e)(2), and (e)(3), in the “Sponsor” column, remove “054771” where it occurs, and in its place add “066104”.
 ■ b. Revise paragraphs (e)(1)(ii), (e)(1)(iii), and (e)(2)(ii) to read as follows:

§ 558.195 Decoquinatate.
 * * * * *
 (e) * * *
 (1) *Chickens*—

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 27.2	Bacitracin (as bacitracin methylenedisalicylate), 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. mivati</i> , <i>E. maxima</i> , and <i>E. brunetti</i> , and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. Do not feed to chickens producing eggs for human consumption. Do not use in feeds containing bentonite. Bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(iii) 27.2	Bacitracin zinc, 10 to 50	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. mivati</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. Do not feed to chickens producing eggs for human consumption. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	066104

(2) *Cattle*—

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 12.9 to 90.8	Monensin, 5 to 30	Growing beef steers and heifers fed in confinement for slaughter: For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for improved feed efficiency.	Feed as the sole ration to provide 22.7 mg of decoquinatate 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 periods of coccidiosis exposure or when experience indicates that coccidiosis is likely to be a hazard. Do not feed to cows producing milk for human consumption. A withdrawal period has not been established for this product in pre-ruminant calves. Do not use in calves to be processed for veal. Also see paragraph (d)(1) of this section and § 558.355(d)(9)(i). Monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	066104

* * * * *

■ 30. In § 558.305,
 ■ a. Retitle the section, and
 ■ b. Revise paragraphs (d)(1) through (d)(3), (e)(1), (e)(2), and (f), to read as follows:

§ 558.305 Laidlomycin propionate potassium.

* * * * *
 (d) * * *
 (1) Laidlomycin propionate potassium Type B liquid medicated feeds may be

manufactured from dry laidlomycin propionate potassium Type A medicated articles. The Type B liquid medicated feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

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

made from the Type B liquid medicated feed is 7 days after date of manufacture.

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

* * * * *
 (e) *Conditions of use.* It is used in growing beef steers and heifers fed in confinement for slaughter as follows:

Laidlomycin propionate potassium in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 5	For increased rate of weight gain and improved feed efficiency.	Feed as the sole ration Type C medicated feeds to provide 30 to 75 mg laidlomycin propionate potassium per head per day.	066104
(2) 5–10	For improved feed efficiency	Feed as the sole ration Type C medicated feeds to provide 30 to 150 mg laidlomycin propionate potassium per head per day.	066104

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

■ 31. In § 558.325, revise paragraphs (a), (b), (d)(3)(i), (d)(4)(i), (d)(4)(ii), (e)(1)(i), (e)(1)(iii), (e)(1)(iv), (e)(1)(vii), (e)(1)(ix), (e)(1)(x), (e)(2)(i), (e)(2)(vii), (e)(2)(xii), and (e)(2)(xiv) to read as follows:

§ 558.325 Lincomycin.

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

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

* * * * *

(d) * * *

(3) * * *

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

* * * * *

(4) * * *

(i) “Occasionally, swine fed lincomycin may within the first 2 days

after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.”

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

(e) * * *

(1) *Chickens*—

Lincomycin (as lincomycin hydrochloride agricultural grade) grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Broiler chickens: For the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin.	Feed as the sole ration. Not for use in laying hens, breeder chickens, or turkeys.	066104
.....
(iii) 2	Clopidol, 113.5	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin.	Feed as the sole ration to broiler chickens. Do not feed to chickens over 16 weeks of age. Not for use in laying hens, breeder chickens, or turkeys. Consult a veterinarian or poultry pathologist if losses exceed 0.5% in a two-day period. 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.	066104
(iv) 2	Decoquate, 27.2	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. mivati</i> , <i>E. maxima</i> , and <i>E. brunetti</i> , and for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin.	Feed as the sole ration. Do not feed to chickens producing eggs for human consumption. Do not use in feeds containing bentonite. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Decoquate as provided by No. 066104 in § 510.600 of this chapter.	066104
.....
(vii) 2	Monensin, 90 to 110	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin in broiler chickens up to 16 weeks of age.	Feed as the sole ration. Do not feed to chickens producing eggs for human consumption. Do not feed to chickens over 16 weeks of age. Not for use in laying hens, breeding chickens, or turkeys. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. 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. Not for broiler breeder replacement chickens. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake, resulting in reduced weight gain. Do not use this medicated feed after 90 days from the date of manufacture. Monensin as provided by No. 058198 in § 510.600 of this chapter.	066104

Lincomycin (as lincomycin hydrochloride agricultural grade) grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ix) 2	Salinomycin sodium activity, 40 to 60.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin.	Feed as the sole ration to broiler chickens. Do not feed to chickens producing eggs for human consumption. Not for use in laying hens, breeding chickens, or turkeys. May be fatal if accidentally fed to adult turkeys or horses. 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. Do not use in Type C medicated feeds containing pellet binders. Salinomycin sodium activity as provided by No. 016592 in §510.600 of this chapter.	066104
(x) 2	Zoalene, 113.5	Broiler chickens: For prevention and control of coccidiosis and for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin in broiler chickens.	Feed as the sole ration from the time chicks are placed in floor pens until slaughtered for meat. Not for use in laying hens, breeding chickens, or turkeys. Consult a veterinarian or poultry pathologist if losses exceed 0.5% in a two-day period. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Zoalene as provided by No. 066104 in §510.600 of this chapter.	066104

(2) Swine—

Lincomycin (as lincomycin hydrochloride agricultural grade) grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40		For the control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as sole ration. For use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis).	066104
(vii) 100		For the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as a sole ration for 3 weeks or until signs of disease (watery, mucoid, or bloody stools) disappear.	066104
(xii) 100 to 200		For reduction in the severity of the effects of respiratory disease associated with <i>Mycoplasma hyopneumoniae</i> .	Feed as sole ration for 21 days	066104
(xiv) 200	Pyrantel tartrate, 96	For reduction in the severity of the effects of respiratory disease associated with <i>Mycoplasma hyopneumoniae</i> ; to aid in the prevention of migration and establishment of large roundworm (<i>Ascaris suum</i>) infections; and to aid in the prevention of establishment of nodular worm (<i>Oesophagostomum</i> spp.) infections in swine.	Feed as the sole ration for 21 days. Not for use in swine that weigh more than 250 pounds. Withdraw 6 days before slaughter. Lincomycin as provided by No. 066104; pyrantel tartrate as provided by No. 066104 in §510.600(c) of this chapter.	066104

- 32. In § 558.363,
- a. Revise paragraph (e)(1)(ii);
- b. Redesignate paragraphs (e)(1)(iii) and (e)(1)(iv) as (e)(1)(v) and (e)(1)(vi) respectively;

- c. Add new paragraphs (e)(1)(iii) and (e)(1)(iv); and
- d. Revise newly redesignated paragraph (e)(1)(v).
The revision and addition read as follows:

§ 558.363 Narasin.
* * * * *
(e) * * *
(1) Chickens—

Narasin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(ii) 54 to 72	Bacitracin (as feed grade bacitracin methylenedisalicylate), 10 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 066104 in §510.600(c) of this chapter.	066104
(iii) 54 to 90	Bacitracin (as feed grade bacitracin methylenedisalicylate), 4 to 50.	Broiler chickens: For increased rate of weight gain and improved feed efficiency, and for the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	Feed as the sole ration throughout the feeding period. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 069254 in §510.600(c) of this chapter.	069254
(iv) 54 to 90	Bacitracin (as feed grade bacitracin methylenedisalicylate), 50.	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> , and for the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 069254 in §510.600(c) of this chapter.	069254
(v) 54 to 72	Bacitracin (as feed grade bacitracin zinc), 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter.	066104
(vi) 54 to 72	Bambermycins, 1 to 2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter.	016592

- * * * * *
- 33. In § 558.500,
- a. Revise paragraphs (b)(2), (d)(1), and (d)(2)(i) and (ii),
- b. Add new paragraphs (d)(2)(iii) and (d)(6),
- c. Revise the heading in the first column in (e)(1) through (3),
- d. In the tables in (e)(1) and (e)(2), in the “Sponsor” column, remove “054771” where it occurs, and in its place add “066104”, and
- e. Revise paragraphs (e)(1)(i), (e)(2)(i), (e)(2)(iii), (e)(2)(vi), and (e)(3).

The revisions and additions read as follows:

§ 558.500 Ractopamine.

- * * * * *
- (b) * * *
- (1) * * *

(2) Nos. 051311 and 066104: Type A medicated articles containing 45.4 g/lb ractopamine hydrochloride.

* * * * *

(d) *Special considerations.*

(1) Labeling of Type A medicated articles and Type B and Type C feeds shall bear the following: “Not for use in animals intended for breeding.”

(2) Labeling of Type A medicated articles and Type B and Type C medicated feeds intended for swine shall bear the following:

(i) “No increased benefit has been shown when ractopamine hydrochloride concentrations in the diet are greater than 4.5 g/ton (5 ppm).”

(ii) “Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as

hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride.”

(iii) “Additional Recommendations: To help mitigate the signs identified in the Animal Safety Warnings section, see the Pork Quality Assurance (PQA Plus) and Transport Quality Assurance (TQA) recommendations for best practices in swine care during handling, transport, and marketing.”

* * * * *

(6) Labeling of Type A medicated articles and Type B and Type C medicated feeds intended for cattle feeds shall bear the following:

(i) “Behavioral signs such as agitation and decreased feed consumption have been reported in cattle fed ractopamine hydrochloride.”

(ii) “Additional Recommendations: See the Beef Quality Assurance (BQA) recommendations for best practices in cattle care and handling during

ractopamine hydrochloride feeding, transport, and marketing to help mitigate the behavioral signs stated in

the Animal Safety Warnings section above.”
(e) * * *
(1) Swine—

Ractopamine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9.0	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing at least 150 lb, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter.	Not for use in swine intended for breeding. Feed as sole ration.	016592 066104 058198
(ii) Reserved.				

(2) Cattle—

Ractopamine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed.	Feed as the sole ration to provide 70 to 430 mg of ractopamine hydrochloride per head per day during the last 28 to 42 days on feed. Not for use in cattle intended for breeding.	016592 051311 066104 058198
* * * * *	* * * * *	* * * * *	* * * * *	
(iii) 9.8 to 24.6	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed.	Feed as the sole ration to provide 90 to 430 mg ractopamine hydrochloride per head per day during the last 28 to 42 days on feed. Not for use in cattle intended for breeding.	016592 051311 066104 058198
* * * * *	* * * * *	* * * * *	* * * * *	
(vi) 100 to 800	For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed.	Feed a minimum of 1 lb per head per day of Type C top-dress medicated feed to provide 70 to 400 mg ractopamine hydrochloride per head per day during the last 28 to 42 days on feed. Not for use in cattle intended for breeding.	016592 051311 066104 058198
* * * * *	* * * * *	* * * * *	* * * * *	

(3) Turkeys—

Ractopamine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *	* * * * *	* * * * *	* * * * *	

* * * * *

§ 558.575 [Amended]

■ 34. In § 558.575,
■ a. In paragraph (e)(1)(i) and (ii), in the column “Indications for Use”, remove the text “*Heterakis gallinarum*” and in

its place add the text “*Haemophilus gallinarum*”, and

■ b. In paragraph (e)(1)(i) and (ii), in the column “Sponsor”, remove the text “054771” and in its place add the text “066104”.

■ 35. In § 558.625, revise paragraph (e)(2)(vi) to read as follows:

§ 558.625 Tylosin.

* * * * *
(e) * * *
(2) Cattle—

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vi) 8 to 10	Monensin, 5 to 30 plus decoquinatate, 13.6 to 27.2.	Growing beef steers and heifers fed in confinement for slaughter: For the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> , for improved feed efficiency, and for the reduction of incidence of liver abscesses associated with <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium pyogenes</i> .	Feed as the sole ration to provide 22.7 mg of decoquinatate per 100 lb. of body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg tylosin (as tylosin phosphate). Feed for at least 28 days during periods of coccidiosis exposure or when experience indicates that coccidiosis is likely to be a hazard. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle feed is safe only for use in cattle. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. Do not use in feeds containing bentonite. Do not feed to cows producing milk for food. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; decoquinatate as provided by No. 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.355(d).	016592 066104

Grace R. Graham,
Deputy Commissioner for Policy, Legislation,
and International Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA-2026-N-2959]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Transcutaneous Electrical Nerve Stimulator for the Relief of Congestion

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the transcutaneous electrical nerve stimulator for the relief of congestion into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the transcutaneous electrical nerve stimulator for the relief of congestion. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’

access to beneficial innovative devices, in part by reducing regulatory burdens. **DATES:** This order is effective April 16, 2026. The classification was applicable on March 5, 2021.

FOR FURTHER INFORMATION CONTACT: Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993-0002, 301-796-6481, *Shu-Chen.Peng@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the transcutaneous electrical nerve stimulator for the relief of congestion as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial

distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying