



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2023-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications, 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) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2023. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2023, 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

(FOIA Summaries) under the Freedom of Information Act (FOIA). These documents, along with marketing exclusivity and patent information, may be obtained at Animal Drugs @ FDA: <https://animaldrugsatfda.fda.gov/adafda/views/#/search>.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During October, November, and December 2023 Requiring Evidence of Safety and/or Effectiveness

Date of Approval	File No.	Sponsor (Drug Labeler Code)	Product Name	Effect of the Action	21 CFR Section
October 11, 2023	141-572	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161 (051311)	AYRADIA (metronidazole oral solution)	Original approval for the treatment of <i>Giardia duodenalis</i> infection in dogs	520.1425
October 13, 2023	141-336	ECO LLC, 344 Nassau St., Princeton, NJ 08540 (066916)	AIVLOSIN (tylvalosin tartrate) Water Soluble Granules	Supplemental approval adding females intended for breeding to approved classes of swine	520.2645
October 20, 2023	141-564	Pharmgate Inc., 1800 Sir Tyler Rd., Wilmington, NC 28405 (069254)	PENNCHLOR (chlortetracycline Type A medicated article) and RUMENSIN (monensin Type A medicated article)	Original approval for treatment of bacterial enteritis and pneumonia; and for increased rate of weight gain or prevention and control of coccidiosis in replacement beef and dairy heifers	558.128
November 8, 2023	200-758	Felix Pharmaceuticals Pvt. Ltd., 25-28 North Wall Quay, Dublin 1, Ireland (086101)	Enrofloxacin Injectable Solution	Original approval for treatment and control of bovine respiratory disease (BRD) in beef cattle and non-lactating dairy cattle and swine respiratory disease (SRD) and control of colibacillosis in groups or pens of weaned pigs, as a generic copy of NADA 141-068	522.812
November 17, 2023	141-580	Orion Corp., Orionintie 1, 02200 Espoo, Finland (052483)	BONQAT (pregabalin) Oral Solution	Original approval for alleviation of acute anxiety and fear associated with transportation and veterinary visits in cats	520.1892
December 14, 2023	141-502	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (054771)	REVOLUTION PLUS (selamectin and sarolaner topical solution)	Supplemental approval for the treatment and control of tick infestations with <i>Amblyomma americanum</i> (lone star tick) in cats and kittens 8 weeks of age and older, and weighing 2.8 pounds or greater	524.2099
December 21, 2023	200-760	Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India (069043)	FLORFENIJECT (florfenicol) Injectable Solution	Original approval for treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon; and for the control of respiratory disease in cattle at high risk of developing BRD, as a generic copy of NADA 141-063.	522.955

December 22, 2023	200-762	Do.	CAROFENVET (carprofen) Injectable Solution	Original approval for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries, as a generic copy of NADA 141-199	522.304
December 22, 2023	200-764	Do.	ENROPRO 22.7 (enrofloxacin) Injectable Solution	Original approval for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin, as a generic copy of NADA 140-913.	522.812
December 22, 2023	200-765	Do.	ENROPRO 100 (enrofloxacin) Injectable Solution	Original approval for treatment and control of bovine respiratory disease (BRD) in beef cattle and non-lactating dairy cattle and swine respiratory disease (SRD) and control of colibacillosis in groups or pens of weaned pigs, as a generic copy of NADA 141-068	522.812

## II. Withdrawals of Approval

ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115 (drug labeler code 012286) requested that FDA withdraw approval of the four NADAs listed in table 2 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

Table 2.--Applications For Which Approval Was Voluntarily Withdrawn During October, November, and December 2023

Date of Withdrawal of Approval	File No.	New Animal Drug	21 CFR Section
November 14, 2023	030-578	E-Z-EX Wormer Pellets (thiabendazole)	n/a
Do.	042-910	E-Z-EX WORMER MINTRATE Block (thiabendazole) Mineral Protein Block	558.600
Do.	118-877	BAN-A-WORM (pyrantel tartrate) Ton Pack	n/a
Do.	132-448	FLAVOMYCIN (bambermycins) Type A Medicated Article	558.95

## III. Change of Sponsor

The sponsors of the approved applications listed in table 3 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 3.--Applications For Which Ownership Was Transferred to Another Sponsor During October, November, and December 2023

File No.	Product Name	Transferring Sponsor (Drug Labeler Code)	New Sponsor (Drug Labeler Code)	21 CFR Section
200-237	Isoflurane, U.S.P.	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India (065085)	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017 (066794)	529.1186
200-576	Gentamicin Sulfate Ophthalmic Solution	Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031 (059399)	Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du- Chateau, Auvergne-Rhône- Alpes, 63430, France (086189)	524.1044a
200-670	SENERGY (selamectin) Topical Solution	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland (061651)	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161 (051311)	524.2098
200-700	PARASEDGE Multi for Dogs (Imidacloprid and moxidectin)	Do.	Do.	524.1146
200-701	PARASEDGE Multi for Cats (Imidacloprid and moxidectin)	Do.	Do.	524.1146

#### IV. Change of Sponsor Address

Accord Healthcare, Inc. 1009 Slater Rd., suite 210-B, Durham, NC 27703 (drug labeler code 016729 in 21 CFR 510.600(c)) has informed FDA that it has changed its address to 126 E. Lincoln Ave., Rahway, NJ 07065. The entries in § 510.600(c) are amended to reflect this action.

#### V. Technical Amendments

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

- 21 CFR 520.1408 is revised to reflect all approved strengths of methylprednisolone tablets for dogs and cats.
- 21 CFR 556.730 is removed because there are no approved products containing thiabendazole for use in food-producing animals.

- 21 CFR 558.4(d) is being revised in the Category II table by removing the row entry for “Thiabendazole” because there are no longer any approved feed products for use in food-producing animals.
- 21 CFR 558.128 is revised to reflect withdrawal periods for different applications approved for use of chlortetracycline in cattle feed.

## VI. 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 pursuant to the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability” 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 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.

2. In § 510.600, in the table in paragraph (c)(1), revise the entry for “Accord Healthcare, Inc.”; and in the table in paragraph (c)(2), revise the entry for “016729” to read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	
Accord Healthcare, Inc., 126 E. Lincoln Ave., Rahway, NJ 07065	016729
* * * * *	

(2) \* \* \*

Drug labeler code	Firm name and address
	* * * * *
016729	Accord Healthcare, Inc., 126 E. Lincoln Ave., Rahway, NJ 07065
	* * * * *

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 § 520.1408, revise paragraph (b) to read as follows:

§ 520.1408 Methylprednisolone.

\* \* \* \* \*

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

\* \* \* \* \*

5. Add § 520.1425 to read as follows:

§ 520.1425 Metronidazole.

(a) *Specifications.* Each milliliter of suspension contains 125 milligrams (mg) metronidazole.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use--(1) Amount.* Administer 25 mg per kilogram (11.3 mg per pound) of body weight twice daily for 5 consecutive days.

(2) *Indications for use.* For the treatment of *Giardia duodenalis* infection in dogs.

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

6. Add § 520.1892 to read as follows:

§ 520.1892 Pregabalin.

(a) *Specifications.* Each milliliter (mL) of solution contains 50 milligrams (mg) pregabalin.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use--(1) Amount.* Administer orally as a single dose of 5 mg/kg (0.1 mL/kg) approximately 1.5 hours before the start of the transportation or veterinary visit.

(2) *Indications for use.* For alleviation of acute anxiety and fear associated with transportation and veterinary visits.

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

7. In § 520.2645, revise paragraph (d)(2) to read as follows:

§ 520.2645 Tylvalosin.

\* \* \* \* \*

(d) \* \* \*

(2) *Indications for use.* For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*, *Glaesserella* (*Haemophilus*) *parasuis*, *Pasteurella multocida*, *Streptococcus suis*, and *Mycoplasma*

*hyopneumoniae* in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of SRD.

\* \* \* \* \*

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

9. In § 522.304, revise paragraph (b) to read as follows:

§ 522.304 Carprofen.

\* \* \* \* \*

(b) *Sponsors*. See Nos. 016729, 017033, 054771, 055529, and 069043 in § 510.600(c) of this chapter.

\* \* \* \* \*

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

§ 522.812 Enrofloxacin.

\* \* \* \* \*

(b) \* \* \*

(1) Nos. 016729, 017033, 055529, 058198, 069043, and 086101 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and

(2) Nos. 051311, 055529, 058005, 058198, 061133, 069043, and 086101 for use of product described in paragraph (a)(2) as in paragraphs (e)(2) and (3) of this section.

\* \* \* \* \*

11. In § 522.955, revise paragraph (b)(3) and the second sentence in paragraph (d)(1)(ii)(C) to read as follows:

§ 522.955 Florfenicol.

\* \* \* \* \*

(b) \* \* \*

(3) Nos. 058005, 058198, and 069043 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(C) *Limitations.* \* \* \* Nos. 000061, 058005, 058198, and 069043: Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. \* \* \*

\* \* \* \* \*

#### PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

13. In 524.1044a, revise paragraph (b) to read as follows:

§ 524.1044a Gentamicin ophthalmic solution.

\* \* \* \* \*

(b) *Sponsors.* See Nos. 000061 and 086189 in § 510.600(c) of this chapter.

\* \* \* \* \*

14. In 524.1146, revise paragraphs (b)(1) and (2) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

\* \* \* \* \*

(b) \* \* \*

(1) Nos. 017030, 051072, 051311, 055529, 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, 051072, 051311, 055529, and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

\* \* \* \* \*

15. In 524.2098, revise paragraph (b) to read as follows:

§ 524.2098 Selamectin.

\* \* \* \* \*

(b) *Sponsors*. See Nos. 051072, 051311, 054771, 055529, and 061133 in § 510.600(c) of this chapter.

\* \* \* \* \*

16. In 524.2099, revise paragraph (c)(2) to read as follows:

§ 524.2099 Selamectin and sarolaner.

\* \* \* \* \*

(c) \* \* \*

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

\* \* \* \* \*

#### PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

18. In § 529.1186, revise paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

\* \* \* \* \*

(b) *Sponsors*. See Nos. 017033, 054771, and 066794 in § 510.600(c) of this chapter.

\* \* \* \* \*

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

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

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

§ 556.730 [Removed]

20. Remove § 556.730.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

22. Amend § 558.4, by removing the entry for “Thiabendazole” in the Category II” table in paragraph (d).

23. In § 558.95, revise paragraphs (b), (e)(2)(i) and (ii), and (e)(3)(i) and (ii) to read as follows:

§ 558.95 Bambermycins.

\* \* \* \* \*

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

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Growing turkeys: For improved feed efficiency	Feed continuously as the sole ration	016592
(ii) 2	Growing turkeys: For increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration	016592

(3) \* \* \*

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
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(i) 2	Growing-finishing swine: For increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration	016592
(ii) 2 to 4	Growing-finishing swine: For improved feed efficiency	Feed continuously as the sole ration	016592

\* \* \* \* \*

24. In § 558.128:

- a. Revise paragraphs (e)(4)(xvi) and (xvii);
- b. Redesignate paragraphs (e)(4)(xxi) through (lviii) as paragraphs (e)(4)(xxiii) through (lx); and
- c. Add new paragraphs (e)(4)(xxi) and (xxii).

The revision and additions read as follows:

§ 558.128 Chlortetracycline.

\* \* \* \* \*

(e) \* \* \*

(4) \* \* \*

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(xvi) to provide 10 mg/lb of body weight daily		Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. To sponsor No. 054771 (NADAs 048-761 and 046-699) and to sponsor No. 069254 (ANADA 200-510): May be mixed in the cattle's daily ration or administered as a top-dress. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor No. 054771 under NADA 046-699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: Zero withdrawal period. See paragraph (d)(3) of this section.	054771 066104 069254
(xvii) to provide 10 mg/lb of body weight daily		Calves (up to 250 lb): For the treatment of bacterial enteritis caused by <i>Escherichia coli</i> susceptible to chlortetracycline	A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal	066104
* * * * *				
(xxi) 400 to 2,000 g/ton	Monensin, 15 to 84	Replacement beef and dairy heifers: For treatment of bacterial enteritis caused	For replacement beef and dairy heifers not currently being fed monensin: Feed as the sole ration for not more than 5	069254

		<p>by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline; and for the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i></p>	<p>days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.</p> <p>For replacement beef and dairy heifers currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone.</p> <p>This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.</p> <p>Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.</p>	
(xxii) 400 to 2,000 g/ton	Monensin, 15 to 400	<p>Replacement beef and dairy heifers: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline; and for increased rate of weight gain</p>	<p>For replacement beef and dairy heifers not currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.</p> <p>For replacement beef and dairy heifers currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone.</p>	069254

			This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
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§ 558.600 [Removed]

25. Remove § 558.600.

Dated: February 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-03765 Filed: 2/26/2024 8:45 am; Publication Date: 2/27/2024]