4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 515, 516, 520, 522, 524, 529, and 558

[Docket No. FDA-2022-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 Name and 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 January, February, and March 2022. 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 of the regulations.

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

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 January, February, and March 2022, 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.

FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During January, February, and March 2022

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 10, 2022	131-675	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	SAFE-GUARD (fenbendazole) Type A Medicated Article	Cattle	Supplemental approval to establish withdrawal periods in accordance with repartitioning of acceptable daily intake; and to add fourth-stage larval indications for certain endoparasites of cattle	
January 13, 2022	141-546	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007	SOLENSIA (frunevetmab injection) Injectable Solution	Cats	Original approval for the control of pain associated with osteoarthritis	FOI Summary
January 20, 2022	141-547	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	ZORBIUM (buprenorphine transdermal solution) Transdermal Solution	Cats	Original approval for the control of postoperative pain associated with surgical procedures	FOI Summary
January 25, 2022	200-707	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	TILMOVET AC (tilmicosin) Solution	Swine	Original approval as a generic copy of NADA 141-361	FOI Summary
January 28, 2022	200-716	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom	MIDAMOX for Dogs (imidacloprid and moxidectin) Topical Solution	Dogs	Original approval as a generic copy of NADA 141-251	FOI Summary
February 7, 2022	200-665	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	INCREXXA 25 (tulathromycin injection) Injectable Solution	Cattle and Swine	Original approval as a generic copy of NADA 141-349	FOI Summary
February 7, 2022	200-717	Aurora Pharmaceutical, Inc,1196 Highway 3 South, Northfield, MN 55057-3009	TIAGARD 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate	Swine	Original approval as a generic copy of NADA 140-916	FOI Summary
February 7, 2022	200-718	Do	BARRIER for Dogs (imidacloprid and moxidectin) Topical Solution	Dogs	Original approval as a generic copy of NADA 141-251	FOI Summary
February 9, 2022	200-715	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	AROVYN (tulathromycin injection) Injectable Solution	Cattle and Swine	Original approval as a generic copy of NADA 141-244	FOI Summary
March 11, 2022	200-720	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom	ENROFLOX (enrofloxacin) Chewable Tablets	Dogs	Original approval as a generic copy of NADA 140-441	FOI Summary

March 23, 2022	200-723	Do	TULIEVE (tulathromycin injection) Injectable Solution	Cattle and Swine	Original approval as a generic copy of NADA 141-244	FOI Summary
March 28, 2022	200-721	Do	MIDAMOX for Cats (imidacloprid and moxidectin) Topical Solution	Cats	Original approval as a generic copy of NADA 141-254	FOI Summary
March 28, 2022	200-722	Do	FIROX (firocoxib) Chewable Tablets	Dogs	Original approval as a generic copy of NADA 141-230	FOI Summary
March 28, 2022	200-688	Virbac AH, Inc., P.O .Box 162059, Fort Worth, TX 76161	TENOTRYL (enrofloxacin) Injectable Solution	Cattle and Swine	Original approval as a generic copy of NADA 141-068	FOI Summary
March 30, 2022	141-551	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland	ZENALPHA (medetomidine and vatinoxan injection)	Dogs	Original approval for use as a sedative and analgesic to facilitate clinical examination, clinical procedures, and minor surgical procedures	FOI Summary

II. Withdrawals of Approval

Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601, has requested that FDA withdraw approval of NADA 140-908 for VET-METH Bolus, a bolus containing sulfamethazine for use in cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 520.2260a are amended to reflect this action.

Ridley USA, Inc., 111 W. Cherry St., suite 500, Mankato, MN 56001, has requested that FDA withdraw approval of NADA 136-214 for VMS Bloat Blox, an oral dosage form containing polyoxyethylene (23) lauryl ether for use in beef and nonlactating dairy cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 520.1846 are amended to reflect this action.

III. Changes of Sponsorship

Halocarbon Products Corp., 6525 The Corners Pkwy., suite 200, Peachtree Corners, GA 30092 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-129 for Isoflurane, USP and ANADA 200-467 for Sevoflurane to Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211. As provided in the regulatory text, the animal drug regulations in 21 CFR 529.1186 and 529.2110, respectively, are amended to reflect these changes of sponsorship.

IV. Change of Sponsor's Name and Address

Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478 has informed FDA that it has changed its name and address to Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505. As provided in the regulatory text, the animal drug regulations in § 510.600(c) (21 CFR 510.600(c)) are amended to reflect this change of a sponsor's name and address.

V. Technical Amendments

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

- Section 510.600 is amended to remove the entry for Halocarbon Products Corp. from, and add Vetcare Oy to, the list of sponsors of approved applications. The entries for Mylan Institutional, Inc. and Norbrook Laboratories Ltd. are revised as well.
- 21 CFR 516.812 is amended to reflect a current drug labeler code for a use of enrofloxacin injectable solution in cattle.
- 21 CFR 520.88g is amended reflect a current sponsor drug labeler code and revised indications for use of tablets containing amoxicillin and clavulanate in dogs and cats.
- 21 CFR 520.530 is amended to conform to content codified for animal drugs available by veterinary prescription.
- 21 CFR 520.905a is amended to reflect revised conditions of use for fenbendazole suspension in horses.
- 21 CFR 520.928 is amended to reflect correct directions for administration of firocoxib chewable tablets in dogs.
- 21 CFR 520.1242a is amended to reflect revised indications for use of a levamisol powder in cattle and sheep.
- 21 CFR 520.1720a is amended to correct an error in the strength of approved phenylbutazone boluses.
- 21 CFR 520.1870 is amended to remove an undefined acronym in the conditions for use of praziquantel tablets.
- 21 CFR 520.1872 is amended to conform to content codified for animal drugs available by veterinary prescription.
- 21 CFR 520.2325a is amended to reflect instructions for use of sulfaquinoxaline powder and solution in poultry and cattle.

- 21 CFR 520.2598 is amended to reflect revised indications for use for trilostane capsules in dogs.
- 21 CFR 522.533 is amended to revise the indications for use of deslorelin injectable solution in mares.
- 21 CFR 522.2615 is amended to reflect revised human food safety warnings for tripelennamine injectable solution in cattle.
- 21 CFR 524.1001 is amended to correct a spelling error in the heading and specifications for fluralaner and moxidectin topical solution.
- 21 CFR 524.2098 is amended to reflect all sponsors of approved applications for selamectin topical solution in dogs and cats.
- 21 CFR 558.4 is amended in the Category II table to reflect the correct assay limits for Type C medicated feeds manufactured using nicarbazin powder.
- 21 CFR 558.128 is amended to reflect the class of cattle and incorporation level for single-ingredient and combination-drug medicated feeds containing chlortetracycline used for control of anaplasmosis in cattle.
- 21 CFR 558.633 is amended to clarify expiration dates for medicated feeds containing tylvalosin.

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)), which requires *Federal Register* publication of "notice[s]… effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

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

Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

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

21 CFR Parts 515 and 516

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

21 CFR Parts 520, 522, 524, and 529

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, 515, 516, 520, 522, 524, 529, 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), remove the entry for "Halocarbon Products Corp."; revise the entries for "Mylan Institutional, Inc." and "Norbrook Laboratories Ltd."; and add in alphabetical order an entry for "Vetcare Oy"; and

b. In the table in paragraph (c)(2), remove the entry for “012164”; revise the entries for “051079” and “055529”; and add in numerical order an entry for “086155”.

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
* * * * * * *	
Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505	051079
* * * * * * *	
Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom	055529
* * * * * * *	
Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland	086155
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051079	Mylan Institutional, Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505
* * * * * * *	
055529	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom
* * * * * * *	
086155	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland
* * * * * * *	

PART 515--MEDICATED FEED MILL LICENSE

3. The authority citation for part 515 continues to read as follows:

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

4. In § 515.10, revise paragraph (a) to read as follows:

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Form FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine at: https://www.fda.gov/animal-veterinary/animal-food-feeds/medicated-feeds.

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

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

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

§ 516.812 [Amended]

6. In § 516.812, in paragraph (b), remove "000859" and in its place add "058198".

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

8. In § 520.88g, revise paragraphs (b)(2), (c)(1)(ii), and (c)(2)(ii) to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

* * * * *

(b) * * *

(2) Nos. 017033 and 069043 for use of tablets as in paragraph (c) of this section.

(c) * * *

(1) * * *

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

* * * * *

(2) * * *

(ii) *Indications for use*. Treatment of skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

* * * * *

§ 520.530 [Amended]

9. In § 520.530, remove paragraph (c) and redesignate paragraph (d) as paragraph (c).

10. In § 520.812, revise paragraphs (b)(1) and (3) to read as follows:

§ 520.812 Enrofloxacin.

* * * * *

(b) * * *

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

* * * * *

(3) Nos. 055529 and 086101 for use of product described in paragraph (a)(2) of this section.

* * * * *

11. In § 520.905a, revise paragraphs (e)(1)(ii) and (iii) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(1) * * *

(ii) *Indications for use*. For the treatment and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* species), small strongyles (*Cyathostomum* species, *Cylicocyclus* species, *Cylicostephanus* species, *Cylicodontophorus* species), pinworms (*Oxyuris equi*) and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Do not use in horses intended for human consumption.

* * * * *

12. In § 520.928, revise the section heading and paragraphs (a), (b), and (c)(1)(i) to read as follows:

§ 520.928 Firocoxib.

(a) *Specifications*--(1) Each chewable tablet contains 57 or 227 milligrams (mg) firocoxib.

(2) Each tablet contains 57 mg firocoxib.

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

(1) Nos. 000010 and 055529 for use of products described in paragraph (a)(1) as in paragraph (c)(1) of this section; and

(2) No. 000010 for use of the product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) * * *

(1) * * *

(i) *Amount.* 5 mg/kg (2.27 mg/lb) body weight. Administer once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. Administer approximately 2 hours before soft tissue or orthopedic surgery.

* * * * *

13. In § 520.1242a, revise paragraph (b)(3) to read as follows:

§ 520.1242a Levamisol powder.

* * * * *

(b) * * *

(3) No. 016592 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section.

* * * * *

14. In § 520.1720a, revise paragraph (a) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) phenylbutazone. Each bolus contains 1, 2, or 4 g phenylbutazone.

* * * * *

§ 520.1846 [Removed]

15. Remove § 520.1846.

§ 520.1870 [Amended]

16. In § 520.1870, in paragraph (c)(2)(iii), in the third sentence, remove "OTC" and in its place add "over the counter".

17. In § 520.1872, revise paragraph (c)(1)(iii) and add reserved paragraph (c)(2) to read as follows:

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

* * * * *

(c) * * *

(1) * * *

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

(2) [Reserved]

18. Revise § 520.2260a to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

(a) *Specifications.* Each oblet or bolus contains:

(1) 2.5, 5, or 15 grams sulfamethazine.

(2) 5 grams sulfamethazine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section.

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

(2) No. 054771 for use of product described in paragraph (a)(2) of this section.

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

(d) *Conditions of use*. (1) Oblets and boluses described in paragraph (a)(1) of this section:

(i) *Amount*. Administer as a single dose 100 milligrams per pound (mg/lb) of body weight the first day and 50 mg/lb of body weight on each following day.

(ii) *Indications for use*. (A) *Beef cattle and nonlactating dairy cattle*. For the treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), and coccidiosis (*Eimeria bovis* and *E. zurnii*).

(B) *Horses*. For the treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus* equi), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations*. Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Do not treat cattle within 10

days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(2) Boluses described in paragraph (a)(2) of this section:

(i) *Amount*. Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use*. (A) *Ruminating beef and dairy calves*. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacillosis) caused by *Escherichia coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(B) [Reserved]

(iii) *Limitations*. Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follow recommended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

19. In § 520.2325a, revise paragraphs (c)(4)(iii) and (d) to read as follows:

§ 520.2325a Sulfaquinoxaline powder and solution.

* * * * *

(c) * * *

(4) * * *

(iii) In lieu of treatment as provided in paragraph (c)(4)(ii) of this section, administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations*. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys, or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20. In § 520.2455, revise paragraph (b)(3) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(3) Nos. 016592, 051072, 051311, and 061133 for product described in paragraph (a)(2) of this section.

* * * * *

21. In § 520.2471, revise paragraph (b) to read as follows:

§ 520.2471 Tilmicosin.

* * * * *

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

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22. In § 520.2598, revise paragraph (c)(2) to read as follows:

§ 520.2598 Trilostane.

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(c) * * *

(2) *Indications for use*. For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism in dogs.

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

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

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

24. In § 522.533, revise paragraphs (c)(1)(ii) and (c)(2)(ii) to read as follows:

§ 522.533 Deslorelin.

* * * * *

(c) * * *

(1) * * *

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters (mm) in diameter.

* * * * *

(c) * * *

(2) * * *

(ii) *Indications for use.* For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mm in diameter.

* * * * *

25. In § 522.812, revise paragraph (b)(2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(2) Nos. 051311, 055529, 058005, 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.

* * * * *

26. Add § 522.1008 to read as follows:

§ 522.1008 Frunevetmab.

(a) *Specifications.* Each milliliter (mL) of solution contains 7 milligrams (mg) frunevetmab.

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

(c) *Conditions of use*--(1) *Cats*--(i) *Amount*. Administer once a month by subcutaneous injection the full contents of one or two 1-mL vials to achieve a minimum dosage of 0.45 mg/lb (1 mg/kg) body weight.

(ii) *Indications for use.* For the control of pain associated with osteoarthritis in cats.

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

(2) [Reserved]

27. Add § 522.1338 to read as follows:

§ 522.1338 Medetomidine and vatinoxan.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) medetomidine hydrochloride and 10 mg vatinoxan hydrochloride.

(b) *Sponsor.* See No. 086155 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount.* Administer by intramuscular injection a dose based on body surface area (BSA). Calculate the dose using 1 mg medetomidine per square meter ($/m^2$) BSA or use the dosing table provided in labeling.

(2) *Indications for use.* For use as a sedative and analgesic in dogs to facilitate clinical examination, clinical procedures, and minor surgical procedures.

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

28. In § 522.2615, revise paragraph (d)(3)(iii) to read as follows:

§ 522.2615 Tripelennamine.

* * * * *

(d) * * *

(3) * * *

(iii) *Limitations.* Milk taken during treatment and for 24 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 4 days following the last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

29. In § 522.2630, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(1) Nos. 000061, 013744, 051311, 054771, 055529, 058198, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Nos. 013744, 051311, 054771, and 058198 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

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

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

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

31. Add § 524.230 to read as follows:

§ 524.230 Buprenorphine.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 milligrams (mg) buprenorphine. The drug is supplied in tubes containing 0.4 mL (8 mg) or 1.0 mL (20 mg).

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

(c) *Conditions of use in cats*--(1) *Amount.* Administer topically to the dorsal cervical area at the base of the skull a single dose of 1.2 to 3.1 mg/lb (2.7 to 6.7 mg/kg) approximately 1 to 2 hours before surgery.

(2) *Indications for use.* For the control of postoperative pain associated with surgical procedures in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Buprenorphine is a Schedule III controlled substance.

32. In § 524.1001, revise the section heading and paragraph (a) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

(a) *Specifications.* Each milliliter of solution contains 280 milligram (mg) fluralaner and 14 mg moxidectin. Each individually packaged tube contains either 112.5 mg fluralaner and 5.6 mg moxidectin; 250 mg fluralaner and 12.5 mg moxidectin; or 500 mg fluralaner and 25 mg moxidectin.

* * * * *

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

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(1) Nos. 017030, 051072, 055529, 058198, and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030, 051072, 055529, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

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

§ 524.2098 Selamectin.

* * * * *

(b) *Sponsors.* See Nos. 051072, 054771, 055529, 061133, and 061651 in § 510.600(c) of this chapter.

* * * * *

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

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

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 017033**,** 054771, 065085, and 066794 in § 510.600(c) of this chapter.

* * * * *

37. In § 529.2110, revise paragraph (b) to read as follows:

§ 529.2110 Sevoflurane.

* * * * *

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

* * * * *

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

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

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

39. In § 558.4, in paragraph (d), in the "Category II" table, revise the entry for "Nicarbazin (powder)" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

Category II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
* * * * * * *			
Nicarbazin (powder)	96-104	9.08 g/lb (2.00%)	85-115/80-120
* * * * * * *			

* * * * *

40. In § 558.128, revise paragraphs (e)(4)(iii) and (xli) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(iii) to provide 0.5 mg/lb of body weight daily		Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	Feed to provide chlortetracycline at the rate of 0.5 mg per pound of body weight daily. Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254
* * * * * * *				
(xli) 25 to 2,800 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate	Growing beef heifers fed in confinement for slaughter under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
* * * * * * *				

* * * * *

41. In § 558.258, revise paragraph (e)(1), paragraph (e)(2) table column headings, and paragraphs (e)(2)(i) and (e)(3) through (5) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(1) * * *

Fenbendazole grams per ton	Combination grams per ton	Indications for use	Limitations	Sponsor
(i) 14.5		Growing turkeys: For the treatment and control of gastrointestinal worms: roundworms, adults and larvae (*Ascaridia dissimilis*); cecal worms, adults and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead)	Feed continuously as the sole ration for 6 days. For growing turkeys only.	000061
(ii) [Reserved]				

(2) *Swine*.

Fenbendazole grams per ton	Combination grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300		Swine: For the treatment and control of Lungworms: adult (*Metastrongylus apri* and *M. pudendotectus*); Gastrointestinal worms: adult and larvae (L3, 4 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, 3, 4 stages--intestinal mucosal forms) whipworms (*Trichuris suis)*; and Kidney worms: adult and larvae (*Stephanurus dentatus*)	Feed as the sole ration to provide 9 mg/kg of body weight (4.08 mg/lb) over a period of 3 to 12 consecutive days. Swine must not be slaughtered for human consumption within 4 days following last treatment with this drug product.	000061
		* * * * * * *		

(3) *Cattle*.

Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
(i) 200 to 1,000	Dairy and beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms	Feed as the sole ration for 1 day to provide 5 mg/kg body weight (2.27 mg/lb). Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days	000061

Fenbendazole grams per ton	Indications for use	Limitations	Sponsor
	(*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*)	following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	
(ii) [Reserved]			

(iii) *Top dress medicated feed*--(A) *Proprietary formulas.* The following feed can be manufactured only per an approved proprietary formula and specifications:

Fenbendazole concentration	Indications for use	Limitations	Sponsor
(*1*) 2.27 g/lb	Beef and dairy cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata and C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed as a top dress for 1 day to provide 5 mg/kg body weight (2.27 mg/lb). Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*2*) [Reserved]			

(B) [Reserved]

(iv) *Free-choice medicated feeds*--(A) *Proprietary formulas (21 CFR 510.455(e)(2))*. The following feeds can be manufactured only per an approved proprietary formula and specifications:

Fenbendazole concentration	Indications for use	Limitations	Sponsor
(*1*) 12,100 g/ton mineral	Beef cattle on pasture: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia*	Feed free-choice at the rate of 0.0375 lb per 100 pounds of body weight over a 3- to 6-day period to provide a total of 2.27 mg fenbendazole per pound of body weight. Not for use in dairy cattle. Beef cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves.	000061

Fenbendazole concentration	Indications for use	Limitations	Sponsor
	punctata and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*)	A withdrawal period has not been established for this product in pre-ruminating calves.	
(*2*) 2.27 g/lb mineral	Beef cattle on pasture: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*)	Feed free-choice at the rate of 0.10 lb (1.6 oz) per 100 pounds of body weight over a 3- to 6-day period, to deliver a total of 2.27 mg fenbendazole per pound of body weight. Not for use in dairy cattle. Beef cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061

(B) *Published formulas (§ 510.455(e)(1) of this chapter)*. The following feeds can be manufactured only per one of the formulas and specifications published below:

(*1*) *Amount.* 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient[1]	Percent	International Feed No.
(*i*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6-04-152
Monosodium phosphate	31.16	6-04-288
Dried cane molasses	3.12	4-04-695
Zinc sulfate	0.76	6-05-556
Copper sulfate	0.45	6-01-720
Fenbendazole 20% Type A article	5.51	n/a
(*ii*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6-04-152
Dicalcium phosphate (18.5% P)	32.44	6-00-080
Calcium carbonate (38% Ca)	15.93	6-01-069
Magnesium oxide (56% Mg)	10.14	6-02-756
Zinc sulfate	1.47	6-05-556
Mineral oil	1.00	8-03-123
Dried cane molasses (46% sugars)	0.98	4-04-695
Potassium iodide	0.01	6-03-759
Fenbendazole 20% Type A article	2.10	n/a
(*iii*) Free-choice, liquid Type C feed[2]:		
Cane molasses[3]	80.902	4-13-251
Water	9.36	n/a
Urea solution, 55%	7.05	5-05-707
Phosphoric acid 75% (feed grade)	2.00	6-03-707
Xantham gum	0.20	8-15-818
Trace minerals[4]	0.20	n/a
Vitamin premix[4]	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1]Formulation modifications require FDA approval prior to marketing. Selenium is not approved for use in the liquid, free-choice formulations described in paragraph (e)(3)(iv)(B) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (*see* 21 CFR 573.920).

[2]The labeling for the liquid free-choice Type C medicated feed must bear an expiration date of 12 weeks after the date of manufacture.

[3]The percentage of cane molasses and water in the formulation may be adjusted as needed to bring the brix value of the molasses to the industry standard of 79.5 brix.
[4]The contents of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds.

(*2*) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(*3*) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Milk taken during treatment and for 60 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 13 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

(4) *Horses*.

Fenbendazole grams per ton	**Indications for use**	**Limitations**	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), and pinworms (*Oxyuris equi*); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (*Parascaris equorum*)	Feed at the rate of 0.1 lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Do not use in horses intended for human consumption.	000061
(ii) [Reserved]			

(5) *Zoo and wildlife animals*.

Species/Class	**Fenbendazole grams per ton**	**Indications for use**	**Limitations**	Sponsor
(i) Feral swine (*Sus scrofa*):	90 to 325	For the treatment and control of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*)	Use as a complete feed at a rate to provide 3 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae)	50 to 300	For the treatment and control of small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm	Use as a complete feed at a rate to provide 2.5 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

		(*Haemonchus* spp.), whipworm (*Trichuris* spp.)		
(iii) Rocky mountain bighorn sheep (*Ovis c. canadensis*)	375 to 1,000	For the treatment and control of *Protostrongylus* spp.	Use as a complete feed at a rate to provide 10 mg/kg/day for 3 consecutive days. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

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§ 558.633 [Amended]

42. In § 558.633, in paragraph (d)(3), remove the first sentence.

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-20836 Filed: 9/28/2022 8:45 am; Publication Date: 9/29/2022]