4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Afoxolaner; Carprofen; Ceftiofur Hydrochloride; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during September 2013. FDA is also informing the public of the availability of summaries on the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsorship for an ANADA.

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, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during September 2013, 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.

In addition, Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-555 for LIBREVIA (carprofen) Soft Chewable Tablets to Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201. Accordingly, the Agency is amending the regulations to reflect this change of sponsorship.

Following this change of sponsorship, Piedmont Animal Health is no longer a sponsor of an approved NADA. Accordingly, FDA is amending 21 CFR 510.600 to remove the entries for this firm.

This rule 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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During September 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-406	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	NEXGARD (afoxolaner) Chewable Tablets	Original approval for the treatment and prevention of flea infestations, and the treatment and control of American dog tick infestations in dogs.	520.43	yes	CE[1,2]
095-735	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	RUMENSIN (monensin) Type A medicated article	Supplement extending the lower dose limit of monensin medicated feed for pasture cattle from 25 grams per ton (g/ton) to 15 g/ton.	558.355	yes	CE[1,3]
141-288	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	EXCENEL RTU EZ (ceftiofur hydrochloride) Injectable Suspension	Supplemental approval of a reformulated product for use in cattle and swine, addition of an intramuscular route of injection in cattle, change in withdrawal period for cattle, and addition of a warning statement.	522.313b	yes	CE[1,4]

[1]The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.
[2]CE granted under 21 CFR 25.33(d)(1).
[3]CE granted under 21 CFR 25.33(a)(1).
[4]CE granted under 21 CFR 25.33(a)(3).

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520 and 522

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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

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

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Piedmont Animal Health"; and in the table in paragraph (c)(2), remove the entry for "058147".

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§§ 520.44, 520.45, 520.45a, and 520.45b [Redesignated as §§ 520.28, 520.38, 520.38a, and 520.38b]

4. Redesignate §§ 520.44, 520.45, 520.45a, and 520.45b as §§ 520.28, 520.38, 520.38a, and 520.38b, respectively.

5. Add § 520.43 to read as follows:

§ 520.43 Afoxolaner.

(a) Specifications. Each chewable tablet contains 11.3, 28.3, 68, or 136 milligrams (mg) afoxolaner.

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

(c) Conditions of use--(1) Amount. Administer orally once a month at a minimum dosage of 1.14 mg/pound (lb) (2.5 mg/kilogram (kg)).

(2) Indications for use. For the treatment and prevention of flea infestations (Ctenocephalides felis), and the treatment and control of American dog tick (Dermacentor variabilis) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month.

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

§ 520.309 [Amended]

6. In paragraph (b)(2) of § 520.309, remove "Nos. 000115, 055529, 058147, and 062250" and in its place add "Nos. 000115, 000859, 055529, and 062250".

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

7. The authority citation for 21 CFR part 522 continues to read as follows:

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

8. In 522.313b, revise paragraphs (b), (d), (e)(2)(i), and (e)(2)(iii) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

* * * * *

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

* * * * *

(d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) * * *

(2) * * *

(i) Amount. Administer by subcutaneous or intramuscular injection as follows:

(A) For bovine respiratory disease and acute bovine interdigital necrobacillosis: 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days.

(B) For bovine respiratory disease: 2.2 mg/kg of body weight administered twice at a 48 hour interval.

(C) For acute metritis: 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days.

* * * * * *

(iii) Limitations. Treated cattle must not be slaughtered for 4 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

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

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

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

§ 558.355 [Amended]

10. In § 558.355, in the introductory text in paragraph (f)(3)(iii), remove "Monensin, 25 to 400 grams" and in its place add "Monensin, 15 to 400 grams".

Dated: October 31, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-26473 Filed 11/04/2013 at 8:45 am; Publication Date: 11/05/2013]