4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 529, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Enrofloxacin; Melengestrol; Meloxicam; Pradofloxacin; Tylosin

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 November 2012. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

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,

email: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect original and supplemental approval actions during November 2012, as listed in table 1 of this document. 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.

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 November 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-344	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	VERAFLOX (pradofloxacin) Oral Suspension for Cats	Original approval for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pasteurella multocida, Streptococcus canis, S. aureus, S. felis, and S. pseudintermedius.	520.1860	Yes	CE[1]
141-346	Abbott Laboratories, Inc., North Chicago, IL 60064	OROCAM (meloxicam) Transmucosal Oral Spray	Original approval for the control of pain and inflammation associated with osteoarthritis in dogs.	529.1350	Yes	CE[1]
141-068	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	BAYTRIL 100 (enrofloxacin) Injectable Solution	Supplemental approval adding treatment and control of swine respiratory disease associated with Bordetella bronchiseptica and Mycoplasma hyopneumoniae.	522.812	Yes	CE[1]
200-534	Huvepharma AD, 5th Floor, 3A Nikolay Haitov St., 1113 Sophia, Bulgaria	TYLOVET 100 (tylosin phosphate) and RUMENSIN (monensin) and MGA (melengestrone acetate) liquid and dry, combination drug Type C medicated feeds	Original approval as a generic copy of NADA 138-870.	558.342	Yes	CE[1]

[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.

List of Subjects

21 CFR Parts 520, 522, 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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, 529, and 558 are amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

2. Add § 520.1860 to read as follows:

§ 520.1860 Pradofloxacin.

(a) Specifications. Each milliliter of suspension contains 25 milligrams (mg) pradofloxacin.

(b) Sponsor. See No. 000859 in § 510.600(c) of this chapter.

(c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) Conditions of use in cats--(1) Amount. Administer 3.4 mg/lb (7.5 mg/kg) body weight once daily for 7 consecutive days.

(2) Indications for use. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pasteurella multocida, Streptococcus canis, Staphylococcus aureus, Staphylococcus felis, and Staphylococcus pseudintermedius.

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

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

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

4. In § 522.812, revise paragraph (e)(3)(ii) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(e) * * *

(3) * * *

(ii) Indications for use. For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica, and Mycoplasma hyopneumoniae.

* * * * *

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 529 continues to read as follows:

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

6. Add § 529.1350 to read as follows:

§ 529.1350 Meloxicam.

(a) Specifications. Each milliliter of solution contains 5 milligrams (mg) meloxicam.

(b) Sponsor. See No. 000074 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer 0.1 mg per kilogram of body weight once daily using the metered dose pump.

(2) Indications for use. For the control of pain and inflammation associated with osteoarthritis in dogs.

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

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

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

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

§ 558.342 [Amended]

8. In § 558.342, in the table, in paragraph (e)(1)(xi), in the "Limitations" column, revise the last sentence to read "Monensin provided by No. 000986 and tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter."; and in the "Sponsor" column, add "016592".

Dated: December 26, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2012-31397 Filed 12/28/2012 at 8:45 am; Publication Date: 12/31/2012]