4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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

Oral Dosage Form New Animal Drugs; Amprolium; Meloxicam

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 August 2013. FDA is also informing the public of the availability of summaries of 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, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during August 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 CVM 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 August 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-514	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	BOVIPROL (amprolium) 9.6% Oral Solution	Original approval as a generic copy of NADA 13-149	520.100	Yes	CE[1]
200-550	Ceva Sante Animale, 10 Avenue de la Ballastiére 33500 Libourne, France	MELOXIDYL (meloxicam) Oral Suspension	Original approval as a generic copy of NADA 141-213	520.1350	Yes	CE[1]

[1]The Agency has determined under 21 CFR 25.33(a)(1) 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 in 21 CFR Part 520

Animal drugs.

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 part 520 is 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. In § 520.100, revise paragraph (b)(2) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(2) No. 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

* * * * *

§ 520.1350 [Redesignated as § 520.1367]

3. Redesignate § 520.1350 as § 520.1367.

4. Amend newly redesignated § 520.1367 by revising paragraphs (a) and (b) to read as follows:

§ 520.1367 Meloxicam.

(a) Specifications--(1) Each milliliter of suspension contains 0.5 milligrams (mg) meloxicam.

(2) Each milliliter of suspension contains 1.5 mg meloxicam.

(b) Sponsors. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section:

(1) No. 000010 for use of the products described in paragraph (a) of this section; and

(2) No. 013744 for use of the product described in paragraph (a)(2) of this section.

* * * * *

Dated: September 11, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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