



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

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

Implantation or Injectable Dosage Form New Animal Drugs; Maropitant; Tildipirosin

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 May 2012. 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:

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SUPPLEMENTARY INFORMATION: FDA's Center for Veterinary Medicine (CVM) is adopting use of a monthly Federal Register document to codify approval actions for NADAs and ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during May 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 (freedom of information 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 at <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 May 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-334	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901	ZUPREVO 18% (tildipirosin) Injectable Solution	Original approval for the treatment of bovine respiratory disease (BRD) in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD	522.2460 556.733	yes	CE ¹
141-263	Pfizer, Inc., 235 East 42d St., New York, NY 10017	CERENIA (maropitant citrate) Injectable Solution	Supplemental approval adding treatment of vomiting in cats	522.1315	yes	CE ¹

¹The Agency has determined under 21 CFR 25.33 that this action is categorically excluded 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 Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are amended as follows:

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

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

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

2. In § 522.1315, revise paragraph (c) to read as follows:

§ 522.1315 Maropitant.

* * * * *

(c) Conditions of use--(1) Dogs--(i) Amount. Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) Indications for use. For the prevention and treatment of acute vomiting.

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

(2) Cats--(i) Amount. Administer 1.0 mg/kg of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) Indications for use. For the treatment of vomiting.

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

3. Section 522.2460 is added to read as follows:

§ 522.2460 Tildipirosin.

(a) Specifications. Each milliliter of solution contains:

(1) 180 milligrams (mg) tildipirosin.

(2) [Reserved]

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.733 of this chapter.

(d) Conditions of use--(1) Cattle--(i) Amount. Administer 4 mg/kg of bodyweight one time by subcutaneous injection in the neck.

(ii) Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with M. haemolytica, P. multocida, and H. somni.

(iii) Limitations. Cattle intended for human consumption must not be slaughtered within 21 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

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

4. The authority citation for 21 CFR part 556 continues to read as follows:

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

5. Add § 556.733 to read as follows:

§ 556.733 Tildipirosin.

(a) Acceptable Daily Intake (ADI). The ADI for total residues of tildipirosin is 10 micrograms per kilogram of body weight per day.

(b) Tolerances. The tolerances for tildipirosin (the marker residue) are:

(1) Cattle--(i) Liver (the target tissue): 10 parts per million.

(ii) [Reserved]

(2) [Reserved]

(c) Related conditions of use. See § 522.2460 of this chapter.

Dated: June 27, 2012.

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Director,

Center for Veterinary Medicine.