

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2010-N-0002]

Oral Dosage Form New Animal Drugs; Praziquantel and Pyrantel

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 of a supplemental new animal drug application (NADA) filed by Bayer HealthCare LLC. The supplement provides for two new sizes of praziquantel and pyrantel pamoate tablets used in cats and kittens for the removal of various internal parasites and for a revised kitten age and weight restriction.

DATES: This rule is effective September 3, 2010.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, email: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141-008 for DRONTAL (praziquantel and pyrantel pamoate) Tablets used in cats and kittens for the removal of various internal parasites. The supplement provides for two new tablet sizes and for a revised kitten age and weight restriction. The supplemental NADA is approved as of June 15, 2010, and 21 CFR 520.1871 is amended to reflect the approval.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

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 § 520.1871, in paragraph (b)(1), remove "tablet" and in its place add "tablets"; and revise paragraphs (a)(1), (d)(1)(i), and (d)(1)(iii) to read as follows:

§ 520.1871 Praziquantel and pyrantel.

(a) * * *

(1) Each tablet contains 13.6 milligrams (mg) praziquantel and 54.3 mg pyrantel base (as pyrantel pamoate), 18.2 mg praziquantel and 72.6 mg pyrantel base (as pyrantel pamoate), or 27.2 mg praziquantel and 108.6 mg pyrantel base (as pyrantel pamoate).

* * * * *

(d) * * *

(1) * * *

(i) *Dosage.* Administer a minimum dose of 2.27 mg praziquantel and 9.2 mg pyrantel pamoate per pound of body weight according to the dosing tables on labeling. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated.

* * * * *

(iii) *Limitations.* Not for use in kittens less than 2 months of age or weighing less than 2.0 pounds. Consult your veterinarian before giving to sick or pregnant animals.

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Dated: August 31, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2010-N-0002]

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol and Flunixin

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 of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA adds *Mycoplasma bovis* to the bovine respiratory disease (BRD) pathogens for which use of an injectable solution containing florfenicol and flunixin meglumine is an approved treatment.

DATES: This rule is effective September 3, 2010.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed a supplement to NADA 141-299 that provides for use of RESFLOR GOLD (florfenicol and flunixin meglumine), a combination drug injectable solution. The supplement adds *M. bovis* to the BRD pathogens for which the use of this product is approved. The supplemental NADA is approved as of June 7, 2010, and the regulations in 21 CFR 522.956 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

List of Subjects in 21 CFR Part 522

Animal drugs.