

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier R. LEDESMA

2002 10 27 23 11 51

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of two strengths of pyrantel pamoate suspension in dogs for the management of various internal parasites.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-352 for PRIMEX CANINE (pyrantel pamoate) and PRIMEX CANINE-2X (pyrantel pamoate). PRIMEX CANINE contains 2.27 milligrams (mg) pyrantel base per milliliter (/mL); PRIMEX CANINE-2X contains 4.54 mg pyrantel base/mL. Both products are for oral use in dogs and puppies for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and in dogs, puppies, and lactating bitches to prevent reinfections of *T. canis*. First Priority's PRIMEX CANINE and PRIMEX CANINE-2X are approved as

generic copies of Pfizer, Inc.'s RFD Suspension and NEMEX-2 Suspension, respectively, approved under NADA 100-237. ANADA 200-352 is approved as of August 20, 2003, and the regulations are amended in § 520.2043 (21 CFR 520.2043) to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, § 520.2043 is being amended to correct the spelling of one of the subject parasites.

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.

FDA has determined under 21 CFR 25.33(a)(1) 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 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:

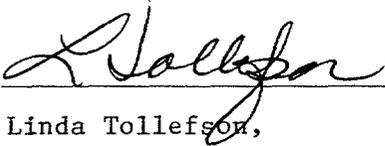
Authority: 21 U.S.C. 360b.

§ 520.2043 [Amended]

- 2. Section 520.2043 *Pyrantel pamoate suspension* is amended in paragraph (b)(2) by numerically adding “058829,”; and in paragraph (d)(2)(i)(B) by removing “*Toxascarias*” and by adding in its place “*Toxascaris*”.

Dated: 9/15/03

September 15, 2003.



Linda Tollefson,
Deputy Director,
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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