

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier L. CLAWSON
DDM

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 an original new animal drug application (NADA) filed by Virbac AH, Inc. The NADA provides for use of chewable tablets containing praziquantel and pyrantel pamoate in dogs and puppies for the treatment and control of various internal parasites.

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

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed NADA 141-261 for WORMXPLUS (praziquantel and pyrantel pamoate) Flavored Chewables and VIRBANTEL (praziquantel and pyrantel pamoate) Flavored Chewables that provides for their use in dogs and puppies for the treatment and control of various internal parasites. The NADA is approved as of March 13, 2007, and 21 CFR 520.1871 is 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)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 13, 2007.

FDA has determined under 21 CFR 25.33(d)(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 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. Amend § 520.1871 as follows:

a. Revise the section heading and paragraphs (a) and (b);

- b. Redesignate paragraph (c) as paragraph (d) and add new paragraph (c); and
- c. Revise newly redesignated paragraphs (d)(1)(i), (d)(1)(iii), and (d)(2).

The revisions, redesignation, and addition read as follows:

§ 520.1871 Praziquantel and pyrantel.

(a) *Specifications*—(1) Each tablet contains 18.2 milligrams (mg) praziquantel and 72.6 mg pyrantel (as pyrantel pamoate).

(2) Each chewable tablet contains 30 mg praziquantel and 30 mg pyrantel pamoate or 114 mg praziquantel and 114 mg pyrantel pamoate.

(b) *Sponsors*. See sponsors in § 510.600(c) for use as in paragraph (d) of this chapter.

(1) See No. 000859 for use of tablet described in paragraph (a)(1) of this section for use as in paragraph (d)(1) of this section.

(2) See No. 051311 for use of tablets described in paragraph (a)(2) of this section for use as in paragraph (d)(2) of this section.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) * * *

(1) * * *

(i) *Dosage*. 1.5 to 1.9 pounds, 1/4 tablet; 2 to 3 pounds, 1/2 tablet; 4 to 8 pounds, 1 tablet; 9 to 12 pounds, 1 1/2 tablets; 13 to 16 pounds, 2 tablets.

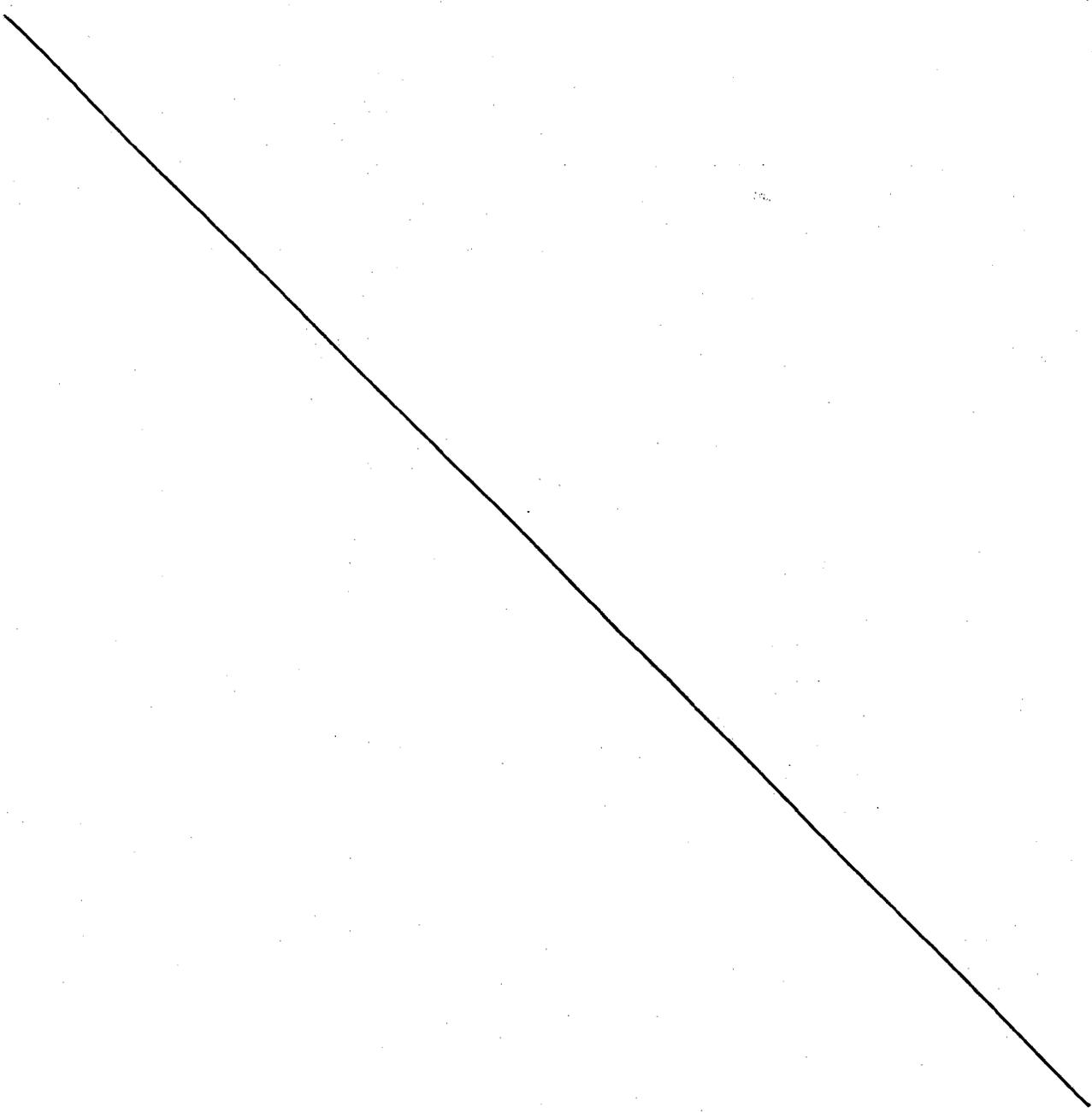
If reinfection occurs, treatment may be repeated.

* * * * *

(iii) *Limitations*. Not for use in kittens less than 1 month of age or weighing less than 1.5 pounds. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. Consult your veterinarian before giving to sick or pregnant animals.

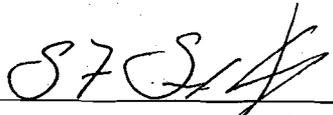
(2) *Dogs*—(i) *Amount*. Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) *Indications for use*. For the treatment and control of roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum*,



Ancylostoma braziliense, and *Uncinaria stenocephala*), and tapeworms
(*Dipylidium caninum* and *Taenia pisiformis*) in dogs and puppies.

Dated: 3/26/07
March 26, 2007.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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