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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Praziquantel Tablets

Display Date 10-2-03
Publication Date 10-3-03
Certifier G. Penley

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 Phoenix Scientific, Inc. The ANADA provides for the oral use of praziquantel tablets for the removal and control of certain cestode parasites in dogs.

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: Phoenix Scientific, Inc., 3915 South 48th St. Terr., St. Joseph, MO 64503, filed ANADA 200-265 that provides for the use of Praziquantel Tablets for the removal and control of certain cestode parasites in dogs. Phoenix Scientific, Inc.'s Praziquantel Tablets are approved as a generic copy of Bayer HealthCare LLC's DRONCIT (praziquantel) Canine Tablets approved under NADA 111-798. The ANADA is approved as of August 28, 2003, and the regulations are amended in 21 CFR 520.1870 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

NFR

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.

The agency 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 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. Section 520.1870 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

§ 520.1870 Praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 34 milligrams (mg) praziquantel.

(2) 11.5 or 23 mg praziquantel.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 000859 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section, as in paragraph (c)(2) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(1) of this section, as in paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii)(B) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 pounds (lb) and under, 1/2 tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1 1/2 tablets (51 mg); 16 to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 3 tablets (102 mg); 46 to 60 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.

(ii) *Indications for use*—(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(B) For removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*—(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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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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