

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DDM

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Certifier	R. LEDESMA

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Paste

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 Phoenix Scientific, Inc. The NADA provides for the oral use of pyrantel pamoate paste for the removal and control of mature infections of tapeworms in horses and ponies.

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, 301-827-7543, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed supplemental NADA 200-342 that provides for the use of Pyrantel Pamoate Paste for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*) in horses and ponies. The supplemental NADA is approved as of April 18, 2005, and the regulations are amended in 21 CFR 520.2044 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 cv04115

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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 April 18, 2005.

The agency 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. Section 520.2044 is revised to read as follows:

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications*—(1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).

(2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

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

(1) No. 000069 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

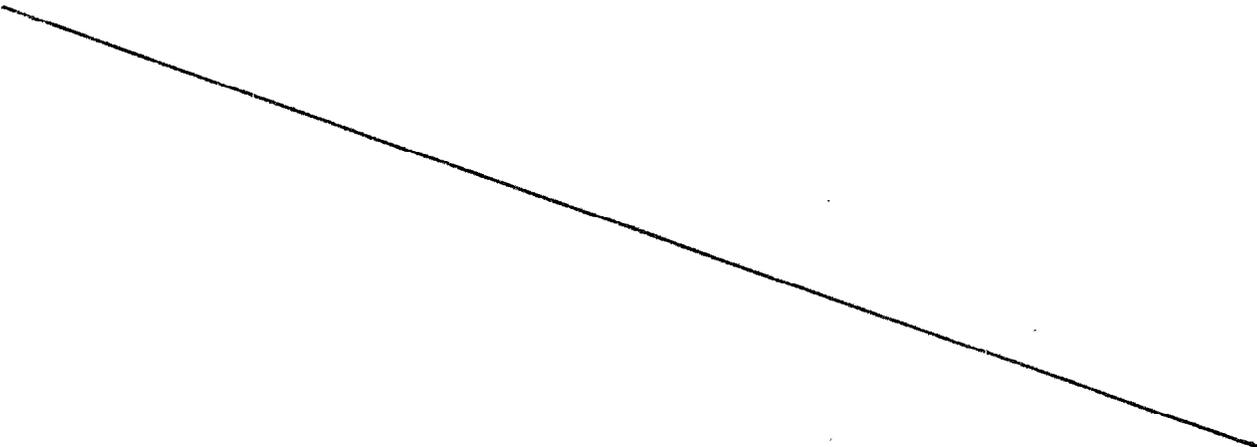
(2) No. 059130 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

(3) No. 061623 for use of product described in paragraph (a)(3) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

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

(d) *Conditions of use*. It is used in horses and ponies as follows:

(1) *Amounts and indications for use*—(i) 3 mg per pound (/lb) body weight as single oral dose for removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).



(ii) 6 mg/lb body weight as single oral dose for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*).

(2) *Limitations*. Not for use in horses intended for food.

Dated: May 11, 2005
May 11, 2005.

Dr. Steven D. Vaughn

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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