

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for over-the-counter marketing status for pyrantel pamoate suspension, when labeled for oral administration to horses and ponies for the removal and control of certain 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: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed a supplement to ANADA 200-246 that currently provides for the veterinary prescription use of ANTHELBAN V (pyrantel pamoate) Equine Anthelmintic Suspension, administered orally or by nasogastric tube (stomach tube) to horses and ponies for the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles. The supplemental ANADA provides for the

over-the-counter use of Pyrantel Pamoate Equine Anthelmintic Suspension, an identical formulation labeled for the same conditions of use, except administration by stomach tube, a veterinary procedure. Phoenix Scientific, Inc.'s Pyrantel Pamoate Equine Anthelmintic Suspension is approved as a generic copy of Pfizer, Inc.'s PAMOBAN Horse Wormer Suspension, approved with over-the-counter marketing status under NADA 91-739. The supplemental ANADA is approved as of August 19, 2003, and the regulations are amended in 21 CFR 520.2043 to reflect the approval and the current indications for use. 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 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 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 520.2043 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

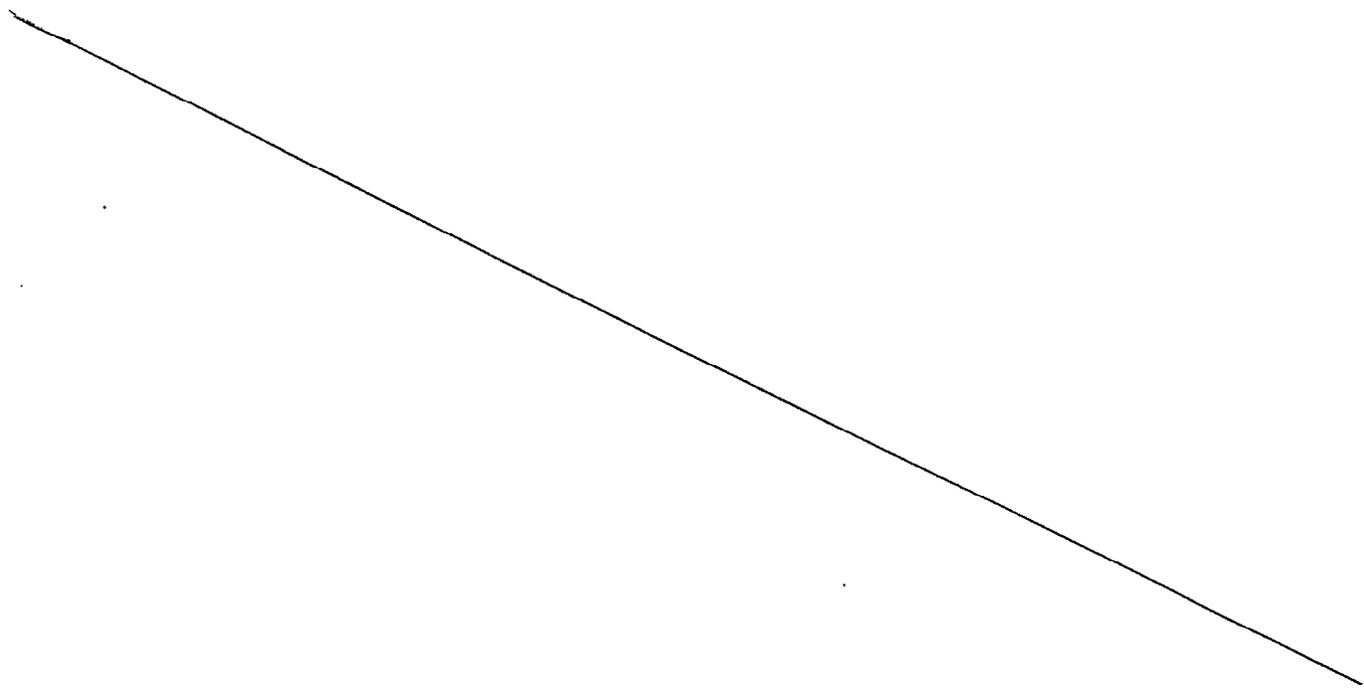
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(ii) *Indications for use.* For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

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Dated: September 15, 2003
September 15, 2003.

Steven D. Vaughn, DVM

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

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September 15, 2003