

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DMB

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Certifier N. Hawkins

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 an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the oral use of pyrantel pamoate paste for the removal and control of certain internal parasites in horses and ponies.

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: Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-350 that provides for the use of EXODUS (pyrantel pamoate) Paste for the removal and control of certain internal parasites in horses and ponies. Cross Vetpharm Group Ltd.'s EXODUS Paste is approved as a generic copy of Pfizer, Inc.'s STRONGID (pyrantel pamoate) Paste approved under NADA 129-831. The ANADA is approved as of March 25, 2003, 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 information submitted to support approval of this application may be seen in the Dockets Management Branch (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 520.2044 is amended by adding paragraphs (a)(3) and (b)(3) to read as follows:

§ 520.2044 Pyrantel pamoate paste.

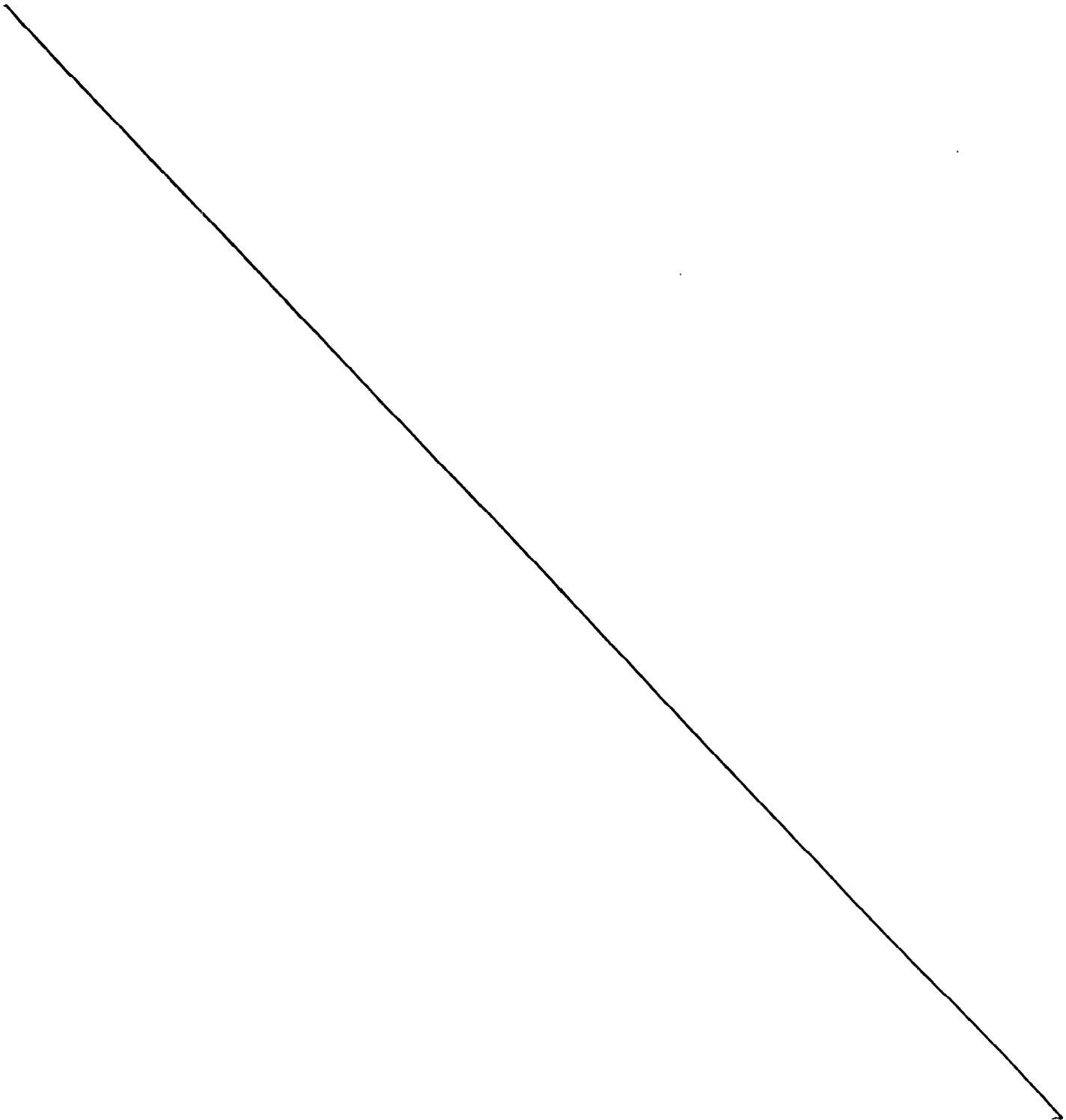
(a) * * *

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

(b) * * *

(3) No. 061623 for use of product described in paragraph (a)(3) of this section.

* * * * *



Dated: 5/27/03
May 27, 2003.

S F S / A

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

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

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Dawn P. Hawkins