

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SMB

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21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Chewable Tablets

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 Blue Ridge Pharmaceuticals, Inc. The ANADA provides for use of pyrantel pamoate chewable tablets for the removal of certain gastrointestinal parasites and prevention of reinfection in puppies and 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-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed ANADA 200-281 that provides for use of WORMEXX® (pyrantel pamoate) Chewable Tablets for the removal of certain gastrointestinal parasites and prevention of reinfection in puppies and dogs. Blue Ridge's WORMEXX® Chewable Tablets is approved as a generic copy of Farnam Co.'s D-WORM® (pyrantel pamoate) Dog Wormer Chewable Tablets, approved under NADA 139-191. ANADA 200-281 is approved as of January 3, 2001, and 21 CFR 520.2041 is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

cv00124

ANADA 200-281

NFR-1

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(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.

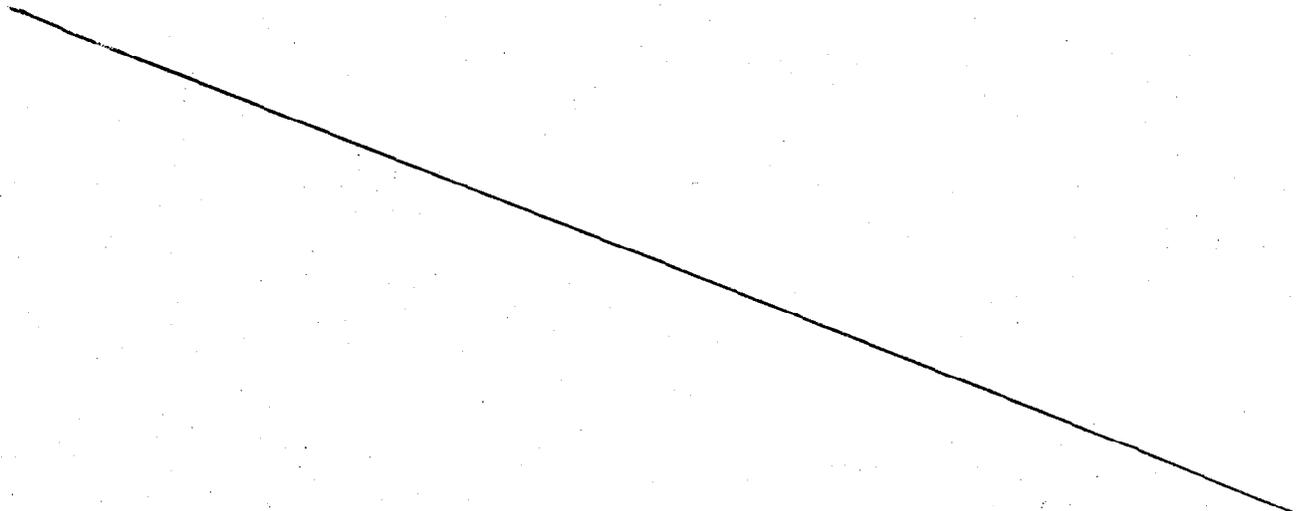
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

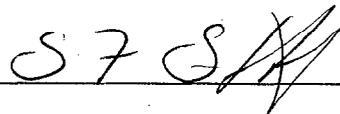
Authority: 21 U.S.C. 360b.

§ 520.2041 [Amended]



2. Section 520.2041 *Pyrantel pamoate chewable tablets* is amended in paragraph (b) by removing "No. 017135" and adding in its place "Nos. 017135 and 065274".

Dated: 01/31/01
January 31, 2001.



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

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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