

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin and 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 chewable tablets containing ivermectin and pyrantel pamoate for prevention of heartworm disease and for treatment and control of certain gastrointestinal parasites in dogs.

DATES: This rule is effective [insert date 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 200-302 that provides for veterinary prescription use of Iverhart™ Plus (ivermectin and pyrantel pamoate) Flavored Chewables for Dogs for prevention of canine heartworm disease caused by *Dirofilaria immitis* and for treatment and control of ascarids (*Toxocara canis*, *T. leonina*) and hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) in dogs. Blue Ridge's Iverhart™ Plus Flavored Chewables for Dogs is approved as a generic copy of Merial's Heartgard™ Plus Chewables, approved under NADA 140-971. ANADA 200-302 is approved as of May 30, 2001, and 21 CFR 520.1196 is amended 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 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(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.

§ 520.1196 [Amended]

2. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (b) by removing "Sponsor. See 050604" and by adding in its place "Sponsors. See Nos. 050604 and 065274".

Dated: 6/20/01
June 20, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Wanda Oliver

S F S / H

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine

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

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