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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulation concerning veterinary prescription use of Hoechst Roussel Vet's fenbendazole suspension for cattle. The amendment clarifies the oral dose of fenbendazole suspension used as a dewormer in cattle.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, is sponsor of new animal drug application (NADA) 128-620 that provides for oral, veterinary prescription use of Panacur® (fenbendazole) 10 percent suspension. The drug is used as a dewormer in cattle, including dairy cattle of breeding age at 5 milligrams per kilogram (mg/kg) of body weight, and only in beef cattle at 10 mg/kg of body weight. The regulations are amended in 21 CFR 520.905a to clarify the approval.

The amendments clarify the drug dose used to treat various classes of animals and insert certain technical revisions. No additional safety or effectiveness data were required. A revised freedom of information summary is provided to reflect the clarification.

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 520.905a is amended by removing paragraph (a); by redesignating paragraphs (b) and (c) as paragraphs (a) and (b); by adding paragraph (c); by revising the heading of paragraph (d)(2); by redesignating paragraph (d)(3) as paragraph (d)(4); by redesignating paragraphs (d)(2)(ii), (d)(2)(ii)(A), and (d)(2)(ii)(B) as paragraphs (d)(3)(i), (d)(3)(ii), and (d)(3)(iii); by adding a heading for newly redesignated paragraph (d)(3) by redesignating paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) as paragraphs (d)(2)(ii) and (d)(2)(iii) to read as follows:

§ 520.905a Fenbendazole suspension.

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(c) *Related tolerances.* See § 556.275 of this chapter.

(d) * * *

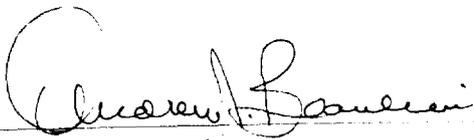
(2) Cattle including dairy cows of breeding age—* * *

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(3) Beef cattle—* * *

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Dated: Nov. 9, 1998
November 9, 1998



Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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