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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier A. Corbin

Oral Dosage Form New Animal Drugs; Oxfendazole Suspension

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 a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for over-the-counter (OTC) marketing status for oral use of oxfendazole suspension in cattle.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 140-854 for SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, approved for oral use in cattle for the removal of various internal parasites. The supplemental NADA provides for OTC marketing status. The supplemental application is approved as of January 29, 2007, and the regulations are amended in 21 CFR 520.1630 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

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NFR.3

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.

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 Parts 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. Amend § 520.1630 as follows:

- a. Redesignate paragraph (d) as paragraph (e);
- b. Add new paragraph (d);

c. Revise the introductory text in newly redesignated paragraphs (e)(1) and (e)(2); and

d. Revise paragraph (a) and newly redesignated paragraphs (e)(1)(i), (e)(1)(iii), (e)(2)(i), and (e)(2)(iii).

The redesignation, addition, and revisions read as follows:

§ 520.1630 Oxfendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains:

(1) 90.6 milligrams (mg) oxfendazole (9.06 percent).

(2) 225.0 mg oxfendazole (22.5 percent).

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter. If labeled for administration by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 10 mg per kilogram (/kg) of body weight by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks.

* * * * *

(iii) *Limitations.* Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for human consumption.

(2) *Cattle.* Use the products described in paragraphs (a)(1) and (a)(2) of this section as follows:

(i) *Amount.* 4.5 mg/kg of body weight by dose syringe. Treatment may be repeated in 4 to 6 weeks.

* * * * *

(iii) *Limitations.* Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle.

Dated: February 21, 2007
February 21, 2007.

Steven J. Vaughn

Steven J. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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