

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. 2008-N-0039]

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 revised scientific nomenclature for an internal parasite for which oxfendazole suspension is used orally in cattle.

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

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8343, e-mail: donald.prater@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 revised scientific nomenclature for a parasite. The supplemental application is approved as of July 7, 2008, and the regulations are amended in 21 CFR 520.1630 to reflect the approval.

DPM
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Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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. In § 520.1630, in paragraph (e)(2)(ii), remove “*C. mcmasteri*” and in its place add “*C. surnabada*”; and revise paragraph (e)(2)(iii) to read as follows:

§ 520.1630 Oxfendazole suspension.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Dated: 07/24/08
July 24, 2008.

Bernadette Dunham DVM PhD

Bernadette Dunham,
Director,
Center for Veterinary Medicine.

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