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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxibendazole 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 Pfizer, Inc. The supplemental NADA provides for revised food safety labeling for oxibendazole suspension administered orally to horses as an antiparasitic.

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

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed a supplement to NADA 109–722 for use of ANTHELCIDE EQ (oxibendazole) Suspension administered orally to horses as an antiparasitic. The supplemental NADA provides for revised food safety labeling. The supplemental application is approved as of April 17, 2006, and the regulations are amended in 21 CFR 520.1640 to reflect the approval.

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.

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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.

§ 520.1640 [Amended]

■ 2. Amend paragraph (c)(3) of § 520.1640 by removing "Not for use in horses intended for food." and adding in its place "Not for use in horses intended for human consumption.".

Dated: May 26, 2006

May 26, 2006.

cv069

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