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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier J. COOKE

Oral Dosage Form New Animal Drugs; Omeprazole Paste

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 new animal drug application (NADA) filed by Merial Ltd. The NADA provides for oral administration of omeprazole paste to horses for the prevention of gastric ulcers.

**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: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-227 for ULCERGARD (omeprazole) Paste. The application provides for oral use of omeprazole paste in horses for the prevention of gastric ulcers. The NADA is approved as of February 18, 2004, and the regulations are amended in 21 CFR 520.1615 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 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning February 18, 2004.

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.

■ 2. Section 520.1615 is revised to read as follows:

#### **§ 520.1615 Omeprazole.**

(a) *Specifications.* Each gram of paste contains 0.37 gram omeprazole.

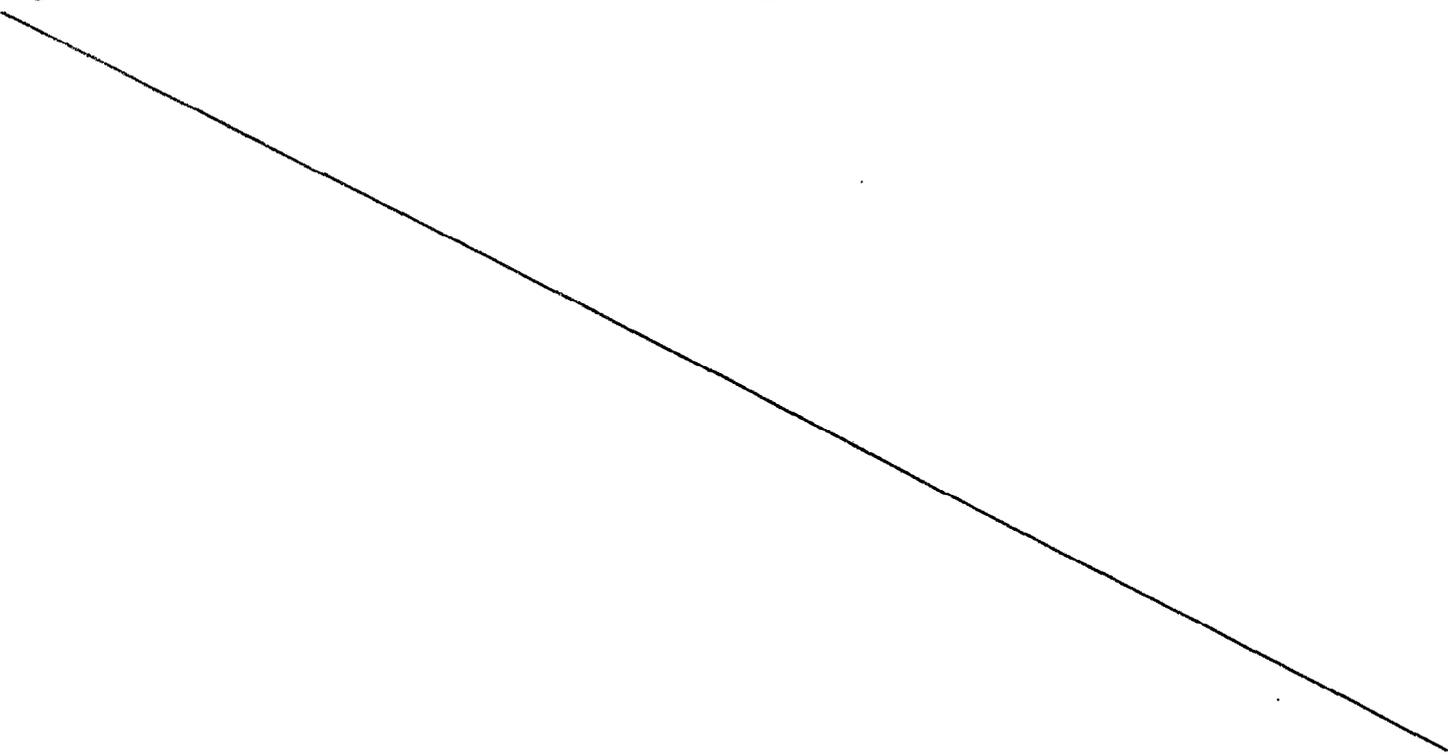
(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) *Conditions of use in horses—(1) Amount—(i)* For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for up to 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use—(i)* For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.



(ii) For prevention of gastric ulcers in horses.

(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: 3/11/04

March 11, 2004.

Linda Tollefson

Linda Tollefson,  
Deputy Director, Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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