

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Trimethoprim and Sulfadiazine Oral Paste

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 Schering-Plough Animal Health Corp. The supplemental NADA provides for revised food safety labeling for trimethoprim and sulfadiazine oral paste, administered to horses as a systemic antibacterial.

**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](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 131-918 for use of TRIBRISSEN (trimethoprim and sulfadiazine) 400 Paste, administered orally to horses as a systemic antibacterial. The supplement provides for revised food safety labeling. The supplemental NADA is approved as of April 25, 2006, and the regulations are amended in 21 CFR 520.2611 to reflect the approval and a current format. 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.

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 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. Revise § 520.2611 to read as follows:

**§ 520.2611 Trimethoprim and sulfadiazine paste.**

(a) *Specifications.* Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

### 3

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 000856 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use*. For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 18, 2006.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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