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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; Cefpodoxime Proxetil Tablets

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 Pharmacia and Upjohn Co. The NADA provides for veterinary prescription use of cefpodoxime proxetil tablets in dogs for treatment of skin infections (wounds and abscesses) caused by susceptible strains of certain bacteria.

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.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed NADA 141-232 for use of SIMPLICEF (cefpodoxime proxetil) Tablets. The NADA provides for veterinary prescription use of cefpodoxime proxetil tablets in dogs for treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, β -hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*. The NADA is approved as of July 22, 2004, and the regulations are amended in part 520

(21 CFR part 520) by adding § 520.370 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 22, 2004.

FDA 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 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 520.370 is added to read as follows:

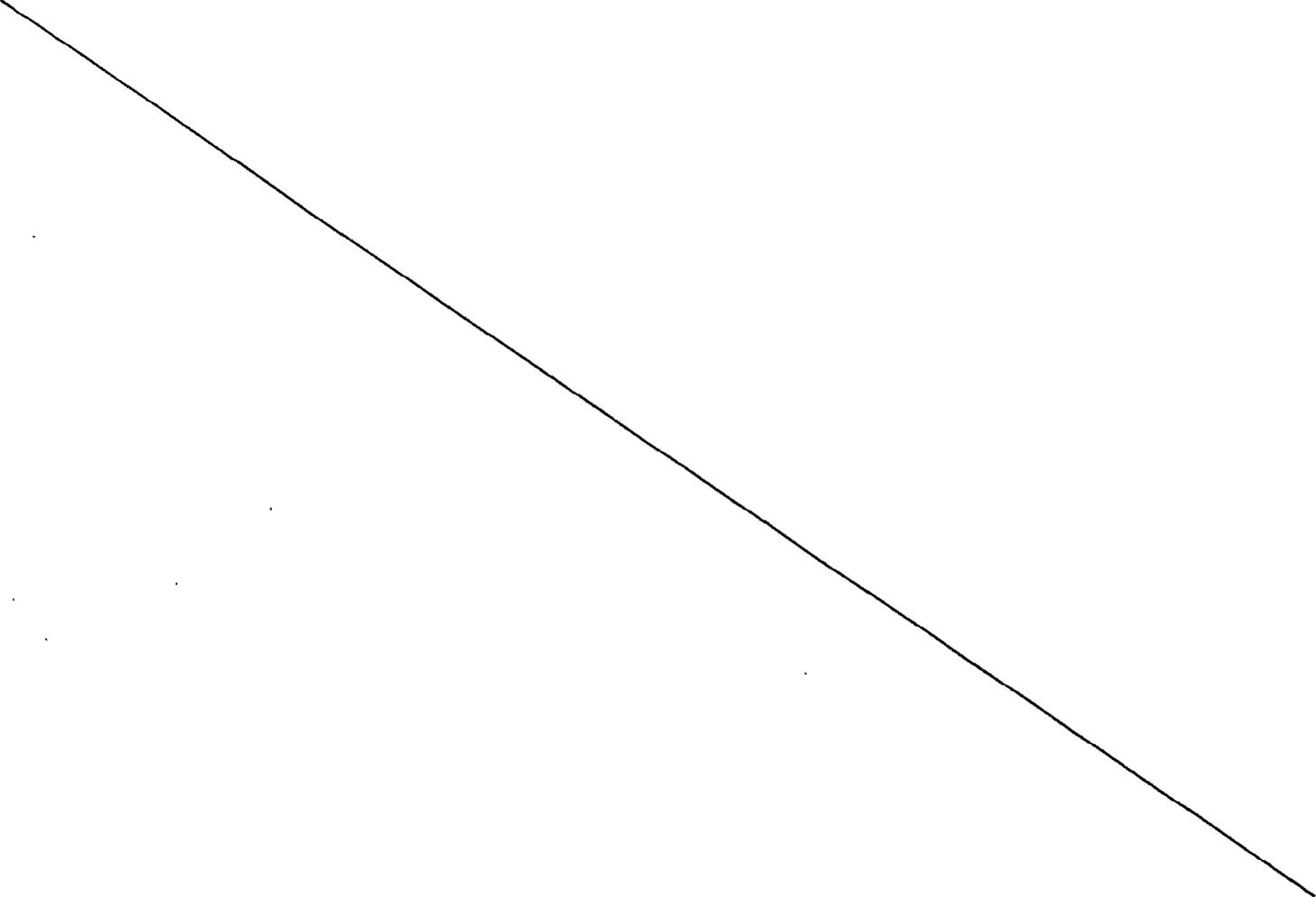
§ 520.370 Cefpodoxime tablets.

(a) *Specifications.* Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(b) *Sponsors.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, β -hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.



(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 8/17/04
August 17, 2004.

S F Sundlof
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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