

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Orbifloxacin

**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 animal safety labeling for orbifloxacin tablets used in dogs and cats for the management of diseases associated with susceptible 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, 301-827-7543, 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 141-081 for the veterinary prescription use of ORBAX (orbifloxacin) Tablets for management of diseases in dogs and cats associated with bacteria susceptible to orbifloxacin. The supplemental NADA provides for revised animal safety labeling, specifically, the addition of postapproval adverse drug experience information and fluoroquinolone class statements regarding retinal toxicity in

cats. The supplemental NADA is approved as of March 3, 2006, and the regulations are amended in 21 CFR 520.1616 to reflect 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(d)(5) 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 “articular 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**

■ 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 § 520.1616 to read as follows:

**§ 520.1616 Orbifloxacin.**

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

Dated: March 14, 2006.

**Steven D. Vaughn,**

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

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