## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

### § 524.2620 [Amended]

4. Section 524.2620 *Liquid crystalline trypsin, Peru balsam, castor oil* is amended in paragraph (a)(2) by removing ''000514'' and adding in its place ''062794''.

Dated: August 23, 2001.

**Claire M. Lathers,**

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

[FR Doc. 01–22198 Filed 9–4–01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Marbofloxacin 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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for the use of marbofloxacin tablets in cats for the treatment of infections associated with bacteria susceptible to marbofloxacin.

**DATES:** This rule is effective September 5, 2001.

**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.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is the sponsor of NADA 141–151 that provides for use of Zeniquin™ (marbofloxacin) Tablets for the treatment of infections in dogs associated with bacteria susceptible to marbofloxacin. Pfizer, Inc., filed a supplemental NADA which provides for the addition of cats to product indications. The supplemental NADA is approved as of August 1, 2001, and the regulations in 21 CFR 520.1310 are amended 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 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 Dockets Management Branch (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)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for non-food-producing animals qualifies for 3 years of marketing exclusivity beginning August 1, 2001, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

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 520.1310 is amended by revising paragraphs (a) and (d) to read as follows:

### § 520.1310 Marbofloxacin tablets.

(a) *Specifications.* Each tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

* * * * *

(d) *Conditions of use*—(1) *Amount.* 1.25 mg per pound (/lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use.* For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

(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: August 21, 2001.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 01–22165 Filed 9–4–01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 524

### Ophthalmic and Topical Dosage Form New Animal Drugs; Moxidectin

**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 Fort Dodge Animal Health. The supplemental NADA provides for topical use of a 0.5 percent moxidectin solution on cattle for treatment and control of infections of additional life stages and species of gastrointestinal roundworms.

**DATES:** This rule is effective September 5, 2001.

**FOR FURTHER INFORMATION CONTACT:** Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141–099 that provides for use of Cydectin® (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections of additional life stages and species of gastrointestinal roundworms. The supplemental NADA is approved as of June 18, 2001, and the regulations are amended in 21 CFR 524.1451 to reflect the approval. The basis of approval is discussed in the freedom of information summary.