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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; Carprofen**

**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 veterinary prescription use of carprofen oral caplets in dogs for the control of postoperative pain associated with soft tissue and orthopedic surgery.

**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.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d Street, New York, NY 10017-5755, filed a supplement to NADA 141-053 for RIMADYL (carprofen) Caplets for Dogs. The supplemental NADA provides for the veterinary prescription use of carprofen oral caplets in dogs for the control of postoperative pain associated with soft tissue and orthopedic surgery. The supplemental application is approved as of July 8, 2002, and the regulations are amended in 21 CFR 520.309 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

cv0277

**NADA 141-053**

**NFR-1**

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 qualifies for 3 years of marketing exclusivity beginning July 8, 2002.

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 520.309 is amended by revising paragraphs (a), (b), and (d) to read as follows:

**§ 520.309 Carprofen.**

(a) *Specifications.* (1) Each caplet contains 25, 75, or 100 milligrams (mg) carprofen.

(2) Each chewable tablet contains 25, 75, or 100 mg carprofen.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter for use of caplets described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2), and (d)(3) of this section and chewable tablets described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

\* \* \* \* \*

(d) *Conditions of use in dogs*—(1) *Amount*—(i) 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(ii) 2 mg/lb of body weight once daily or 1 mg/lb twice daily.

(2) *Indications for use.* (i) For the control of postoperative pain associated with soft tissue and orthopedic surgery.

(ii) For the relief of pain and inflammation associated with osteoarthritis.

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

Dated: 9/30/02

September 30, 2002.

S F Sundlof

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

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[Signature]