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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen

**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 new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for veterinary prescription use of carprofen chewable tablets for the relief of pain and inflammation associated with osteoarthritis in dogs.

**EFFECTIVE DATE:** *(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.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed NADA 141-111 that provides for oral veterinary prescription use of Rimadyl® (carprofen) chewable tablets for the relief of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of May 14, 1999. The regulations are amended in 21 CFR 520.309 by revising the section heading, by revising paragraph (a), by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraphs (d)(1) and (d)(2) to reflect the approval.

The regulations currently provide for use of carprofen caplets in NADA 141-053. A revision of the indications for use has been approved by letter of April 21, 1999. At this time, the regulation is amended to reflect that approval.

NFR1

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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning May 14, 1999, because the application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant. Three years of marketing exclusivity applies only to use of carprofen chewable tablets for relief of pain and inflammation associated with osteoarthritis in dogs.

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. Section 520.309 is amended by revising the section heading, by revising paragraph (a), by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraphs (d)(1) and (d)(2) to read as follows:

**§ 520.309 Carprofen.**

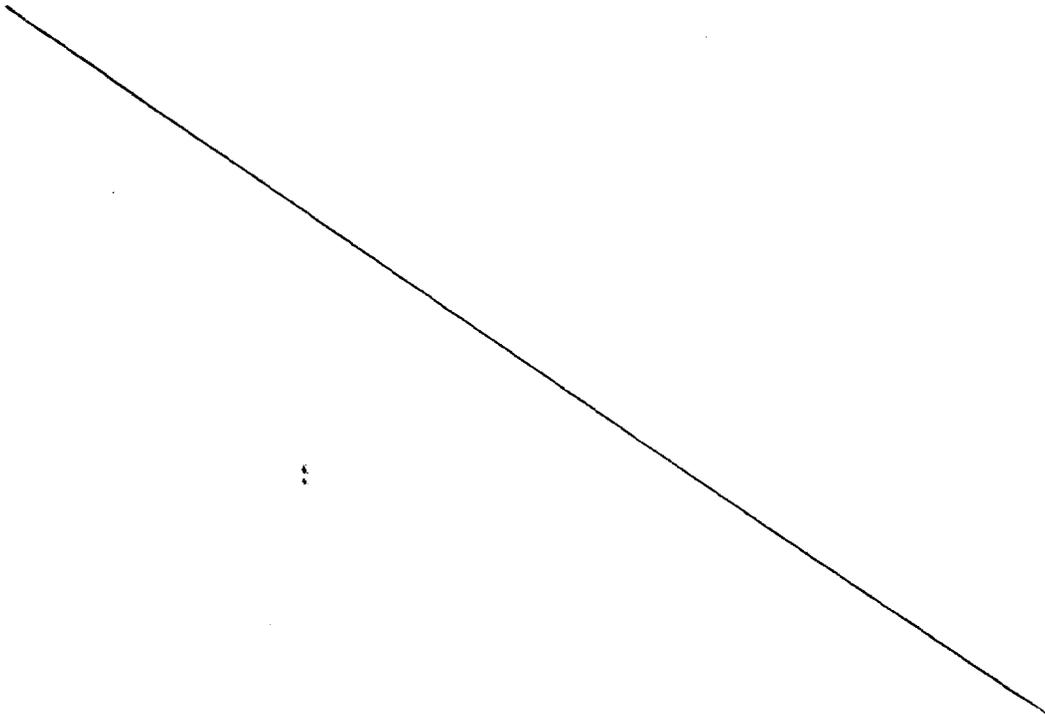
(a) *Specifications.* Each caplet or chewable tablet contains 25, 75, or 100 milligrams of carprofen.

\* \* \* \* \*

(c) [Reserved]

(d) \* \* \*

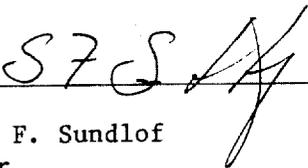
(1) *Amount.* 1 milligram per pound of body weight twice daily. Caplets and chewable tablets are scored and dosage should be calculated and given in half-caplet or half-chewable tablet increments.



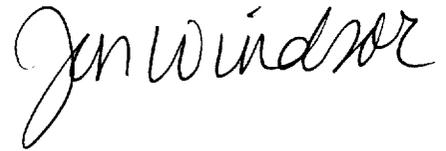
(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis in dogs.

\* \* \* \* \*

Dated: 6/4/99  
June 4, 1999

  
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Stephen F. Sundlof  
Director  
Center for Veterinary Medicine

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**



[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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