

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Display Date	5/26/05
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Certifier	L. CLAWSON
	DSM

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 an abbreviated new animal drug application (ANADA) filed by IMPAX Laboratories, Inc. The ANADA provides for veterinary prescription use of carprofen caplets in dogs for the relief of pain and inflammation associated with osteoarthritis.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: [daniel.benz@fda.gov](mailto:daniel.benz@fda.gov).

**SUPPLEMENTARY INFORMATION:** IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544, filed ANADA 200-366 for veterinary prescription use of Carprofen Caplets in dogs for the relief of pain and inflammation associated with osteoarthritis. IMPAX Laboratories, Inc.'s Carprofen Caplets is approved as a generic copy of Pfizer, Inc.'s RIMADYL Caplets, approved under NADA 141-053. ANADA 200-366 is approved as of April 27, 2005, and 21 CFR 520.309 is 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 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(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 paragraphs (b) and (d)(2) to read as follows:

**§ 520.309 Carprofen.**

\* \* \* \* \*

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

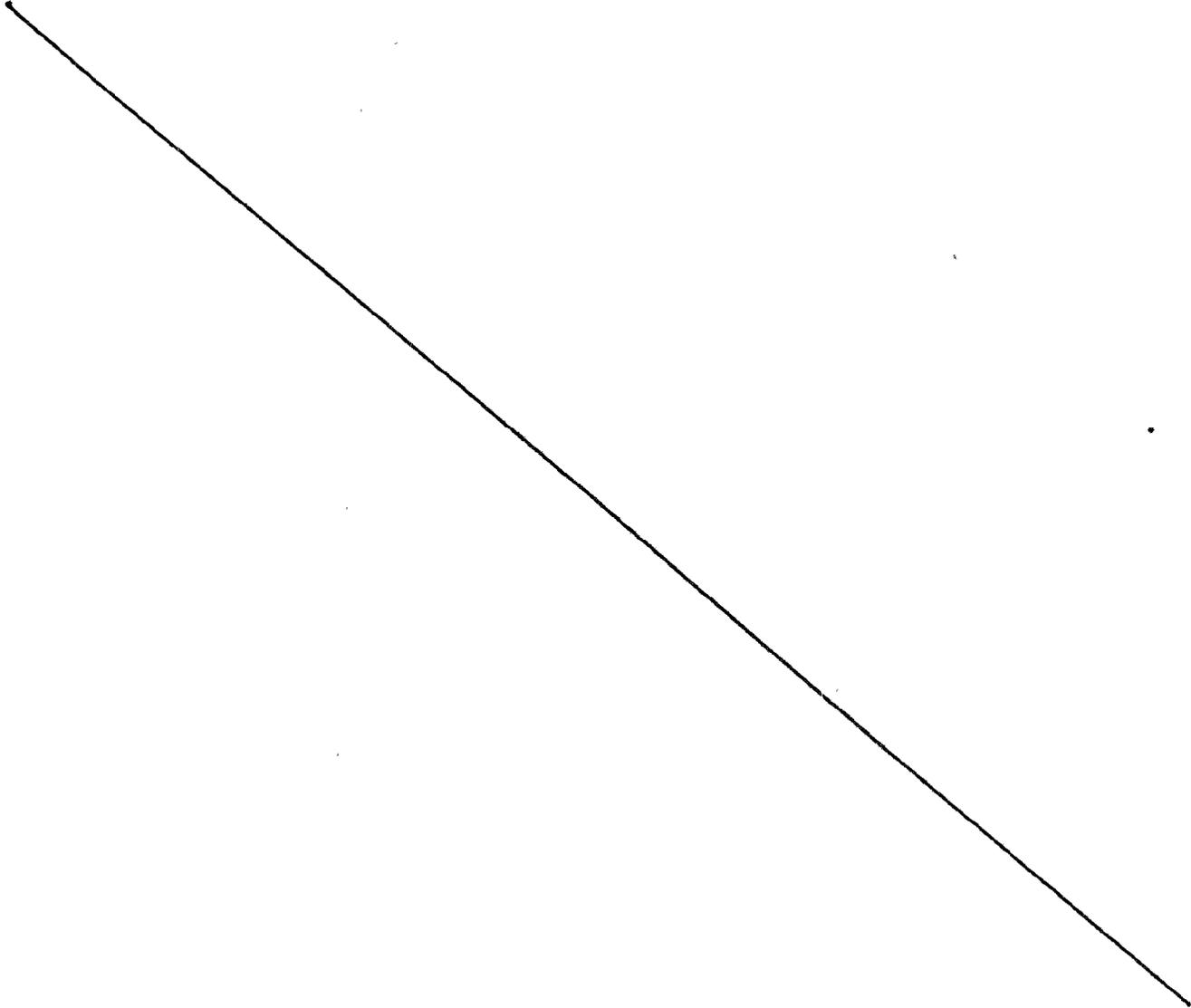
(1) No. 000069 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) No. 000115 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

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(d) \* \* \*

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



(ii) For the control of postoperative pain associated with soft tissue and orthopedic surgery.

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Dated: 5/13/05

May 13, 2005.

*SFS/A*

Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.  
[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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