

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Carprofen

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DDM
Display Date 12-4-07
Publication Date 12-5-07
Certifier D. Hawkins

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Belcher Pharmaceuticals, Inc. The ANADA provides for veterinary prescription use of carprofen caplets in dogs.

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

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773, filed ANADA 200-397 for VETPROFEN (carprofen) Caplets. The ANADA provides for veterinary prescription use in dogs for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries. Belcher Pharmaceuticals, Inc.'s VETPROFEN Caplets are approved as a generic copy of RIMADYL Caplets, sponsored by Pfizer, Inc., under NADA 141-053. The ANADA is approved as of November 7, 2007, and 21 CFR 520.309 is amended to reflect the approval.

In addition, Belcher Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

- 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for “Belcher Pharmaceuticals, Inc.” and in the table in paragraph (c)(2) by numerically adding a new entry for “062250” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773	062250

(2) * * *

Drug labeler code	Firm name and address
062250	Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. In paragraph (b)(2) of § 520.309, remove “No. 000115” and add in its place
“Nos. 000115 and 062250”.

Dated: Nov 20 2007

November 20, 2007.

Bernadette Dunham DVM, PhD

Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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Dawn P. Hawkins