Date of Approval: March 25, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-578

Carprofen Flavored Tablets

Carprofen

Flavored Tablets

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 in dogs

Sponsored by:

Belcher Pharmaceuticals, LLC

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-578

B. Sponsor

Belcher Pharmaceuticals, LLC
6911 Bryan Dairy Rd.
Largo, FL 33777

Drug Labeler Code: 062250

C. Proprietary Name

Carprofen Flavored Tablets

D. Product Established Name

carprofen

E. Pharmacological Category

Non-steroidal anti-inflammatory drug (NSAID)

F. Dosage Form

Tablets

G. Amount of Active Ingredient

25 mg, 75 mg, and 100 mg

H. How Supplied

Tablets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per tablet. Each tablet strength is packaged in bottles containing 30, 60, or 180 tablets.

I. Dispensing Status

Rx

J. Dosage Regimen

The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2. mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Tablets are scored and dosage should be calculated in half-tablet increments.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indication

For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs

N. Reference Listed New Animal Drug

RIMADYL caplets; carprofen; NADA 141-053; Zoetis Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug or RLNAD). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product and an *in vitro* dissolution study, Belcher Pharmaceuticals, LLC, was granted a waiver from the requirement to demonstrate bioequivalence for the generic Carprofen Flavored Tablets. The RLNAD is RIMADYL (carprofen) caplets, sponsored by Zoetis Inc. under NADA 141-053, and was approved for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Bioequivalence Waiver

Belcher Pharmaceuticals, LLC has an approval for unflavored VETPROFEN (carprofen) caplets under ANADA 200-397. A blood-level bioequivalence study was conducted to demonstrate that the generic unflavored carprofen caplet (25 mg) was bioequivalent to the RLNAD caplet (25 mg). As compared to the approved unflavored caplets, this formulation has only the addition of artificial beef flavor. A waiver from the requirement to demonstrate *in vivo* bioequivalence for the generic 25 mg, 75 mg, and 100 mg flavored tablets was requested. To qualify for a waiver for each of these product strengths, comparative dissolution studies were conducted to determine the dissolution profiles of the flavored generic and the RLNAD products. The dissolution study compared the following tablets:

- Generic 25 mg and RLNAD 25 mg
- Generic 75 mg and RLNAD 75 mg
- Generic 100 mg and RLNAD 100 mg

Dissolution Parameters:

Dissolution medium:	0.05 M phosphate buffer, pH 7.5
Dissolution medium volume:	900 ± 9 mL
Apparatus:	USP apparatus II (paddle)
Paddle speed:	50 ± 1 rpm
Temperature:	37 ± 0.5 °C
Number of vessels:	12
Sampling time:	5, 15, 30 minutes
UV wavelength:	300 nm

All the individual tablets for the generic drug product and RLNAD exhibited greater than 85% dissolution within 5 minutes for each of the tablet strengths. The profile comparison using a similarity factor is unnecessary under this circumstance. Therefore, a waiver from the requirement to demonstrate bioequivalence for the generic 25 mg, 75 mg, and 100 mg carprofen flavored tablets was granted.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Carprofen Flavored Tablets:

WARNINGS: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Carprofen Flavored Tablets, when used according to the label, are safe and effective.