Date of Approval: July 12, 2014

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-520

CARPRIEVE Injection

carprofen

Injectable Solution

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:

Norbrook Laboratories, Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-520

B. Sponsor

Norbrook Laboratories, Ltd.,
Station Works, Newry BT35 6JP,
Northern Ireland

Drug Labeler Code: 055529

Representative Name and Address: S. Lee Whaley
Norbrook, Inc.
9733 Loiret Blvd
Lenexa, KS 66219

C. Proprietary Name

CARPRIEVE Injection

D. Established Name

carprofen

E. Pharmacological Category

Non-steroidal, anti-inflammatory drug

F. Dosage Form:

Injectable solution

G. Amount of Active Ingredient

Each milliliter (mL) contains 50 milligrams (mg) of carprofen

H. How Supplied

20 mL and 50 mL, amber, glass, sterile, multi-dose vials

I. Dispensing Status

Rx

J. Dosage Regimen

The recommended dosage for subcutaneous administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as either 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For control of postoperative pain, administer approximately 2 hours before the procedure.

K. Route of Administration

Subcutaneous injection

L. Species / Class

Dogs

M. Indication

CARPRIEVE Injection is indicated 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; carprofen; NADA 141-199; 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). 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, Norbrook Laboratories, Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product CARPRIEVE (carprofen) Injection. The generic product is administered as a injectable solution,contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD, RIMADYL (carprofen) Injectable, was approved for use in dogs on March 3, 2003.

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:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to CARPRIEVE Injection:

Keep out of reach of children. Not for human use. Consult a physician in cases of accidental human exposure. For use in dogs only.

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 CARPRIEVE Injection, when used according to the label, is safe and effective.