Date of Approval: April 19, 2017

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-593

Carprofen Injection

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

Sponsored by:

Accord Healthcare, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-593

B. Sponsor

Accord Healthcare, Inc.
1009 Slater Rd., suite 210-B
Durham, NC 27703

Drug Labeler Code: 016729

C. Proprietary Name

Not Applicable

D. Product Established Name

Carprofen Injection

E. Pharmacological Category

Non-steroidal anti-inflammatory, pain reliever

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

50 mg/mL

H. How Supplied

20 mL vial

I. Dispensing Status

Rx

J. Dosage Regimen

2 mg/lb. (4.4 mg/kg) body weight once daily or 1 mg/lb. (2.2 mg/kg) body weight twice daily

K. Route of Administration

Subcutaneous Injection

L. Species/Class

Dogs

M. Indication(s)

Carprofen 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 injection; 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 (GADPTRA) 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 (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 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 period 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, Accord Healthcare, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Carprofen Injection. The generic drug product is an 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 is RIMADYL® (carprofen injection), sponsored by Zoetis Inc., under NADA 141-199 and, was approved for use in dogs on March 03, 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:

CVM did not require user safety studies for this approval.

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