Date of Approval: December 21, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-485

Meloxicam Injection
(meloxicam)

Sterile solution

Dogs and cats

For the control of pain and inflammation associated with osteoarthritis in dogs and control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery in cats.

Sponsored by:

Accord Healthcare, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-485

B. Sponsor

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

Drug Labeler Code: 016729

C. Proprietary Name

Meloxicam Injection

D. Established Name

Meloxicam

E. Pharmacological Category

Non-steroidal anti-inflammatory

F. Dosage Form:

Sterile solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

10 mL vial

I. Dispensing Status

Rx

J. Dosage Regimen

Dogs: Administer initially as a single dose at 0.09 mg/lb (0.2 mg/kg) body weight intravenously (IV) or subcutaneously (SQ), followed, after 24 hours, by meloxicam oral suspension at the daily dose of 0.045 mg/lb (0.1 mg/kg) body weight, either mixed with food or placed directly in the mouth.

Cats: Administer a single, one**–time subcutaneous dose** of 0.14 mg/lb (0.3 mg/kg) body weight. Use of additional meloxicam or other NSAIDs is contraindicated.

K. Route of Administration

Dogs: Intravenous or subcutaneous

Cats: Subcutaneous

L. Species/Class

Dogs and cats

M. Indications

Dogs: Meloxicam Injection 5 mg/mL Solution for Injection is indicated for the control of pain and inflammation associated with osteoarthritis.

Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery.

N. Reference Listed New Animal Drug

METACAM Injectable Solution; meloxicam; NADA 141-219; Boehringer Ingelheim Vetmedica, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act (the 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.

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 an *in vivo* bioequivalence study. (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 *in vivo* bioequivalence for the generic product Meloxicam (meloxicam) Injection. The generic product is administered as a sterile 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 absorption of the active ingredient. The RLNAD, METACAM (meloxicam) Solution for Injection, was originally approved for use in dogs on November 12, 2003, and supplemental approval was granted for use in cats on October 28, 2004.

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 and cats, 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 Meloxicam Injection:

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the act and demonstrates that Meloxicam Injection, when used according to the label, is safe and effective.