Date of Approval: December 19, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-491

LOXICOM

(meloxicam)

Solution for Injection

Dogs and Cats

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

Sponsored by:

Norbrook Laboratories, Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-491

B. Sponsor

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

Drug Labeler Code: 055529

US Agent Name and Address: S. Lee Whaley
Norbrook Inc.,
9733 Loiret Boulevard
Lenexa, KS 66219

C. Proprietary Name

LOXICOM

D. Established Name

Meloxicam

E. Pharmacological Category

Non-steroidal anti-inflammatory (NSAID)

F. Dosage Form:

Solution for injection

G. Amount of Active Ingredient

5.0 mg/mL meloxicam solution

H. How Supplied

10 mL and 20 mL vials

I. Dispensing Status

Rx

J. Dosage Regimen

Dogs: LOXICOM 5 mg/mL Solution for Injection should be administered initially as a single dose at 0.2 mg/kg body weight intravenously or subcutaneously followed after 24 hours by meloxicam oral suspension at the daily dose of 0.1 mg/kg body weight, either mixed with food or placed directly into the mouth.

Cats: Administer a single, one-time subcutaneous dose of LOXICOM 5 mg/mL Solution for Injection to cats at a dose of 0.3 mg/mL body weight. Use of additional meloxicam or other NSAIDs is contraindicated.

K. Route of Administration

Intravenous or subcutaneous injection

L. Species

Dogs and Cats

M. Indication

LOXICOM (meloxicam) 5 mg/mL Solution for Injection is indicated for the control of pain and inflammation associated with osteoarthritis in dogs and for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery in cats.

N. Reference Listed New Animal Drug

METACAM; 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 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 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, Norbrook Laboratories, Ltd., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product LOXICOM (meloxicam) 5 mg/mL Solution for Injection. The generic product is administered as an injectable, 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 was approved for use in dogs on November 12, 2003, and for use in cats on February 20, 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 LOXICOM 5 mg/mL Solution for 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 LOXICOM 5 mg/ml Solution for Injection, when used according to the label, is safe and effective.