Date of Approval: August 2, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-550

MELOXIDYL

Meloxicam

Oral Suspension

Dogs

For control of pain and inflammation associated with osteoarthritis in dogs

Sponsored by:

Ceva Sante Animale

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-550

B. Sponsor

Ceva Sante Animale
10 Avenue de la Ballastière
33500 Libourne, France

Drug Labeler Code: 013744

U.S. Subsidiary: Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

C. Proprietary Name

MELOXIDYL

D. Established Name

meloxicam

E. Pharmacological Category

Non-steroidal anti-inflammatory

F. Dosage Form

Oral suspension

G. Amount of Active Ingredient

1.5 mg/mL

H. How Supplied

10 mL, 32 mL, 100 mL, and 200 mL bottles

I. Dispensing Status

Rx

J. Dosage Regimen

MELOXIDYL Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, MELOXIDYL Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringes are calibrated to deliver the daily maintenance dose in lbs.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indication

MELOXIDYL Oral Suspension is indicated for control of pain and inflammation associated with osteoarthritis in dogs.

N. Reference Listed New Animal Drug

METACAM; meloxicam; NADA 141-213; Boehringer Ingelheim Vetmedica, Inc.

II. BIOEQUIVALENCE:

For this ANADA, an *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD formulations of meloxicam 1.5 mg/mL oral suspensions in dogs.

1. Protocol:
   A randomized, two-way crossover, single dose, replicate design bioequivalence study to evaluate the relative bioavailability of a generic formulation of meloxicam 1.5 mg/mL oral suspension compared to an equivalent dose of a commercially available reference drug product METACAM (meloxicam) Oral Suspension (1.5 mg/mL, Boehringer Ingelheim Vetmedica, Inc.) was performed in 24, fasted, healthy female beagle dogs.
2. Testing Facility:
   Sinclair Research Center (SRC), LLC.
3. Study Number:
   SRC Study No. S10051; CEVA Animal Health, Inc. Study No. ST-BEQ/C531.0/0947
4. Objective:
   The objective of this study was to determine the comparative *in vivo* blood level bioequivalence of Ceva Sante Animale's generic meloxicam 1.5 mg/mL oral suspension and Boehringer Ingelheim Vetmedica, Inc.'s METACAM (meloxicam) 1.5 mg/mL oral suspension in a crossover, single dose study in dogs.
5. Study Summary:
   The study was conducted as a 2-period, 2-treatment crossover design using 24 dogs with a 14 day washout between periods. Variables evaluated are area under the concentration (AUC) curve from time 0 to the first value below the limit of quantitation, the observed maximum concentration (CMAX) and time to maximum concentration (TMAX). The statistical model included sequence, treatment, and period as fixed effects, and animal-within-sequence as a random effect.

The criteria for determining bioequivalence is to construct a 90% confidence interval about the difference of the two means, generic minus RLNAD, based on the log scale of AUC (LAUC) and CMAX (LCMAX) and then take the anti-log of the confidence limits multiplied by 100. The resulting bounds should be between 80.00% and 125.00%. As seen in the table below, both AUC and CMAX fall within the prescribed bounds.

TMAX values observed for the test and reference product indicate that these drugs will provide equivalent therapeutic results.

Table 1 Bioequivalence Evaluation

Variable	MELOXIDYL Mean	METACAM Mean	Lower Bound	Upper Bound
AUC (mg/L)*hr.	33939*	35102*	91.18%	102.54%
CMAX (mg/mL)	1129*	1166*	91.67%	102.17%
TMAX (hours)	5.3 ˆ	4.4 ˆ	n/a	n/a

* Geometric Mean
ˆ Arithmetic Mean

These results demonstrate that the generic and RLNAD formulations of meloxicam 1.5 mg/mL oral suspension are bioequivalent.

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 MELOXIDYL:

- Warnings: Not for use in humans. Keep out of reach of children.
- Consult a physician in case of accidental ingestion by humans.
- People should not take MELOXIDYL. Keep MELOXIDYL and all medications out of reach of children. Call your physician immediately if you accidentally take MELOXIDYL.

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