Date of Approval: October 28, 2004

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA 141-213

METACAM

Meloxicam Oral Suspension

METACAM (meloxicam) Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Sponsored by:

Boehringer Ingelheim Vetmedica, Inc.

Table of Contents

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a.	File Number:	NADA 141-213
b.	Sponsor:	Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway St. Joseph, MO 64506-2002 Drug Labeler Code: 000010
c.	Established Name:	meloxicam
d.	Proprietary Name:	METACAM Oral Suspension
e.	Dosage Form:	Oral Suspension
f.	How Supplied:	0.5 mg/mL: 15 and 30 mL bottles 1.5 mg/mL: 10, 32 and 100 mL botttles
g.	How Dispensed:	Rx
h.	Amount of Active Ingredients:	0.5 mg/mL and 1.5 mg/mL
i.	Route of Administration:	This product is to be administered orally either mixed with food or placed directly in the mouth.
j.	Species/Class:	Dogs
k.	Recommended Dosage:	Always provide client information sheet with prescription. METACAM 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, METACAM Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.
l.	Pharmacological Category:	Non steroidal anti-inflammatory (NSAID)

m. Indications:	METACAM Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.
n. Effect of Supplement:	This supplement to NADA 141-213 provides revisions to 21 CFR 520.1350 (1) *Amount*. To change the format to read "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, METACAM Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg)." This supplement also provides for revisions to labeling, including minor changes facilitating use of the drug and the addition of a Post-Approval section.

2. EFFECTIVENESS:

a. Dosage Characterization:

Refer to the original Freedom of Information summary dated April 15, 2003.

b. Substantial Evidence:

Refer to the original Freedom of Information summary dated April 15, 2003.

3. TARGET ANIMAL SAFETY:

Refer to the original Freedom of Information summary dated April 15, 2003.

4. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: 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.

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that METACAM Oral

Suspension when used under the labeled conditions of use is safe and effective for the control of pain and inflammation associated with osteoarthritis in dogs.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose canine osteoarthritis and to monitor response to treatment.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Meloxicam is under the following U.S. patent number:

U.S. Patent Number	Date of Expiration
6,184,220	February 6, 2021

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

a. Package insert/Client Information Sheet

b. Box

c. Bottle

d. Shipping label

Labeling is included for the 15 mL container of the 0.5 mg/mL concentration
the 30 mL container of the 0.5 mg/mL concentration
the 10 mL container of the 1.5 mg/mL concentration
the 32 mL container of the 1.5 mg/mL concentration
the 100 mL container of the 1.5 mg/mL concentration