Date of Approval: April 20, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-786

Loxicom®

(meloxicam oral suspension)

Dogs

Loxicom® oral suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Sponsored by:

Norbrook Laboratories Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-786

B. Sponsor

Norbrook Laboratories Ltd.,
Carnbane Industrial Estate,
Newry, County Down,
BT35 6QQ, United Kingdom

Drug Labeler Code: 055529

C. Proprietary Name

Loxicom®

D. Drug Product Established Name

meloxicam oral suspension

E. Pharmacological Category

Non-steroidal anti-inflammatory

F. Dosage Form

Oral suspension

G. Amount of Active Ingredient

0.5 mg/mL

H. How Supplied

15 mL and 30 mL bottles with 1 mL and 3 mL measuring syringes

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Loxicom® 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, Loxicom® oral suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The provided syringes are calibrated to deliver the daily maintenance dose in pounds.

K. Route of Administration

Oral

L. Species

Dogs

M. Indication

Loxicom® oral suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

N. Reference Listed New Animal Drug (RLNAD)

Metacam®; meloxicam oral suspension; NADA 141-213; Boehringer Ingelheim Animal Health USA, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). 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. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (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 biowaiver for the generic product Loxicom® (meloxicam oral suspension) 0.5 mg/mL. The generic drug product is an oral suspension, 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 Metacam® (meloxicam oral suspension) 0.5 mg/mL, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-213, and was approved for use in dogs on April 15, 2003.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, the Food and Drug Administration (FDA) did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Loxicom®:

Warnings: 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. **For oral use in dogs only.**

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Loxicom®, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.