Date of Approval: April 20, 2026

UPDATED 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.

Executive Summary

Loxicom® (meloxicam oral suspension), 0.5 mg/mL, is approved for the control of pain and inflammation associated with osteoarthritis in dogs. The reference listed new animal drug (RLNAD) is Metacam® (meloxicam oral suspension), 0.5 mg/mL, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in dogs to show that the 1.5 mg/mL Loxicom® oral suspension is bioequivalent to the 1.5 mg/mL Metacam® oral suspension. No serious adverse events were reported during the study.

The sponsor conducted a comparative *in vitro* dissolution study for the additional product strength. Based on the dissolution data, the 0.5 mg/mL oral suspension qualified for a waiver from the requirement to perform separate *in vivo* bioequivalence studies (a biowaiver). FDA granted a biowaiver for this strength.

Conclusions

Based on the data submitted by the sponsor for the approval of Loxicom®, FDA determined that the drug is safe and effective when used according to the label.

Table of Contents

I. GENERAL INFORMATION 4
II. BIOEQUIVALENCE 5
III. HUMAN FOOD SAFETY 6
IV. USER SAFETY 6
V. AGENCY CONCLUSIONS 7
VI. APPENDIX 7

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.

Bioequivalence Waiver

A pivotal *in vivo* blood bioequivalence study was conducted to demonstrate product bioequivalence using the generic 1.5 mg/mL LOXICOM (meloxicam) Oral Suspension and RLNAD METACAM (meloxicam) 1.5 mg/mL Oral Suspension in dogs (Ref A-200497 FOI). A waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) for the generic 0.5 mg/mL Oral Suspension strength was requested. To qualify for a biowaiver for this product strength, comparative *in vitro* dissolution studies were conducted to determine the dissolution profiles of the both generic 1.5 mg/mL and 0.5 mg/mL strengths and RLNAD 1.5 mg/mL strength (METACAM Oral Suspension).

Dissolution profiles were submitted for the following oral solutions:

- Generic 0.5 mg/mL
- Generic 1.5 mg/mL
- RLNAD 1.5 mg/mL

The objective was to satisfy the f2 criteria between the generic 0.5 mg/mL oral solution strength and the generic 1.5 mg/mL oral solution, and also between the generic 0.5 mg/mL oral solution and the RLNAD 1.5 mg/mL oral solution.

Test conditions were as follows:

- Dissolution apparatus: USP Type 2 (paddles)
- Dissolution medium: pH 7.5 Phosphate buffer
- Dissolution medium volume: 900 mL ± 1%
- Temperature: 37 ± 0.5 °C
- Paddle speed: 25 rpm
- Number of vessels: 12
- Sampling time points: 5, 10, 15, 20 and 30 minutes
- Volume of sample: 10 mL

The generic drug lot number used in the *in vivo* bioequivalence study was the same lot used to support the *in vitro* profile comparisons. Analytical method validation was required to ensure that the quantification of drug concentrations in all samples was accurate and precise.

To allow use of mean data, the percent coefficient of variation at the earlier time points (e.g., 15 minutes) should not be more than 20%, and at other time points should not be more than 10%. The percent coefficient of variation for all generic product profiles was within acceptable limits. Only one measurement should be considered after 85% dissolution of one of the products. The similarity factor (f_2) should be greater than 50 to ensure sameness or equivalence of two profiles.

Study results demonstrate similar dissolution profiles for all comparisons. However, because of rapid dissolving characteristics (>85% in 15 minutes) in all strengths, a dissolution profile comparison using the f_2 test is unnecessary. When comparative profiles between products do not require an f_2 test because of rapid dissolution or when the f_2 value is ≥50, the product strengths used in the comparison qualify for a biowaiver. Therefore, a biowaiver for the generic 0.5 mg/mL LOXICOM (meloxicam) Oral Suspension is granted.

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.

VI. APPENDIX

The following update was made to the **BIOEQUIVALENCE** section on June 25, 2026:

Original text:

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Added text:

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