Date of Approval: February 23, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-841

Firocoxib Tablets for Horses

(firocoxib)

Horses

Firocoxib Tablets for Horses are administered once daily for up to 14 days for the control of pain and inflammation associated with osteoarthritis in horses.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

Executive Summary

Firocoxib Tablets for Horses (firocoxib) are approved for administration once daily for up to 14 days for the control of pain and inflammation associated with osteoarthritis in horses. The reference listed new animal drug (RLNAD) is Equioxx® (firocoxib) tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-458.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in horses to show that the 57 mg Firocoxib Tablets for Horses are bioequivalent to the 57 mg Equioxx® tablets. There were no serious adverse events related to the test or reference article reported during the study.

Conclusions

Based on the data submitted by the sponsor for the approval of Firocoxib Tablets for Horses, the Food and Drug Administration (FDA) determined that the drug is safe and effective when used according to the label.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-841

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:

Sreejith Kurup
Felixvet Inc.
1300 NW Briarcliff Parkway
Suite 100
Kansas City, MO 64150

C. Proprietary Name

Firocoxib Tablets for Horses

D. Drug Product Established Name

firocoxib

E. Pharmacological Category

Non-steroidal anti-inflammatory

F. Dosage Form

Tablets

G. Amount of Active Ingredient

57 mg firocoxib per tablet

H. How Supplied

Round, brownish yellow to pale brown, half-scored tablets, supplied in blister packs of 30 tablets and in bottles of 60 and 180 count.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

One 57 mg tablet administered orally to horses weighing 800-1300 lbs, once daily for up to 14 days. For ease of administration, Firocoxib Tablets for Horses may be given with food.

K. Route of Administration

Oral

L. Species

Horses

M. Indication

Firocoxib Tablets for Horses are administered once daily for up to 14 days for the control of pain and inflammation associated with osteoarthritis in horses.

N. Reference Listed New Animal Drug

Equioxx®; firocoxib; NADA 141-458; 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 this ANADA, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD firocoxib 57 mg tablets. The RLNAD is only available in 57 mg tablets. The *in vivo* blood-level study was conducted in 32 healthy, fasted horses. The pivotal parameters to evaluate bioequivalence are the observed maximum plasma drug concentration (C_{MAX}) and area under the concentration-time curve (AUC) from time 0 to the last sampling time before the first unquantifiable concentration after C_{MAX}. Bioequivalence was demonstrated between the 57 mg Equioxx® (firocoxib) tablets and the 57 mg Firocoxib Tablets for Horses by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

1. Blood-level Bioequivalence Study in Horses

Title: Pivotal (GLP) Four Period Bioequivalence Study of Equioxx® Tablets and a Generic Formulation of Firocoxib Chewable Tablets When Administered Orally to Horses. (Study No. 11824)

Study Dates: October 4, 2024 to May 15, 2025

Study Locations:

In-life phase: Las Cruces, NM

Bioanalytical testing: Ontario, Canada

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 57 mg Firocoxib Tablets for Horses and the RLNAD 57 mg Equioxx® (firocoxib) tablets in fasted horses.

Study Animals: Thirty-two (32) healthy horses (17 geldings and 15 mares) between 3 and 12 years of age and weighing 963 to 1,225 lb (438 to 557 kg).

Experimental Design: A randomized, masked, four-period, two-sequence, single-dose crossover study conducted according to Good Laboratory Practice for Nonclinical Laboratory Studies.

Drug Administration: Each animal received 57 mg of either the generic or RLNAD firocoxib according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Measurements and Observations: The plasma concentrations of firocoxib were measured using a validated bioanalytical method. Pharmacokinetic parameters were determined for each animal individually in each period. Animal observations were made throughout the study for assessment of general health and adverse events.

Statistical Methods:

The laboratory study was conducted with a randomized, masked, four-period, two-sequence, two-treatment, single-dose crossover design using 32 horses with a 21-day washout between periods. Appropriate randomization of animal to sequence and pen/treatment order was performed. Primary variables evaluated were C_{MAX} and AUC. Time to maximum concentration (T_{MAX}) was summarized and evaluated clinically.

The reference-scaled average bioequivalence (RSABE) was used as appropriate to evaluate bioequivalence through the mixed scaling approach. Prior to the analysis, C_{MAX} and AUC values were natural logarithm transformed. The estimated within-subject standard deviation (s_{WR}) of the RLNAD was calculated separately for transformed C_{MAX} and AUC to select the appropriate analysis approach based on FDA Guidances.

- The s_{WR} was less than 0.294 for C_{MAX} and AUC, so the average bioequivalence method was used to evaluate bioequivalence. The statistical model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Period was modeled as a repeated factor. Bioequivalence was established because the back-transformed estimated upper and lower bounds of the pertinent 90% confidence interval for geometric mean ratios (generic/RLNAD) were contained within the acceptance limits of 0.80 to 1.25.

Results:

As seen in the table below, C_{MAX} and AUC fall within the prescribed bounds (Table II.1). The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table II.1. Bioequivalence Evaluation

Parameter	s_{WR}	Generic Mean	RLNAD Mean	Ratio◊	Lower 90% CI	Upper 90% CI
AUC (ng/mL)*hour	0.2756	3475†	3517†	0.99	0.91	1.07
C_{MAX} (ng/mL)	0.2445	111.9†	106.8†	1.05	0.97	1.13
T_{MAX} (hours) (SD)‡	NE	3.2 (3.1)‡	3.5 (3.7)‡	NE	NE	NE

† Geometric mean
‡ Arithmetic mean and standard deviation (SD)
◊ Ratio = Generic/RLNAD
CI = confidence interval
NE = not estimated

Adverse Reactions:

There were no serious adverse events related to the test or reference article reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 57 mg Firocoxib Tablets for Horses and the RLNAD 57 mg Equioxx® (firocoxib) tablets are bioequivalent in horses.

III. HUMAN FOOD SAFETY

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

The product labeling contains the following Warning statement: **For use in horses only. Do not use in horses intended for human consumption.**

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Firocoxib Tablets for Horses:

Not for use in humans. Keep this and all medications out of the reach of children. Consult a physician in case of accidental ingestion by humans.

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 Firocoxib Tablets for Horses, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.