Date of Approval: July 21, 2026

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-861

Firocoxib Chewable Tablets

(firocoxib)

Dogs

Firocoxib Chewable Tablets are indicated for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

Sponsored by:

Ajenat Pharmaceuticals, LLC

Executive Summary

Firocoxib Chewable Tablets are approved for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs. The reference listed new animal drug (RLNAD) is Previcox® (firocoxib) chewable tablets sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-230.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in dogs to show that the 57 mg Firocoxib Chewable Tablets are bioequivalent to the 57 mg Previcox® chewable tablets. 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 227 mg generic chewable tablet qualified for a waiver from the requirement to perform separate *in vivo* bioequivalence studies (a biowaiver). FDA granted a biowaiver for this strength.

Conclusion

Based on the data submitted by the sponsor for the approval of Firocoxib Chewable Tablets, 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 200-861

B. Sponsor

Ajenat Pharmaceuticals, LLC
6911 Bryan Dairy Rd.
Suite 210
Largo, FL 33777

Drug Labeler Code: 082983

C. Proprietary Name

Firocoxib Chewable Tablets

D. Drug Product Established Name

firocoxib

E. Pharmacological Category

Non-steroidal anti-inflammatory drug (NSAID)

F. Dosage Form

Chewable tablet

G. Amount of Active Ingredient

57 mg or 227 mg of firocoxib per tablet

H. How Supplied

Firocoxib Chewable Tablets is available as round, beige to tan, half-scored tablets in two strengths, containing 57 mg or 227 mg firocoxib. Each tablet strength is supplied in 60 count bottles.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The recommended dosage of Firocoxib Chewable Tablets for oral administration in dogs is 2.27 mg/lb (5.0 mg/kg) body weight once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. The dogs can be treated with Firocoxib Chewable Tablets approximately two hours prior to surgery. The tablets are scored and dosage should be calculated in half tablet increments. Firocoxib Chewable Tablets can be

administered with or without food. Use the lowest effective dose for the shortest duration consistent with individual response.

K. Route of Administration

Oral

L. Species

Dogs

M. Indications

Firocoxib Chewable Tablets are indicated for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.

N. Reference Listed New Animal Drug (RLNAD)

Previcox®; firocoxib; NADA 141-230; 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).

For this ANADA, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD firocoxib 57 mg chewable tablets in dogs. The RLNAD is available in 57 mg and 227 mg chewable tablet sizes. The *in vivo* blood-level study was conducted in 40 healthy, fasted dogs. 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 RLNAD 57 mg firocoxib chewable tablets and the generic 57 mg firocoxib chewable tablets by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. A waiver from the requirement to demonstrate *in vivo* bioequivalence (biowaiver) for the generic 227 mg chewable tablet was granted. The study information is summarized below.

A. Blood-level Bioequivalence Study in Dogs

Title: A Pivotal Blood-Level Bioequivalence Study of Firocoxib Chewable Tablets in Dogs. (Study No. 023-01925)

Study Dates: February 6, 2024 to July 16, 2024

Study Locations:

In-life phase: Las Cruces, NM

Bioanalytical testing: Somerset, NJ

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 chewable tablets and the RLNAD 57 mg Previcox® (firocoxib) chewable tablets in fasted dogs.

Study Animals: Forty healthy non-pregnant intact male and female dogs between 4 to 8 years of age and weighing 9.4 to 12.8 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 chewable tablet 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 Method:

The laboratory study was conducted as a randomized, masked, four-period, two-sequence, two-treatment, single-dose crossover design using 40 dogs with a 7-day washout between periods 1 and 2, and periods 3 and 4, and a 14-day washout period between periods 2 and 3. 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 Guidance.

- The s_{WR} was less than 0.294 for 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.

- The s_{WR} was equal to or greater than 0.294 for C_{MAX}, so the RSABE method was used and bioequivalence was established based on the following two criteria:
    - The estimated 95% upper confidence bound for $(\mu_T-\mu_R)^2 - \theta^*\sigma^2_{WR}$ is less than zero (0), where μ_T and μ_R are the population means of the natural log transformed primary variable for the generic article and RLNAD, respectively, $\theta = (\log(1.25)/\sigma_{W0})^2$ and $\sigma_{W0} = 0.25$.
    - The point estimate of the generic to RLNAD geometric mean ratio is contained within the acceptance limits of 0.80 and 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◊	95% Upper Bound$	90% CI for the Ratio
AUC (ng/mL)*hour	0.24	7702.50†	7830.64†	0.98	NE	(0.91, 1.06)
C_{MAX} (ng/mL)	0.37	652.62†	668.48†	0.97	-0.07	NE
T_{MAX} (hours) (SD‡)	NE	1.53 (0.86)‡	1.87 (0.82)‡	NE	NE	NE

† Geometric mean
‡ Arithmetic mean and standard deviation (SD)
◊ Ratio = Generic:RLNAD
$ 95% upper confidence bound for $(\mu_T-\mu_R)^2 - \theta^*\sigma^2_{WR}$
CI = confidence interval
NE = not estimated

Adverse Reactions:

There were no serious adverse events reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 57 mg firocoxib chewable tablets and the RLNAD 57 mg Previcox® (firocoxib) chewable tablets are bioequivalent in dogs.

B. Bioequivalence Waiver

A pivotal *in vivo* blood bioequivalence study was conducted using the 57 mg chewable tablets in dogs. A waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) for the additional 227 mg chewable tablet strength in dogs was requested. To qualify for a biowaiver for the additional strength of the generic product, comparative *in vitro* dissolution studies were conducted to determine the comparability of dissolution profiles as listed below.

Between generic strengths:

- Generic 57 mg chewable tablet strength and generic 227 mg chewable tablet strength (calculated by CVM)

Between generic and RLNAD strengths:

- Generic 57 mg chewable tablet strength and the RLNAD 57 mg chewable tablet strength
- Generic 227 mg chewable tablet strength and the RLNAD 227 mg chewable tablet strength

The similarity factor (f_2) calculation was used to evaluate dissolution profile comparisons. The dissolution conditions are summarized as below:

- Apparatus: USP Apparatus II (Paddles)
- Speed of rotation: 50 RPM
- Medium: Acetate buffer + 1 % Cetrimide, pH = 4.5
- Volume: 900 mL
- Number of vessels: 12
- Temperature: 37 ± 0.5 °C
- Sampling time: 5, 10, 15, 20, 30, 45, 60, 90, and 120 minutes
- Analytical method: HPLC with UV detection at 220 nm

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 f_2 should be greater than 50 to ensure sameness or equivalence of two profiles.

CVM estimated f_2 metrics based on mean data, and a summary of the results is presented in Table II.2 below:

Table II.2. Similarity Results (f_2)

Dissolution Comparison	Similarity Results
57 mg generic chewable tablets to the 227 mg chewable tablets	89.9
57 mg generic chewable tablets to the 57 mg RLNAD chewable tablets	56.3
227 mg generic chewable tablets to the 227 mg RLNAD chewable tablets	54.7

Study results demonstrate similar dissolution profiles. Therefore, a biowaiver for the generic 227 mg firocoxib chewable tablets 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, 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 Firocoxib Chewable Tablets:

Warnings: 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 Chewable Tablets, when used according to the label, are safe and effective for the conditions of use in the General Information Section above.