Date of Approval: April 6, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-842

Gastrobim™

(omeprazole)

Oral Paste

Horses

For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

Sponsored by:

Bimeda Animal Health Ltd.

Executive Summary

Gastrobim™ (omeprazole) oral paste is approved for treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older. The reference listed new animal drug (RLNAD) is GastroGard® (omeprazole) oral paste sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-123. This is the first generic omeprazole oral paste for horses.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in horses to show that the 37% w/w (370 mg/g) Gastrobim™ oral paste is bioequivalent to the 37% w/w (370 mg/g) GastroGard® oral paste. No serious adverse events were reported during the study.

Conclusion

Based on the data submitted by the sponsor for the approval of Gastrobim™, 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 200-842

B. Sponsor

Bimeda Animal Health Ltd.
1B The Herbert Building, The Park
Carrickmines, Dublin 18
Ireland

Drug Labeler Code: 061133

U.S. Agent Name and Address:

Deb Ann Voss
Bimeda Inc.
291 Forrest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

Gastrobim™

D. Drug Product Established Name

omeprazole

E. Pharmacological Category

Proton pump inhibitor

F. Dosage Form

Oral paste

G. Amount of Active Ingredient

37% w/w omeprazole (370 mg/g)

H. How Supplied

Available in an adjustable-dose syringe in boxes of 7 units or 72 units. Each syringe contains 2.28 g of omeprazole.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

For treatment of gastric ulcers, Gastrobim™ Paste should be administered orally once-a-day for 4 weeks at the recommended dosage of 1.8 mg omeprazole/lb body weight (4 mg/kg). For the prevention of recurrence of gastric ulcers, continue treatment for at least an additional 4 weeks by administering Gastrobim™ Paste at the recommended daily maintenance dose of 0.9 mg/lb (2 mg/kg).

K. Route of Administration

Oral

L. Species/Class

Horses and foals 4 weeks of age and older

M. Indications

For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

N. Reference Listed New Animal Drug (RLNAD)

GastroGard®; omeprazole; NADA 141-123; 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 370 mg/g omeprazole oral paste. The *in vivo* blood-level study was conducted in 40 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 GastroGard® and Gastrobim™ by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

A. Blood-level Bioequivalence Study in Horses

Title: A Replicated Crossover Pharmacokinetic Study to Determine the Levels of Omeprazole in Equine Plasma Following the Oral Administration of Omeprazole 37% Paste (370 mg/g) (Bimeda Animal Health Limited), and GastroGard® Oral Paste (Boehringer Ingelheim Animal Health USA Inc., NADA 141-123). (Study No. 2021-CT-001-OMEP)

Study Dates: April 29, 2022 to April 28, 2023

Study Locations:

In-life phase: Central Bohemian Region, Czech Republic

Bioanalytical testing: Middleton, WI

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 370 mg/g Gastrobim™ (omeprazole) oral paste and the RLNAD 370 mg/g GastroGard® (omeprazole) oral paste in fasted horses.

Study Animals: 40 horses (including warmblood stallions and mares and thoroughbred geldings and mares) between 2 and 6 years of age weighing 428 to 554 kg.

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

Drug Administration: Each animal received 4 mg/kg of body weight of either the generic or RLNAD omeprazole according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Measurements and Observations: The plasma concentrations of omeprazole 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 as a randomized, masked, four-period, two-sequence, two-treatment, single-dose crossover design using 40 horses with a 7-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 Guidance.

- The s_{WR} was equal to or greater than 0.294 for C_{MAX} and AUC, 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, θ = $(\log(1.25)/\sigma_{W0})^2$ and σ_{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, the geometric mean ratio of both C_{MAX} and AUC falls within the prescribed acceptance limit, and the 95% upper confidence bound for the expression is less than zero (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[$]
AUC (ng/mL)*hour	0.430	1264[†]	1166[†]	1.08	-0.091
C_{MAX} (ng/mL)	0.538	452[†]	426[†]	1.06	-0.157
T_{MAX} (hours) (SD)[‡]	NE	1.53 (0.77)[‡]	1.46 (0.80)[‡]	NE	NE

[†] Geometric mean
[‡] Arithmetic mean and standard deviation (SD)
[◊] Ratio = Test/Reference
[$]Confidence bound for $(\mu T-\mu R)^2- \theta*\sigma^2_{WR}$
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 370 mg/g Gastrobim™ (omeprazole) oral paste and the RLNAD 370 mg/g GastroGard® (omeprazole) oral paste 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: **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 Gastrobim™:

Keep this and all drugs out of the reach of children. In case of ingestion, contact a physician. Physicians may contact a poison control center for advice concerning accidental ingestion.

Keep Gastrobim™ Paste in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

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