Date of Approval: December 9, 2019

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-546

BimaGard™ 12.5%

tiamulin hydrogen fumarate

Liquid Concentrate

Swine

BimaGard™ 12.5% (tiamulin hydrogen fumarate), when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-546

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:
Ms. Deb Ann Voss
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

BimaGard™ 12.5%

D. Drug Product Established Name

tiamulin hydrogen fumarate

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Liquid concentrate

G. Amount of Active Ingredient

12.5% tiamulin hydrogen fumarate

H. How Supplied

1 L and 5 L bottles

I. Dispensing Status

OTC

J. Dosage Regimen

Administer in drinking water for five consecutive days at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound body weight daily for swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.

Administer in drinking water for five consecutive days at a dose level of 10.5 mg tiamulin hydrogen fumarate per pound body weight daily for swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

K. Route of Administration

Oral, in drinking water

L. Species/Class

Swine

M. Indications

BimaGard™ 12.5% (tiamulin hydrogen fumarate), when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

N. Reference Listed New Animal Drug (RLNAD)

Denagard™ 12.5%; tiamulin hydrogen fumarate; NADA 140-916; Elanco US 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, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product BimaGard™ 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate. The generic drug product is a liquid concentrate, 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 Denagard™ 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate, sponsored by Elanco US Inc., under NADA 140-916 and, was approved for use in swine on January 29, 1993.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of tiamulin is 25 µg/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.6 ppm is established for 8-alpha-hydroxymutilin (the marker residue) in liver (the target tissue), under 21 CFR 556.732.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 3 days has been established for tiamulin in swine treated at 3.5 mg/lb of body weight and 7 days has been established for tiamulin in swine treated at 10.5 mg/lb of body weight.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of tiamulin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information Summary request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to BimaGard™ 12.5%:

Warning: Keep out of reach of children. Avoid direct contact with the skin. Direct contact with skin or mucous membranes may cause irritation.

Caution: For use in drinking water of swine only – Not for use in humans.

V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that BimaGard™ 12.5% when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from swine treated with BimaGard™ 12.5% will not represent a public health concern when the product is used according to the label.