Date of Approval: November 7, 2014

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-512

TRIAMULOX

tiamulin hydrogen fumarate, 12.3%

Liquid Concentrate

Swine

TRIAMULOX is indicated for the treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae,* susceptible to tiamulin.

Sponsored by:

Zoetis Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-512

B. Sponsor

Zoetis Inc.
333 Portage St., Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

TRIAMULOX Liquid Concentrate

D. Established Name

Tiamulin hydrogen fumarate

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Concentrated liquid solution

G. Amount of Active Ingredient

Each mL of solution contains 123 mg (12.3%) tiamulin hydrogen fumarate

H. How Supplied

Quart (32 fl oz; 946 mL) bottles

I. Dispensing Status

OTC

J. Dosage Regimen

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

K. Route of Administration

Oral

L. Species/Class

Swine

M. Indications

TRIAMULOX, 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

DENAGARD Liquid Concentrate, 12.3%; tiamulin hydrogen fumarate; NADA 140-916; Novartis Animal Health US, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Zoetis Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product TRIAMULOX (tiamulin hydrogen fumarate) Liquid Concentrate, 12.3%. The generic product is administered as a concentrated solution and 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 (tiamulin) Liquid Concentrate, 12.3%, and was approved for use in swine on March 17, 1993.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for swine:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.6 parts per million (ppm) is established for 8-*alpha*-hydroxymutilin (marker compound) in liver (target tissue) of swine, under 21 CFR 556.738.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product.

A withdrawal period of 3 days before slaughter after use at 3.5 mg per pound and 7 days before slaughter after use at 10.5 mg per pound has been established for tiamulin hydrogen fumarate in swine.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of tiamulin hydrogen fumarate is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to TRIAMULOX:

- Keep out of reach of children. Not for human use.
- Avoid direct contact with the skin. Direct contact with skin or mucous membranes may cause irritation.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that TRIAMULOX, when used according to the label, is safe and effective.