Date of Approval: August 5, 2016

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-508

Bilovet

tylosin

Injection

Cattle (beef and non-lactating dairy) and Swine

Beef Cattle and Non-lactating Dairy Cattle for the treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes.*

Swine for the treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

Sponsored by:

Cross Vetpharm Group Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-508

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623

US Agent Name and Address:
Jodi Beaudry
Bimeda Inc.
291 Forest Prairie
Le Sueur, MN 56058

C. Proprietary Name

BILOVET

D. Product Established Name

Tylosin

E. Pharmacological Category

Antibacterial

F. Dosage Form

Liquid (Solution)

G. Amount of Active Ingredient

200 mg/mL

H. How Supplied

100, 250 and 500 mL vials

I. Dispensing Status

OTC

J. Dosage Regimen

Beef Cattle and Non-lactating Dairy Cattle – Inject intramuscularly 8 mg per pound body weight once daily (1 mL per 25 pounds). Treatment should be continued 24 hours following remission of disease signs, not to exceed 5 days. Do not inject more than 10 mL per site.

Swine – Inject intramuscularly 4 mg per pound body weight twice daily (1 mL per 50 pounds) twice daily. Treatment should be continued 24 hours following remission of disease signs, not to exceed 3 days. Do not inject more than 5 mL per site.

K. Route of Administration

Intramuscular injection

L. Species/Class

Cattle (beef and non-lactating dairy)
Swine

M. Indications

In Beef and Non-lactating Dairy Cattle for the treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes.*

In Swine for the treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

N. Reference Listed New Animal Drug

TYLAN; tylosin; NADA 012-965; Elanco Animal Health, A Division of Eli Lilly & Co.

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 (GADPTRA) 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 (RLNAD)). 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 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 period 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, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product BILOVET (tylosin) Injection. The generic drug product is an injectable solution, 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 TYLAN (tylosin) Injection, sponsored by Elanco Animal Health, A Division of Eli Lilly & Co., under NADA 012-965 and was approved for use in Beef Cattle and Non-lactating Dairy Cattle and Swine on April 9, 1962.

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 Cattle and Swine:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) is not cited for total residues of tylosin. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.2 ppm (negligible residue) is established in Cattle and Swine in uncooked fat, muscle, liver and kidney, under 21 CFR 556.740.

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 21 days has been established for tylosin in cattle (beef and non-lactating dairy) and 14 days has been established for tylosin in swine.

C. Regulatory Method for Residues:

The analytical method for the determination of tylosin residues in tissues uses a microbiological assay procedure. The validated regulatory method for the determination and confirmation of residues of tylosin is on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

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

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN

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 BILOVET, when used according to the label, is safe and effective.

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