Date of Approval: July 5, 2011

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-455

TYLOMED-WS
(tylosin tartrate)

Soluble Powder

Chickens, Turkeys, Swine, and Honey bees

- **Chickens:** As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* sensitive to tylosin at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.
- **Turkeys:** For maintaining weight gain and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.
- **Swine:** For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae.*
- **Honey Bees:** For the control of American Foulbrood (*Paenibacillus larvae*).

Sponsored by:
Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number: ANADA 200-455

B. Sponsor: Cross VetPharm Group Ltd.
Broomhill Rd., Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623

U.S. Agent: Linda Duple
Bimeda, Inc.
2836 Dolliver Park Ave., Lehigh, IA 50557

C. Proprietary Name: TYLOMED-WS

D. Established Name: Tylosin tartrate

E. Pharmacological Category: Antimicrobial

F. Dosage Form: Soluble powder

G. Amount of Active Ingredient: 100 grams of tylosin tartrate per pouch or jar, or 256 grams of tylosin tartrate per pouch or jar

H. How Supplied: 100 gram pouch and jar, 256 gram pouch and jar

I. How Dispensed: OTC

J. Dosages: **Chickens:** 2 grams per gallon. Chickens should be treated for three days; however, treatment may be administered for one to five days depending on the severity of infection. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound body weight per day. Only medicated water should be available to birds.

Turkeys: 2 grams per gallon. Turkeys should be treated for three days; however, treatment should be administered for 2 to 5 days depending on the severity of infection. Treated turkeys should consume enough medicated drinking water to prove 60 mg tylosin base per pound body weight per day. Only medicated water should be available to birds.

Swine: 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of infection.

Honey Bees: Mix 200 milligrams tylosin in 20 grams confectioners/powdered sugar. Use immediately. Honey bees should receive 3 treatments. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

K. Route of Administration: Oral in water

L. Species/Class: Chickens, turkeys, swine, and honey bees

M. Indications:

Chickens: As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* sensitive to tylosin at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

Turkeys: For maintaining weight gain and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

Swine: For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae.*

Honey Bees: For the control of American Foulbrood (*Paenibacillus larvae*).

N. Reference listed new animal drug: TYLAN Soluble; tylosin tartrate; NADA 013-076; 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 Paten 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 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 an *in vivo* bioequivalence study. (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 for an *in vivo* bioequivalence study for the generic product TYLOMED-WS (tylosin tartrate). The generic product is administered as a water soluble powder, 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 absorption of the active ingredient. The RLNAD is TYLAN (tylosin tartrate) Soluble, sponsored by Elanco Animal Health, A Division of Eli Lilly & Co., under NADA 013-076, and was approved for use in chickens and turkeys, and for use in swine for the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* on October 13, 1961. The RLNAD was later approved for use in swine for the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* when followed immediately by TYLAN Type A medicated article in feed; and for the control of porcine proliferative enteritis (PPE, ileitis) associated with *Lawsonia intracellularis* when followed immediately by TYLAN Type A medicated article in feed on November 13, 2008. These claims are protected by a marketing exclusivity that expires on November 13, 2011. The RLNAD was also approved for use in honey bees on October 17, 2005.

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 chickens, turkeys, swine, and honey bees:

- **Tolerances for Residues:** The tolerances established for the RLNAD apply to the generic product, under 21 CFR 556.740.
    - In chickens and turkeys: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
    - In swine: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
    - In eggs: 0.2 part per million (negligible residue).
- **Withdrawal Times:** Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.
    - Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption.
    - Turkeys must not be slaughtered for food within 5 days after treatment.
    - Swine must not be slaughtered for food within 48 hours after treatment.
    - Honey bees: The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks prior to main honey flow.
- **Regulatory Method for Residues:** The analytical method for the determination of tylosin residues in tissues uses a microbiological assay procedure. This method is found in the Food Additives Analytical Manual on file at the Center for Veterinary Medicine, FDA, 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 TYLOMED-WS:

Avoid contact with human skin. Exposure to tylosin may cause a rash.

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 TYLOMED-WS, when used according to the label, is safe and effective for:

- **Chickens:** As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* sensitive to tylosin at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.
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