Date of Approval: November 21, 2017

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-473

Tylovet® Soluble

(tylosin tartrate)

Soluble Powder

Broiler Chickens

The purpose of the supplement is to add the following indication for use in chickens: For control of mortality caused by necrotic enteritis (NE) associated with *Clostridium perfringens* in broiler chickens.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-473

B. Sponsor

Huvepharma EOOD
5th Floor, 3A Nikolay Haytov Str.
1113 Sofia
Bulgaria

Drug Labeler Code: 016592

US Agent:
Kelly W. Beers, Ph.D.
Huvepharma, Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

C. Proprietary Name

Tylovet® Soluble

D. Product Established Name

tylosin tartrate

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Soluble Powder

G. Amount of Active Ingredient

100 g tylosin tartrate per pouch and per jar

H. How Supplied

100 g pouch, 100 g jar

I. Dispensing Status

Rx

J. Dosage Regimen

Chickens:
NE indication: 851 to 1,419 mg/gallon (225 to 375 ppm) in drinking water.

K. Route of Administration

Oral in water

L. Species/Class

Chickens

M. Indications

Chickens:
For the control of mortality caused by necrotic enteritis (NE) associated with *Clostridium perfringens* in broiler chickens.

N. Reference Listed New Animal Drug

Tylan® Soluble; tylosin tartrate; NADA 013-076; Elanco US Inc.

O. Effect of Supplement

This supplement provides for the addition of the following indication for use in chickens: "For control of mortality caused by NE associated with *Clostridium perfringens* in broiler chickens."

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, Huvepharma EOOD, was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Tylovet® Soluble (tylosin tartrate) Powder. The generic drug product is a 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 bioavailability of the active ingredient. The RLNAD is Tylan® Soluble (tylosin tartrate) powder, sponsored by Elanco US Inc., under NADA 013-076, and was approved for use in chickens, turkeys, and swine on October 13, 1961. The RLNAD was approved for use in honey bees on October 17, 2005. The RLNAD was also approved for the control of mortality caused by NE associated with *Clostridium perfringens* in broiler chickens on July 30, 2014.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this supplemental approval.

IV. TARGET ANIMAL SAFETY:

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

V. HUMAN FOOD SAFETY:

The following are assigned to this product for chickens:

A. Acceptable Daily Intake and Tolerances for Residues:

An acceptable daily intake (ADI) is not cited for total residues of tylosin. The tolerances established for the RLNAD apply to the generic product. Tolerances are established for residues of tylosin in edible products of animals as follows under 21 CFR 556.740:

a. In chickens: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver and kidney.

b. In eggs: 0.2 part per million (negligible residue)

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.
Withdrawal periods have been established for the indicated species: 24 hours for Chickens (21 CFR 520.2640).

C. Analytical Method for Residues:

The validated analytical method for analysis of residues of tylosin tartrate 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.

VI. USER SAFETY:

CVM did not require user safety studies for this supplemental approval.

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

Not for use in humans. Keep out of reach of children. 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 Tylovet® Soluble, when used according to the label, is safe and effective.

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