Date of Approval: July 13, 2018

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-484

Tylovet® 40

(tylosin phosphate)

Type A medicated article

Beef Cattle and Swine

This supplemental approval provides for the addition of a 40 g/lb strength of this Type A medicated article.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-484

B. Sponsor

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

Drug Labeler Code: 016592

US Agent Name and Address:
Kelly W. Beers, Ph.D.
Huvepharma, Inc.
525 West Park Drive, Suite 230
Peachtree City, GA 30269

C. Proprietary Name

Tylovet® 40

D. Product Established Name

tylosin phosphate

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Type A medicated article

G. Amount of Active Ingredient

40 g/lb

H. How Supplied

50 lb (22.68 kg) bag

I. Dispensing Status

VFD

J. Dosage Regimen

Beef Cattle:

Tylovet® 40 per ton of Type C feed: 0.2 to 0.25 lbs. To be fed so that each animal receives not more than 90 mg per head per day and not less than 60 mg per head

per day. Feed continuously as the sole ration; tylosin per ton of Type C feed: 8 to 10 g.

Swine:

For the reduction in severity of effects of atrophic rhinitis: Feed 100 g of tylosin per ton (2.5 pound Tylovet® 40 per ton) of complete feed. Feed continuously as the sole ration.

For control of swine dysentery: Feed 100 g of tylosin per ton (2.5 pound Tylovet® 40 per ton) of complete feed for at least three weeks. Follow with 40 g tylosin per ton (1.0 pound Tylovet® per ton) of complete feed until pigs reach market weight.

For the treatment and control of swine dysentery: Feed 40 to 100 g of tylosin (1.0 to 2.5 pounds of Tylovet® 40) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as Tylovet® Soluble) per gallon of drinking water for 3 to 10 days.

For the control of porcine proliferative enteropathies (PPE, ileitis): Feed 100 g tylosin per ton (2.5 pounds Tylovet® 40 per ton) of complete feed for 21 days. Alternatively, feed 100 g of tylosin per ton (2.5 pounds Tylovet® 40 per ton) of complete feed for at least three weeks, followed by 40 g tylosin per ton of complete feed until pigs reach market weight. Alternatively, feed 40 to 100 grams of tylosin (1.0 to 2.5 pounds of Tylovet® 40) per ton of complete feed for 2 to 6 weeks immediately after medicating with 250 mg tylosin (as Tylovet® Soluble) per gallon in drinking water for 3 to 10 days. Feed continuously as the sole ration when feeding Tylovet®.

K. Route of Administration

Oral

L. Species/Class

Beef Cattle and Swine

M. Indications

Beef Cattle:

For the reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes.*

Swine:

For reduction in severity of effects of atrophic rhinitis.
For control of swine dysentery associated with *Brachyspira hyodysenteriae*.
For treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with Tylovet® Soluble (tylosin tartrate) drinking water.
For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with Tylovet® Soluble (tylosin tartrate) in drinking water.

N. Reference Listed New Animal Drug

Tylan™ 40; tylosin phosphate; NADA 012-491; Elanco US Inc.

O. Effect of Supplement

The effect of the supplement is to add a 40 g/lb strength of this Type A medicated article which contains 40 grams tylosin phosphate per pound.

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 to perform *in vivo* bioequivalence studies (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 perform *in vivo* bioequivalence studies for the generic product Tylovet® 40 (tylosin phosphate) Type A medicated article. The generic drug product is administered as a Type C medicated feed, 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™ 40 (tylosin phosphate) Type A medicated article, sponsored by Elanco US Inc., under NADA 012-491 and, was approved for use in swine on November 8, 1996, and beef cattle on November 7, 2006.

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 beef cattle and swine:

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. A tolerance of 0.2 parts per million (negligible residue) is established for residues of tylosin in uncooked fat, muscle, liver, and kidney of swine and cattle; 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 0 days has been established for tylosin phosphate in beef cattle and swine.

C. Analytical Method for Residues:

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

CVM did not require human food safety studies for this supplemental approval.

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® 40:

Warning: Tylovet® 40 may be irritating to unprotected skin and eyes. When mixing and handling Tylovet® 40 use protective clothing, impervious gloves and a dust respirator. In case of accidental eye exposure, flush eyes with plenty of water. Exposed skin should be washed with plenty of soap and water. Remove and wash contaminated clothing. Seek medical attention if irritation becomes severe or persists. The safety data sheet (SDS) contains more detailed occupational safety information. To report adverse effects, access medical information or obtain additional product information, call 1 877 426 7765.

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

Additionally, data demonstrate that residues in food products derived from species treated with Tylovet® 40 will not represent a public health concern when the product is used according to the label.