Date of Approval:February 1, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-531

RUMENSIN plus TYLOVET 100

Monensin USP plus tylosin phosphate

Type A Medicated Articles For Use in the Manufacture of Type B and C Medicated Feeds

Cattle Fed in Confinement for Slaughter

For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle being fed in confinement for slaughter

Sponsored by:

Huvepharma AD

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I. GENERAL INFORMATION:

A. File Number:

ANADA 200-531

B. Sponsor:

Huvepharma AD
5th Floor, 3A Nikolay Haitov Str
1113 Sofia, Bulgaria

Drug Labeler Code: 016592

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

C. Proprietary Name:

RUMENSIN plus TYLOVET 100

D. Established Name:

Monensin USP plus tylosin phosphate

E. Pharmacological Category:

Monensin USP – Ionophore/anticoccidial
Tylosin phosphate – Antibiotic

F. Dosage Form:

Type A medicated articles for use in the manufacture of dry and liquid combination Type B and C medicated feeds

G. Amount of Active Ingredient:

Monensin USP – 80 g/lb
Tylosin phosphate - 40 and 100 g/lb

H. How Supplied:

RUMENSIN (monensin USP) – 50 lb bag
TYLOVET (tylosin phosphate) – 50 lb bag

I. Dispensing Status:

OTC

J. Dosage Regimen:

Monensin is added to feedlot cattle diets at concentrations of 10 to 40 g of monensin USP per ton of complete feed at a rate of 0.14 to 0.42 mg

monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day.

Monensin is added to feedlot cattle diets at concentrations of 5 to 40 g of monensin USP per ton of complete feed for improved feed efficiency to provide 50 to 480 mg monensin/head/day.

Tylosin is added to the cattle diets at concentrations of 8 to 10 g of tylosin phosphate per ton of complete feed to provide 60 to 90 mg tylosin/head/day.

K. Route of Administration:

Oral in feed

L. Species/Class:

Cattle fed in confinement for slaughter

M. Indications:

For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle being fed in confinement for slaughter

N. Approved original generic Type A medicated article:

TYLOVET 100; tylosin phosphate; ANADA 200-484; Huvepharma AD

O. Reference listed new animal drug (RLNAD):

RUMENSIN plus TYLAN 100; monensin USP plus tylosin phosphate; NADA 104-646; Elanco Animal Health, A Division of Eli Lilly and Company

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.

According to CVM's fourth policy letter issued on November 2, 1989, with regard to the implementation of GADPTRA, after the approval of an ANADA for a generic Type A medicated article, the generic sponsor is entitled to approval for all the feed-mixed combinations for which the RLNAD is approved. Bioequivalence and tissue residue studies are not required for the approval of the generic feed use combinations (Type B or C medicated feeds). Monensin is codified under 21 CFR 558.355 and tylosin phosphate is codified under 21 CFR 558.625. The combination of monensin and tylosin is codified under 21 CFR 558.355(f)(3)(ii) and (f)(3)(xii).

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 heifers fed in confinement for slaughter:

- Tolerances for Residues:

  The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product.

  A tolerance of 0.2 part per million (ppm) (negligible residue) is established for residues of tylosin in uncooked fat, muscle, liver, and kidney of cattle under 21 CFR 556.740.

  A tolerance of 0.10 part per million is established for residues of monensin in cattle liver and 0.05 ppm in muscle, kidney, and fat of cattle under 21 CFR 556.420. The acceptable daily intake (ADI) for total residues of monensin is 12.5 micrograms per kilogram of body weight per day under 21 CFR 556.420(a).

- Withdrawal Times:

  Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted for the Type A medicated article TYLOVET 100, the withdrawal times for the combination Type B and C medicated feeds are those previously assigned to the RLNAD.

  Monensin and tylosin phosphate in combination are approved with a zero day withdrawal period.

- Regulatory Method for Residues:

  The regulatory analytical method for monensin is the method developed by Eli Lilly & Co., Box 708, Greenfield, IN 46140 (Method 5801654, "Determination of Monensin in Tissues and Eggs") on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

  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

CVM did not require user safety studies for this approval

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 RUMENSIN plus TYLOVET 100, when used according to the label, is safe and effective.