Date of Approval: May 24, 2016

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-596

TILMOVET 90 and RUMENSIN 90

tilmicosin phosphate and monensin

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

Cattle Fed in Confinement for Slaughter

1) For prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.

2) For improved feed efficiency and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-596

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 Westpark Drive, Suite 230
Peachtree City, GA 30269

C. Proprietary Name

TILMOVET 90 and RUMENSIN 90

D. Product Established Name

Tilmicosin phosphate and monensin

E. Pharmacological Category

Tilmicosin phosphate - antimicrobial
Monensin - antimicrobial

F. Dosage Form

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

G. Amount of Active Ingredient in Currently Marketed Products

Tilmicosin phosphate – 90.7 g/lb
Monensin – 90.7 g/lb

H. How Supplied

TILMOVET 90 – 22 lb (10 kg) bag
RUMENSIN 90 – 50 lb (22.68 kg) bag

I. Dispensing Status

VFD

J. Dosage Regimen

Coccidiosis and BRD:
Tilmicosin phosphate – 568 to 757 g/ton*
Monensin – 10 to 40 g/ton**

Feed efficiency and BRD:
Tilmicosin phosphate – 568 to 757 g/ton*
Monensin – 5 to 40 g/ton**

*100% dry matter basis
**90% dry matter basis

K. Route of Administration

Oral, in feed

L. Species/Class

Cattle fed in confinement for slaughter

M. Indications

1) For prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.

2) For improved feed efficiency and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pastuerella multocida*, and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10% of the animals in the group.

N. Approved Original Generic Type A Medicated Article

TILMOVET 90; tilmicosin phosphate; ANADA 200-509; Huvepharma EOOD

O. Reference Listed New Animal Drug

PULMOTIL 90 and RUMENSIN 90; tilmicosin phosphate and monensin; NADA 141-343; Elanco Animal Health, A Division of Eli Lilly & Co.

The individual Type A medicated articles approved for use in the manufacture of combination medicated feeds:
PULMOTIL 90; tilmicosin phosphate; NADA 141-064; Elanco Animal Health, A Division of Eli Lilly & Co.
RUMENSIN 90; monensin; NADA 095-735; 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). 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). Tilmicosin phosphate is codified under 21 CFR 558.618, monensin is codified under 21 CFR 558.355. The combination of tilmicosin phosphate and monensin is codified under 21 CFR 558.618.

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:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of monensin is 12.5 micrograms per kilogram of body weight per day as listed under 21 CFR 556.420. The ADI for total residues of tilmicosin is 25 micrograms per kilogram of body weight per day as listed under 21 CFR 556.735.

The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 0.10 parts per million (ppm) is established for monensin in cattle liver, and 0.05 ppm in cattle muscle, kidney, and fat, under 21 CFR 556.420. A tolerance of 1.2 ppm is established for tilmicosin in cattle liver, and 0.1 ppm in cattle muscle, under 21 CFR 556.735.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate bioequivalence was granted for the Type A medicated article TILMOVET, the withdrawal periods for the combination Type B and C medicated feeds are those previously assigned to the RLNAD product.

When used together, tilmicosin phosphate and monensin are approved with a 28-day withdrawal period.

C. 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 validated regulatory analytical methods for detection (high performance liquid chromatography) and confirmation (reversed-phase high performance liquid chromatography/atmospheric pressure chemical ionization mass spectrometry) of residues of tilmicosin in liver are filed 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 TILMOVET 90 and RUMENSIN 90, when used according to the label, are safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with TILMOVET 90 and RUMENSIN 90 will not represent a public health concern when the product is used according to the label.