Date of Approval: February 21, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-509

TILMOVET 90

(tilmicosin phosphate)

Type A medicated article

Swine

For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Sponsored by:

Huvepharma AD

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-509

B. Sponsor

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

Drug Labeler Code: 016592

US representative:
Huvepharma, Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

C. Proprietary Name

TILMOVET 90

D. Established Name

Tilmicosin phosphate

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Type A medicated article

G. Amount of Active Ingredient

90.7 g/lb

H. How Supplied

1 kg, 5 kg, 10 kg, and 20 kg bag

I. Dispensing Status

VFD

J. Dosage Regimen

181 grams to 363 grams per ton for 21 days

K. Route of Administration

Oral

L. Species/Class

Swine

M. Indication

For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

N. Reference Listed New Animal Drug

PULMOTIL 90; (tilmicosin phosphate); NADA 141-064; Elanco Animal Health, A Division of Eli Lilly & 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.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (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 and an acceptable *in vitro* solubility study conducted according to the solubility requirements defined in Guidance No. 171, "Guidance for Industry on Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles.", Huvepharma AD was granted a waiver from the requirement to demonstrate *in vivo* bioequivalence study for the generic product TILMOVET 90 (tilmicosin phosphate) Type A medicated article. Type A medicated article is used to manufacture Type B medicated feed. The generic product is administered as 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 absorption of the active ingredient. The RLNAD, PULMOTIL 90 (tilmicosin phosphate) Type A medicated article, sponsored by Elanco Animal Health, A Division of Eli Lilly & Co., under NADA 141-064, was originally approved for use in swine on December 27, 1996.

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 swine:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance of 7.5 parts per million (ppm) is established for parent tilmicosin residues (the marker residue) in the uncooked edible tissues of the liver (the target tissue), and 0.1 ppm in the muscle, under 21 CFR 556.735. The acceptable daily intake (ADI) for total residues of tilmicosin is 25 micrograms per kilogram of body weight per day.

B. Withdrawal Times:

Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted, the withdrawal times are those previously assigned to the RLNAD product.

A withdrawal period of 7 days has been established for tilmicosin phosphate in swine.

C. Regulatory Method for Residues:

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:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to TILMOVET 90:

"Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling Tilmovet 90 should use protective clothing, impervious gloves, goggles, and a NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Material Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a material safety data sheet, 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 TILMOVET 90, when used according to the label, is safe and effective.