Date of Approval: February 15, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-484

TYLOVET 100
(tylosin phosphate)

Type A medicated article

Beef Cattle, Chickens (broilers, layers, replacements), and Swine

Indications: In beef cattle for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

In chickens for increased rate of weight gain and improved feed efficiency. In laying chickens for improved feed efficiency. In broilers and replacement chickens to aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum.*

In swine for increased rate of weight gain and improved feed efficiency, for maintaining weight gains and feed efficiency in the presence of atrophic rhinitis, for control of swine dysentery associated with *Brachyspira hyodysenteriae*, for the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin tartrate in drinking water, and for control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.*

Sponsored by:

Huvepharma AD

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I. GENERAL INFORMATION:

A. File Number: ANADA 200-484

B. Sponsor: Huvepharma AD
5th Floor, 3A Nikolay Haitov Str.
1113 Sofia, Bulgaria

Drug Labeler Code: 016592

U.S. Agent**:**
Kelly W. Beers, PhD
Huvepharma Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

C. Proprietary Name: TYLOVET 100

D. Established Name: Tylosin phosphate

E. Pharmacological Category: Antimicrobial

F. Dosage Form: Type A medicated article

G. Amount of Active Ingredient: 100 g/lb

H. How Supplied: 50 lb (22.68 kg) bag

I. How Dispensed: OTC

J. Dosage: Beef cattle: 8 to 10 g/ton (60 to 90 mg/head/day). Feed continuously as the sole ration.

Chickens: 4 to 50 g/ton.

Laying chickens: 20 to 50 g/ton.

Broiler chickens: 800 to 1000 g/ton. Administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

Replacement chickens: 1000 g/ton. Administer in feed to chickens 0-5 days of age, follow with second administration in feed for 24 to 48 hours

at 3 to 5 weeks of age.

Swine: 10 to 100 g/ton: Continuous use as follows: 20 to 100 g/ton, prestarter or starter; 20 to 40 g/ton, grower; 10 to 20 g/ton, finisher.

40 to 100 g/ton: Use 100 g/ton for at least 3 weeks followed by 40 g/ton until market weight.

40 to 100 g/ton: Administer in feed after treatment with tylosin in drinking water as tylosin base; 0.25 g/gallon in drinking water for 3 to 10 days, 40 to 100 g/ton in feed for 2 to 6 weeks.

100 g/ton.

100 g/ton: Administer for 21 days.

K. Route of Administration: Oral, in feed

L. Species/Classes: Beef cattle, Chickens, Broiler chickens, Laying chickens, Replacement chickens, and Swine

M. Indications: Beef cattle: for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

Chickens: for increased rate of weight gain and improved feed efficiency.

Laying chickens: for improved feed efficiency.

Broilers and replacement chickens: to aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum.*

Swine: for increased rate of weight gain and improved feed efficiency, for maintaining weight gains and feed efficiency in the presence of atrophic rhinitis, for control of swine dysentery associated with *Brachyspira hyodysenteriae*, for the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* immediately after medicating with tylosin tartrate in drinking water, and for control of porcine proliferative enteropathies

	(ileitis) associated with *Lawsonia intracellularis.*
N. Reference listed new animal drug:	TYLAN 100; tylosin phosphate; NADA 012-491; 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 Paten 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 meeting the solubility criteria 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 for an *in vivo* bioequivalence study for their generic TYLOVET 100 (tylosin phosphate) Type A medicated article. The generic 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 absorption of the active ingredient. The RLNAD is TYLAN 100 (tylosin phosphate) Type A medicated article, sponsored by Elanco Animal Health, a Division of Eli Lilly & Co., under NADA 012-491, and was approved for use in beef cattle, chickens, and swine on November 8, 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 beef cattle, chickens, and swine:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product under 21 CFR 556.740 as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver and kidney of beef cattle, chickens, and swine. There is a 0.2 part per million (negligible residue) in eggs.

- **Withdrawal Times:**
  The withdrawal time for broiler and replacement chickens is 5 days before slaughter.

- **Regulatory Method for Residues:**
  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.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to TYLOVET 100:

Warning: TYLOVET 100 may be irritating to unprotected skin and eyes. When mixing and handling TYLOVET 100 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 material safety data sheet (MSDS) contains more detailed occupational safety information.

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