Date of Approval: October 18, 2024

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-748

Pennchlor® and Monovet®

(chlortetracycline Type A medicated article) and (monensin Type A medicated article)

Type A medicated articles to be used in the manufacture of Type B and Type C medicated feeds

Replacement beef and dairy heifers

Supplemental abbreviated new animal drug approval of a medicated feed combination for the addition of replacement beef and dairy heifers with the indications listed in Section I.L

Sponsored by:

Huvepharma EOOD

Table of Contents

I. GENERAL INFORMATION 3
II. BIOEQUIVALENCE 5
III. HUMAN FOOD SAFETY 6
IV. USER SAFETY 6
V. AGENCY CONCLUSIONS 7

I. GENERAL INFORMATION

A. File Number

ANADA 200-748

B. Sponsor

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

Drug Labeler Code: 016592

C. Proprietary Name

Pennchlor® and Monovet®

D. Drug Product Established Name

chlortetracycline Type A medicated article and monensin Type A medicated article

E. Pharmacological Categories

Pennchlor®: Antimicrobial
Monovet®: Anticoccidial

F. Dosage Form

Type A medicated articles to be used in the manufacture of Type B and Type C medicated feeds.

G. Amount of Active Ingredients in Currently Marketed Products[1]

Pennchlor®: 50 g/lb, 90 g/lb, and 100 g/lb of chlortetracycline
Monovet®: 90.7 g/lb of monensin

H. How Supplied

Pennchlor®: 50 lb (22.68 kg) bag
Monovet®: 25 kg (55.12 lb) bag

I. Dispensing Status

Veterinary feed directive (VFD)

J. Route of Administration

Oral

[1] The sponsors of these individual currently marketed Type A medicated articles may have approvals for other strengths that are for use in the same species and class, for the same indications, and at the same dosages, but are not currently marketing those strengths of these Type A medicated articles. Such strengths, when legally marketed, are also approved for use in the manufacture of Type B and Type C medicated feeds that are the subject of this approval.

K. Species/Classes

Replacement beef and dairy heifers

L. Indications and Dosage Regimens

1. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in replacement beef and dairy heifers.

   a. 400 to 2,000 g/ton of chlortetracycline (as Pennchlor®) for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline

   b. 15 to 84 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*

   For replacement beef and dairy heifers not currently being fed monensin: feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.

   For replacement beef and dairy heifers currently being fed monensin: feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone.

2. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for increased rate of weight gain in replacement beef and dairy heifers.

   a. 400 to 2,000 g/ton of chlortetracycline (as Pennchlor®) for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline

   b. 15 to 400 g/ton of monensin (as Monovet®) for increased rate of weight gain

   For replacement beef and dairy heifers not currently being fed monensin: feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.

For replacement beef and dairy heifers currently being fed monensin: feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone.

M. Reference Listed New Animal Drug Combination (RLNAD)

Pennchlor® and Rumensin™; chlortetracycline Type A medicated article and monensin Type A medicated article; NADA 141-564; Pharmgate Inc.

N. Approved Original Generic Type A Medicated Article

Monovet®; monensin Type A medicated article; ANADA 200-639; Huvepharma EOOD

O. Individual Type A medicated articles approved for use in the manufacture of the Type B and Type C combination medicated feeds in this application

Pennchlor® (chlortetracycline Type A medicated article); NADA 138-935; Pharmgate Inc.
Monovet® (monensin Type A medicated article); ANADA 200-639; Huvepharma EOOD

P. Effect of Supplement

This supplement provides for the addition of replacement beef and dairy heifers with the following indications:

For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in replacement beef and dairy heifers; and

For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for increased rate of weight gain in replacement beef and dairy heifers.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). Target animal safety and effectiveness data are not required for approval of an ANADA.

Following the approval of an ANADA for a generic Type A medicated article, CVM's fourth policy letter issued on November 2, 1989, with regard to the implementation of GADPTRA, entitles the generic sponsor to submit an ANADA for each feed use combination (Type B or C medicated feed) for which the RLNAD is approved, without additional bioequivalence. CVM's fourth policy letter reaffirms that bioequivalence and tissue residues for each generic drug in the combination were adequately established in

the ANADA at the time of its approval. Chlortetracycline is codified under 21 CFR 558.128 and monensin is codified under 21 CFR 558.355. The combination of chlortetracycline and monensin is codified under 21 CFR 558.128.

III. HUMAN FOOD SAFETY

The following are assigned to this product for beef calves 2 months of age and older, growing beef steers and heifers fed in confinement for slaughter, and replacement beef and dairy heifers:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residue of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 µg/kg of body weight *per* day. The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 6 parts per million (ppm) is established for the sum of tetracycline residues in liver, 12 ppm in kidney and fat, and 2 ppm in muscle, under 21 CFR 556.150.

The ADI for total residue of monensin is 12.5 µg/kg body weight *per* day. The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 0.10 ppm is established for monensin in liver, and 0.05 ppm in muscle, kidney, and fat, under 21 CFR 556.420.

B. Withdrawal Period

Consistent with 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 with the RLNAD is approved. Tissue residue studies are not required for the approval of the generic feed use combinations (Type B or Type C medicated feeds).

To this end, the withdrawal period for the generic combination Type B and Type C medicated feeds are those previously assigned to the RLNAD feed use combination. When used together, Pennchlor® (chlortetracycline Type A medicated article) and Monovet® (monensin Type A medicated article) are approved for a 0-day withdrawal period.

C. Analytical Methods for Residues

The validated analytical methods for analysis of residues of chlortetracycline and monensin are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical methods, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

CVM did not require user safety studies for this supplemental approval.

The combination labeling contains the following information regarding safety to humans handling, administering, or exposed to the Type B and C medicated feeds:

User Safety Warnings:

Keep this and all drugs out of the reach of children. Not for human use.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(n) of the FD&C Act and demonstrate that Pennchlor® and Monovet®, when used according to the label, are safe and effective for the effect of supplement in the General Information Section above. Additionally, data demonstrate that residues in food products derived from replacement beef and dairy heifers administered Pennchlor® and Monovet® will not represent a public health concern when the combination medicated feed is used according to the label.