Date of Approval: May 10, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL 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

Beef calves 2 months of age and older, and growing beef steers and heifers fed in confinement for slaughter

Original abbreviated new animal drug approval of a medicated feed combination for the indications listed in Section I.L

Sponsored by:

Huvepharma EOOD

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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

U.S. Agent Name and Address:

Dr. Kelly Beers, Ph.D.
Huvepharma, Inc.
525 West Park Drive
Peachtree City, GA 30269

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 as chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride
Monovet®: 90.7 g/lb of monensin

[1] The sponsors of these individual currently marketed Type A medicated articles may have approvals for other strengths of these products 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.

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

K. Species/Classes

Beef calves 2 months of age and older, and growing beef steers and heifers fed in confinement for slaughter

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 due to *Eimeria bovis* and *Eimeria zuernii* in beef calves 2 months of age and older.

    a. 400 to 2000 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. 10 to 200 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration for not more than 5 days, then continue to feed monensin Type C medicated feed alone.

2. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.

    a. 33.33 to 66.67 g/ton of chlortetracycline (as Pennchlor®) for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

    b. 10 to 40 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration.

3. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.

    a. 33.33 to 66.67 g/ton of chlortetracycline (as Pennchlor®) for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

    b. 5 to 40 g/ton of monensin (as Monovet®) for improved feed efficiency.

    Feed as the sole ration. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day).

4. 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 due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter.

    a. 400 to 2000 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. 10 to 40 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration for not more than 5 days, then continue to feed monensin Type C medicated feed alone.

5. For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

    a. 400 to 2000 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. 5 to 40 g/ton of monensin (as Monovet®) for improved feed efficiency.

    Feed as the sole ration for not more than 5 days, then continue feeding monensin Type C medicated feed alone. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day).

6. For the reduction of the incidence of liver abscesses and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.

    a. 7 to 17.5 g/ton of chlortetracycline (as Pennchlor®) for the reduction of the incidence of liver abscesses.

    b. 10 to 40 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration.

7. For the reduction of the incidence of liver abscesses and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.

    a. 7 to 17.5 g/ton of chlortetracycline (as Pennchlor®) for the reduction of the incidence of liver abscesses.

    b. 5 to 40 g/ton of monensin (as Monovet®) for improved feed efficiency.

    Feed as the sole ration. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day).

8. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.

    a. 50 to 117 g/ton of chlortetracycline (as Pennchlor®) for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

    b. 10 to 40 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration.

9. For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.

    a. 50 to 117 g/ton of chlortetracycline (as Pennchlor®) for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

    b. 7.14 to 40 g/ton of monensin (as Monovet®) for improved feed efficiency.

Feed as the sole ration. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day).

10. For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing beef steers and heifers fed in confinement for slaughter.

    a. 50 to 117 g/ton of chlortetracycline (as Pennchlor®) for the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.

    b. 10 to 40 g/ton of monensin (as Monovet®) for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed as the sole ration.

11. For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

    a. 50 to 117 g/ton of chlortetracycline (as Pennchlor®) for the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.

    b. 7.14 to 40 g/ton of monensin (as Monovet®) for improved feed efficiency.

    Feed as the sole ration. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day).

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

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*,* 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, and growing beef steers and heifers fed in confinement for slaughter:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues 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 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 residues of monensin is 12.5 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 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 which 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 with a 0-day withdrawal period.

C. Analytical Method 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 method, 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 original 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 they are used according to the label, are safe and effective for the indications listed in Section I.L. Additionally, data demonstrate that residues in food products derived from beef calves 2 months of age and older, and growing beef steers and heifers fed in confinement for slaughter administered Pennchlor® and Monovet® will not represent a public health concern when the combination medicated feed is used according to the label.