Date of Approval: August 15, 2024

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-770

MGA® and Deracin™

(melengestrol acetate Type A medicated article) and (chlortetracycline Type A medicated article)

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

Growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers

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

Sponsored by:

Pharmgate Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-770

B. Sponsor

Pharmgate Inc.
1800 Sir Tyler Dr.
Wilmington, NC 28405

Drug Labeler Code: 069254

C. Proprietary Name

MGA® and Deracin™

D. Drug Product Established Name

melengestrol acetate Type A medicated article and chlortetracycline Type A medicated article

E. Pharmacological Categories

MGA®: Steroid hormone
Deracin™: Antimicrobial

F. Dosage Form

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

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

MGA® 200: 200 mg/lb of melengestrol acetate
MGA® 500: 500 mg/lb of melengestrol acetate
Deracin™ 50 Meal: 50 g/lb of chlortetracycline
Deracin™ 90 Meal: 90 g/lb of chlortetracycline
Deracin™ 100 Meal: 100 g/lb of chlortetracycline

H. How Supplied

MGA® 200: 50 lb. bag
MGA® 500: 40 lb. container (liquid)
Deracin™ 50 Meal: 50 lb. bag
Deracin™ 90 Meal: 50 lb. bag
Deracin™ 100 Meal: 50 lb. bag

[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 C medicated feeds that are the subject of this approval.

I. Dispensing Status

Veterinary feed directive (VFD)

J. Route of Administration

Oral

K. Species/Classes

Growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers

L. Indications and Dosage Regimens

1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to provide 0.25 to 0.5 mg melengestrol acetate per head per day for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

    b. 4,000 to 20,000 g/ton of chlortetracycline (as Deracin™) to provide 10 mg chlortetracycline per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

    Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone.

2. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

    a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to provide 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

    b. 4,000 to 20,000 g/ton of chlortetracycline (as Deracin™) to provide 10 mg chlortetracycline per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

    Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding.

3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the reduction of the incidence of liver abscesses in growing beef heifers fed in confinement for slaughter over 400 lbs.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.25 to 0.5 mg melengestrol acetate per head per day for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

    b. 5.83 to 14 g/ton of chlortetracycline (as Deracin™) to provide 70 mg chlortetracycline per head per day for the reduction of the incidence of liver abscesses.

    The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline.

4. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.25 to 0.5 mg melengestrol acetate per head per day for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

    b. 20 to 350 g/ton of chlortetracycline (as Deracin™) to provide 350 mg chlortetracycline per head per day for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.

    The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline.

5. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.25 to 0.5 mg melengestrol acetate per head per day for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

    b. 500 to 4,000 g/ton of chlortetracycline (as Deracin™) to provide chlortetracycline at the rate of 10 mg per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone.

6. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

    a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

    b. 500 to 4,000 g/ton of chlortetracycline (as Deracin™) to provide chlortetracycline at the rate of 10 mg per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

    The melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 5 days. After completing feeding this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding.

7. For suppression of estrus (heat), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

    a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

    b. 20 to 350 g/ton of chlortetracycline (as Deracin™) to provide 350 mg chlortetracycline per head per day for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.

    The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

8. For suppression of estrus (heat), and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers over 700 pounds.

    a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

b. 33.33 to 50 g/ton of chlortetracycline (as Deracin™) to provide 0.5 mg chlortetracycline per pound of body weight per day for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

9. For suppression of estrus (heat) and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers under 700 pounds.

   a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

   b. 50 to 350 g/ton of chlortetracycline (as Deracin™) to provide 350 mg chlortetracycline per head per day for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

M. Reference Listed New Animal Drug Combination (RLNAD)

MGA® (melengestrol acetate Type A medicated article) and Aureomycin® (chlortetracycline Type A medicated article); NADA 141-530; Zoetis Inc.

N. Approved Original Generic Type A Medicated Article

Deracin™; chlortetracycline Type A medicated article; ANADA 200-510; Pharmgate Inc.

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

MGA® (melengestrol acetate Type A medicated article); NADA 039-402; Zoetis Inc.
Deracin™ (chlortetracycline Type A medicated article); ANADA 200-510; Pharmgate Inc.

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, Center for Veterinary Medicine's (CVM) 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. Melengestrol acetate is codified under 21 CFR 558.342, chlortetracycline is codified under 21 CFR 558.128. The combination of chlortetracycline and melengestrol acetate is codified under 21 CFR 558.128.

III. HUMAN FOOD SAFETY

The following are assigned to this product for growing beef heifers fed in confinement for slaughter, replacement dairy heifers, and replacement beef heifers:

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 body weight *per* day. An ADI is not cited for total residues of melengestrol acetate. The tolerances established for the feed use combination RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 2 parts *per* million (ppm) is established for the sum of tetracycline residues in cattle muscle, 6 ppm in cattle liver, and 12 ppm in cattle fat and kidney, under 21 CFR 556.150. A tolerance of 25 parts *per* billion (ppb) is established for melengestrol in cattle fat, under 21 CFR 556.380.

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 C medicated feeds are those previously assigned to the RLNAD feed use combination. When used together, MGA® (melengestrol acetate Type A medicated article) and Deracin™ (chlortetracycline 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 melengestrol acetate 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 C medicated feeds:

User Safety Warnings: Not for use in humans. Keep out of reach of children.

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 MGA® and Deracin™, when they are used according to the label, are safe and effective for the conditions of use in the General Information Section above. Additionally, data demonstrate that residues in food products derived from cattle (growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers) administered MGA® and Deracin™ will not represent a public health concern when the combination medicated feed is used according to the label.