Date of Approval: November 18, 2024

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-805

MEL™ 500

(melengestrol acetate Type A liquid medicated article)

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

Cattle (heifers fed in confinement for slaughter and heifers intended for breeding)

Heifers Fed in Confinement for Slaughter: For increased rate of weight gain, improved feed efficiency and suppression of estrus (heat).

Heifers Intended for Breeding: For suppression of estrus (heat).

Sponsored by:

Virbac AH, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-805

B. Sponsor

Virbac AH, Inc.
PO Box 162059
Fort Worth, US-TX 76161

Drug Labeler Code: 051311

C. Proprietary Name

MEL™ 500

D. Drug Product Established Name

melengestrol acetate Type A liquid medicated article

E. Pharmacological Category

Steroid

F. Dosage Form

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

G. Amount of Active Ingredient

melengestrol acetate; 500 mg/lb

H. How Supplied

40 lb (18 kg) container

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Heifers Fed in Confinement for Slaughter:

MEL™ 500 (melengestrol acetate Type A liquid medicated article) should be thoroughly mixed in liquid Type C medicated feed which must be fed at 0.5 to 2.0 pounds per head daily to provide 0.25 to 0.5 mg of melengestrol acetate per head per day. Average daily intakes approximating the middle of this range provide the most optimal and economical improvements in rate of gain and feed utilization. Constant daily intakes of 0.35 to 0.50 mg per head per day give a high degree of estrus

suppression. Levels of 0.25 to 0.35 mg provide a lower but still effective degree of estrus suppression.

Heifers Intended for Breeding:

MEL™ 500 should be thoroughly mixed in the supplement to provide 0.5 mg of melengestrol acetate per head per day.

K. Route of Administration

Oral

L. Species/Class

Cattle (heifers fed in confinement for slaughter and heifers intended for breeding)

M. Indications

Heifers Fed in Confinement for Slaughter:

For increased rate of weight gain, improved feed efficiency and suppression of estrus (heat).

Heifers Intended for Breeding:

For suppression of estrus (heat).

N. Reference Listed New Animal Drug (RLNAD)

MGA® 500; melengestrol acetate Type A liquid medicated article; NADA 039-402; Zoetis 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 ANADA to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Virbac AH, Inc., was granted a biowaiver for the generic product MEL™ 500 (melengestrol acetate Type A liquid medicated article). The generic drug product is a Type A liquid medicated article to be used in the manufacture of Type B and Type C medicated feeds, 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 bioavailability of the active ingredient. The RLNAD is MGA® 500 (melengestrol acetate Type A liquid medicated article) to be used in the manufacture of Type B and Type C medicated feeds, sponsored by Zoetis Inc., under NADA 039-402, and was approved for use in heifers fed in confinement for slaughter on May 22, 1968, and heifers intended for breeding on February 18, 1997.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product in cattle:

A. Acceptable Daily Intake and Tolerances for Residues

An acceptable daily intake (ADI) is not cited for total residues of melengestrol acetate. The tolerances established for the RLNAD apply to the generic product. A tolerance of 25 parts per billion is established for melengestrol acetate (the marker residue) in fat of cattle (the target tissue) under 21 CFR 556.380.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 0 days has been established for melengestrol acetate Type A liquid medicated article in cattle (heifers fed in confinement for slaughter and heifers intended for breeding).

C. Analytical Method for Residues

The validated analytical method for analysis of residues of melengestrol acetate Type A liquid medicated article is 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

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to MEL™ 500:

- Not for human use.
- Precautions: Use only as directed. Excessive contact with skin should be avoided. Destroy empty container. Do not reuse.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that MEL™ 500, when used according to the label, is 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 (heifers fed in confinement for slaughter and heifers intended for breeding) treated with MEL™ 500 will not represent a public health concern when the product is used according to the label.