Date of Approval: June 4, 2020

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-399

CycleGuard® 500

(melengestrol acetate Type A liquid medicated article)

Cattle/Beef Heifers

For increased rate of weight gain, improved feed efficiency and suppression of estrus (heat) in heifers fed in confinement for slaughter and for suppression of estrus (heat) in heifers intended for breeding.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION

A. File Number

ANADA 200-399

B. Sponsor

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

Drug Labeler Code: 016592

U.S. Agent Name and Address:
Kelly Beers, Ph.D.
Huvepharma, Inc.
525 West Park Drive
Peachtree City, Georgia 30269

C. Proprietary Name

CycleGuard® 500

D. Drug Product Established Name

Melengestrol acetate Type A liquid medicated article

E. Pharmacological Category

Glucocorticoid

F. Dosage Form

Type A liquid medicated article

G. Amount of Active Ingredient

500 mg/lb.

H. How Supplied

40 lb. container

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

Heifers fed in confinement for slaughter: 0.25 to 0.5 mg melengestrol acetate per day.
Heifers intended for breeding: 0.5 mg melengestrol acetate per day. Do not exceed 24 days of feeding.

K. Route of Administration

Oral

L. Species/Class

Cattle/Beef Heifers

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 abbreviated new animal drug application (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, Huvepharma EOOD, was granted a biowaiver for the generic product CycleGuard® 500 (melengestrol acetate Type A liquid medicated article). The generic drug product is a Type A liquid medicated article, 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), sponsored by Zoetis Inc., under NADA 039-402 and, was approved for use in cattle on May 22, 1968.

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 for 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 ppb is established for melengestrol (the marker residue) in fat (the target tissue) under 21 CFR 556.380 (b)(1).

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.

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 Summary 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 CycleGuard® 500:

Excessive contact with skin should be avoided.

V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that CycleGuard® 500 when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from cattle treated with CycleGuard® 500 will not represent a public health concern when the product is used according to the label.