Date of Approval: February 1, 2021

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-683

CycleGuard® and Monovet®

(melengestrol acetate Type A liquid medicated article and monensin Type A medicated article)

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

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

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-683

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, GA 30269

C. Proprietary Name

CycleGuard® and Monovet®

D. Drug Product Established Name

melengestrol acetate Type A liquid medicated article and monensin Type A medicated article

E. Pharmacological Categories

CycleGuard®: Steroid hormone
Monovet®: Ionophore, anticoccidial

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]

CycleGuard®: 500 mg/lb of melengestrol acetate
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 C medicated feeds that are the subject of this approval.

H. How Supplied

CycleGuard®: 40 lb (18 kg) (4.627 gal [17.5L]) container
Monovet®: 25 kg (55.12 lb) bags

I. Dispensing Status

Over-the-counter (OTC)

J. Route of Administration

Oral

K. Species/Class

Heifers fed in confinement for slaughter

L. Indications and Dosage Regimens

1. Increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in heifers fed in confinement for slaughter.

    a. 0.25 to 2 g/ton (0.0000276 to 0.00022%) fed at a rate of 0.5 to 2.0 lb/head/day to provide 0.25 to 0.5 mg/head/day of melengestrol acetate (as CycleGuard®) for increased rate of weight gain, improved feed efficiency and suppression of estrus (heat).

    b. 10 to 40 g/ton to provide 0.14 to 0.42 mg/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day, of monensin (as Monovet®) for improved feed efficiency and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed continuously as sole ration.

    Increased benefit for improved feed efficiency, when CycleGuard® and Monovet® are used together vs. individually cannot be assumed because demonstration of increased effectiveness was not required for approval of this generic combination or the RLNAD combination, NADA 125-476.

M. Reference Listed New Animal Drug Combination (RLNAD)

MGA® (melengestrol acetate Type A medicated article) and Rumensin™ (monensin Type A medicated article); NADA 125-476; Zoetis Inc.

N. Approved Original Generic Type A Medicated Article

CycleGuard®; melengestrol acetate Type A liquid medicated article; ANADA 200-399; Huvepharma EOOD

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

CycleGuard® (melengestrol acetate Type A liquid medicated article); ANADA 200-399; Huvepharma EOOD
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 and human food safety data (other than tissue residue 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 and tissue residue studies. 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, monensin is codified under 21 CFR 558.355. The combination of melengestrol acetate and monensin is codified under 21 CFR 558.342.

III. HUMAN FOOD SAFETY

The following are assigned to this product for heifers fed in confinement for slaughter:

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 feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 25 parts *per* billion (ppb) is established for residues of melengestrol in fat, under 21 CFR 556.380.

The ADI for total residues of monensin is 12.5 micrograms *per* kilogram 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 parts *per* million (ppm) is established for residues of 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 C medicated feeds are those previously assigned to the RLNAD feed use combination. When used together, CycleGuard® (melengestrol acetate Type A liquid 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 method for analysis of residues of melengestrol 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.

V. AGENCY CONCLUSIONS

The information submitted in support of this ANADA satisfies the requirements of section 512(n) of the FD&C Act and demonstrate that CycleGuard® and Monovet®, when 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 heifers fed in confinement for slaughter administered CycleGuard® and Monovet® will not represent a public health concern when the combination medicated feed is used according to the label.