Date of Approval: October 11, 2019

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-658

MGA® and Monovet®

(melengestrol acetate Type A 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

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# I. GENERAL INFORMATION

## A. File Number

ANADA 200-658

## B. Sponsor

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

Drug Labeler Code: 016592

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

## C. Proprietary Name

MGA® and Monovet®

## D. Drug Product Established Name

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

## E. Pharmacological Categories

MGA®: Steroid hormone
Monovet®: Ionophore, anticoccidial

## F. Dosage Form

Type A medicated articles for use in the manufacture of Type C medicated feeds.

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

MGA®: 200 mg/lb and 500 mg/lb of melengestrol acetate
Monovet®: 90.7 g/lb of monensin

## H. How Supplied

MGA® (melengestrol acetate Type A medicated article): 50 lb (22.7 kg) bags (dry), 40 lb (18 kg) container (liquid)
Monovet® (monensin Type A medicated article): 55.12 lb (25 kg) bags

[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.

## I. Dispensing Status

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. This indication and the below dosage regimen apply to the dry and liquid heifer supplement Type C medicated feed blue bird labels.

    a. 0.25 to 2 g/ton of MGA® for increased rate of weight gain, improved feed efficiency and suppression of estrus (heat) in heifers fed in confinement for slaughter.

    b. 10 to 40 g/ton of Monovet® for improved feed efficiency and prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

    Feed continuously as sole ration to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day. The melengestrol acetate portion of this Type C medicated feed must be added to a complete feed containing 10 to 40 g/ton monensin at feeding into the amount of complete feed consumed by an animal per day.

    Increased benefit for improved feed efficiency, when MGA® 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

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

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 C combination medicated feeds in this application

MGA® (melengestrol acetate Type A medicated article); NADA 039-402; Zoetis Inc.
Monovet® (monensin Type A medicated article); ANADA 200-639; Huvepharma EOOD

## II. BIOEQUIVALENCE

Under the provisions of 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, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

According to 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. Bioequivalence and tissue residue studies are not required for the approval of the generic feed use combinations (Type B or C medicated feeds). Melengestrol acetate is codified under 21 CFR 558.342 and monensin is codified under 21 CFR 558.355. The combination of melengestrol acetate and monensin is codified under 21 CFR 558.342.

## III. EFFECTIVENESS

CVM did not require effectiveness studies for this approval.

## IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

## V. 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 the parent compound, melengestrol acetate (the marker residue) 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 (the marker residue) 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, MGA® (melengestrol acetate 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 melengestrol acetate and monensin 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.

## VI. USER SAFETY

CVM did not require user safety studies for this original approval.

## VII. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the FD&C Act and demonstrates that MGA® and Monovet®, when used according to the label, are safe and effective.

Additionally, data demonstrate that residues in food products derived from heifers fed in confinement for slaughter administered MGA® and Monovet® will not represent a public health concern when the combination medicated feed is used according to the label.