Date of Approval: July 8, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-807

MGA® and Experior™ and Monovet®

(melengestrol acetate Type A medicated article) and (lubabegron 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

Growing beef 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 200-807

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

MGA® and Experior™ and Monovet®

D. Drug Product Established Name

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

E. Pharmacological Categories

MGA®: steroid hormone
Experior™: beta-adrenergic agonist/antagonist
Monovet®: ionophore

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 (dry formulation): 200 mg per lb of melengestrol acetate
MGA® 500 (liquid formulation): 500 mg per lb of melengestrol acetate
Experior™: 10 g per kg (4.54 g per lb) and 50 g per kg (22.7 g per lb) of lubabegron (as lubabegron fumarate)
Monovet®: 90.7 g per lb of monensin

[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.

H. How Supplied

MGA® 200 (dry formulation): 50 lb (22.7 kg) bag
MGA® 500 (liquid formulation): 40 lb (18 kg) container
Experior™: 10 kg (22.04 lb) bag
Monovet®: 25 kg (55.12 lb) bag

I. Dispensing Status

Over-the-counter (OTC)

J. Route of Administration

Oral

K. Species/Class

Growing beef heifers fed in confinement for slaughter

L. Indications and Dosage Regimens

1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA® 200 or MGA® 500) 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. 1.25 to 4.54 g/ton of lubabegron (as Experior™) to provide 13 to 90 mg lubabegron per head per day for reduction of ammonia gas emissions per pound of live weight and hot carcass weight

    c. 10 to 40 g/ton of monensin (as Monovet®) to provide 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, up to a maximum of 480 mg monensin per head per day for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*

    The melengestrol acetate Type C top-dress medicated feed (0.5 to 2 lb per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing lubabegron and monensin. Feed as the sole ration during the last 14 to 91 days on feed.

M. Reference Listed New Animal Drug (RLNAD) Combination

MGA® and Experior™ and Rumensin™ (melengestrol acetate Type A medicated article and lubabegron Type A medicated article and monensin Type A medicated article); NADA 141-590; Elanco US 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.
Experior™ (lubabegron Type A medicated article); NADA 141-508; Elanco US Inc.
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 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 of 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, lubabegron is codified under 21 CFR 558.330, and monensin is codified under 21 CFR 558.355. The combination of melengestrol acetate, lubabegron, and monensin is codified under 21 CFR 558.330.

III. HUMAN FOOD SAFETY

The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

An acceptable daily intake (ADI) for melengestrol acetate has not been established. 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 melengestrol (the maker residue) in fat (the target tissue), under 21 CFR 556.380.

The ADI for total residues of lubabegron is 3 µg/kg 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 10 ppb is established for lubabegron (the marker residue) in liver (the target tissue), 3 ppb in muscle, and 20 ppb in kidney, under 21 CFR 556.370.

The ADI for total residues of monensin is 12.5 µg/kg 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 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 B and Type C medicated feeds are those previously assigned to the RLNAD feed use combination. When used together, MGA® (melengestrol acetate Type A medicated article), Experior™ (lubabegron Type A medicated article), and Monovet® (monensin Type A medicated article) are approved with a zero-day withdrawal period.

C. Analytical Method for Residues

The validated analytical methods for analysis of residues of melengestrol acetate, lubabegron, and monensin are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical methods, 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. The active ingredient in Experior, lubabegron, is a beta-adrenergic agonist/antagonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. When mixing and handling Experior, use protective clothing, impervious gloves, protective eye wear, and a NIOSH- approved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water; if wearing contact lenses, rinse eyes first, then remove contact lenses and continue to rinse for 5-20 minutes. If irritation persists, seek medical attention. The safety data sheet contains more detailed occupational safety information.

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®, Experior™, and Monovet®, 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 growing beef heifers fed in confinement for slaughter administered MGA®, Experior™, and Monovet® will not represent a public health concern when the combination medicated feed is used according to the label.