

Date of Approval: July 1, 2011

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-422

HEIFERMAX 500 plus RUMENSIN

(melengestrol acetate and monensin sodium)

Type A Medicated Articles to be Used in the Manufacture of
Combination Type C Medicated Feeds

Heifers Fed in Confinement for Slaughter

This supplement provides for an increase in the upper dose limit of melengestrol acetate to 0.5 mg/hd/day and monensin sodium to 480 mg/hd/day based on the October 1, 2009, supplemental approval (NADA 125-476, C-0034) of MGA plus RUMENSIN, for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in heifers being fed in confinement for slaughter.

Sponsored by:

Ivy Laboratories, Division of Ivy Animal Health, Inc.

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I. GENERAL INFORMATION:

- A. File Number:** ANADA 200-422
- B. Sponsor:** Ivy Laboratories
Division of Ivy Animal Health, Inc.
8857 Bond Street
Overland Park, KS 66214

Drug Labeler Code: 021641
- C. Proprietary Name(s):** HEIFERMAX 500 plus RUMENSIN
- D. Established Name(s):** Melengestrol acetate and monensin sodium
- E. Pharmacological Category:** Hormone and ionophore
- F. Dosage Form:** Type A medicated articles to be used in the manufacture of combination Type C medicated feeds
- G. Amount of Active Ingredients:** Melengestrol acetate: 500 g/lb
Monensin: 80 g/lb
- H. How Supplied:** Melengestrol acetate: 40 lb container (liquid)
Monensin: 50 lb bag
- I. How Dispensed:** OTC
- J. Dosage:** Melengestrol acetate is added to the diet of heifers at 0.5 to 2.0 pounds per head per day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate per pound to provide 0.25 to 0.5 mg melengestrol acetate per head per day.

Monensin is added to feedlot cattle diets at concentrations of 10 to 40 g of monensin per ton of complete feed at a rate of 0.14 mg to 0.42 mg monensin per pound of body weight depending on the severity of coccidiosis challenge up to 480 mg per head per day.
- K. Route of Administration:** Oral, in feed

- L. Species/Class:** Heifers fed in confinement for slaughter
- M. Indications:** For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in heifers being fed in confinement for slaughter.
- N. Approved original generic Type A medicated article:** HEIFERMAX 500; melengestrol acetate; ANADA 200-343; Ivy Laboratories, Division of Ivy Animal Health, Inc.
- O. Reference listed new animal drugs:** MGA plus RUMENSIN; melengestrol acetate plus monensin sodium; NADA 125-476; Pharmacia & Upjohn Co., a Division of Pfizer, Inc.
- Each individually approved in NADA 039-402 and NADA 095-735, respectively.
- P. Effects of Supplement:** This supplement provides for an increase in the upper dose limit of melengestrol acetate to 0.5 mg/hd/day and monensin sodium to 480 mg/hd/day based on the October 1, 2009, supplemental approval (NADA 125-476, C-0034) of MGA plus RUMENSIN for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in heifers being fed in confinement for slaughter.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic 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 (pioneer product). 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.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

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 pioneer 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. Monensin is codified under 21 CFR 558.355. The combination of melengestrol acetate and monensin is codified under 21 CFR 558.342(e)(1)(v).

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this supplemental approval.

IV. TARGET ANIMAL SAFETY

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

V. HUMAN FOOD SAFETY:

CVM did not require human food safety studies for this approval.

VI. USER SAFETY:

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

VII. AGENCY CONCLUSIONS:

This information submitted according in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act satisfies the

requirements and demonstrates that HEIFERMAX 500 plus RUMENSIN, when used according to the label, is safe and effective for for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in heifers being fed in confinement for slaughter.