Date of Approval: March 12, 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-451

HEIFERMAX 500 (melengestrol acetate) plus BOVATEC (lasalocid sodium)

Type A Medicated Articles for manufacture of two-way Type B or C Medicated Feeds

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

Sponsored by:

Ivy Laboratories
Div. of Ivy Animal Health, Inc.

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-451
b. Sponsor:	Ivy Laboratories Div. of Ivy Animal Health, Inc. 8857 Bond Street Overland Park, KS 66214 Drug Labeler Code: 021641
c. Established Names:	Melengestrol acetate and lasalocid sodium
d. Proprietary Names:	HEIFERMAX 500 and BOVATEC
e. Dosage Form:	Type A medicated articles for use in combination for the manufacture of two-way dry and liquid Type B or Type C medicated feeds
f. How Supplied:	Melengestrol acetate – 40 lb container (liquid premix) Lasalocid sodium – 50 lb container (liquid or dry premix)
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	HEIFERMAX 500: 500 mg of melengestrol acetate activity per pound of premix BOVATEC : BOVATEC 68 – 68 g/lb (15%) as lasalocid sodium; BOVATEC 91 – 91 g/lb (20%) as lasalocid sodium; BOVATEC 150 FP – 150 g/lb (33.1%) as lasalocid sodium; BOVATEC Liquid 20 – 90.7 g/lb (20%) as lasalocid sodium
i. Route of Administration:	Orally in feed
j. Species/Class:	Beef cattle; heifers fed in confinement for slaughter
k. Recommended Dosage:	Feed to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg melengestrol acetate per head per day in combination with 100-360 mg lasalocid sodium per head per day. Prior to feeding, this Type C product must be top-dressed onto a complete feed or mixed into the amount of complete feed consumed by an animal per day.

l. Pharmacological Category:	Steroid hormone / Ionophore
m. Indications:	For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat) in heifers fed in confinement for slaughter.
n. Generic Product:	HEIFERMAX 500 Liquid Premix; melengestrol acetate; ANADA 200-343; Ivy Laboratories, Div. of Ivy Animal Health, Inc.
o. Pioneer Products:	MGA 500; melengestrol acetate; NADA 039-402; Pharmacia & Upjohn Co., a Division of Pfizer, Inc. BOVATEC; lasalocid sodium; NADA 96-298; Alpharma Inc. MGA 500; melengestrol acetate; in combination with BOVATEC; lasalocid sodium; NADA 140-288; Pharmacia & Upjohn Co., a Division of Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

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 that 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 Guideline, October 9, 2002).

This approval is for the use of HEIFERMAX 500 (melengestrol acetate) in combination with BOVATEC (lasalocid sodium) for the manufacture of two-way combination Type B or C medicated feeds. This combination product is a generic copy of MGA 500 (melengestrol acetate) plus BOVATEC (lasalocid sodium) sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 140-288.

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. Lasalocid sodium is codified under 21 CFR 558.311. The combination of melengestrol acetate and lasalocid sodium is codified under 21 CFR 558.342(e).

3. Human Safety:

No human food safety data are required for the approval of the generic use combinations (Type B or Type C medicated feeds).

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat of cattle under 21 CFR 556.380.

  A tolerance of 0.7 parts per million is established for residues of the parent compound, lasalocid sodium, in liver of cattle as codified under 21 CFR 556.347. The acceptable daily intake (ADI) for total residues of lasalocid is 10 micrograms per kilogram of body weight per day.

- **Withdrawal Time:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  A withdrawal time is not required for the use of this generic two-way drug combination.

- **Regulatory Method for Residues:**
  Practical regulatory methods for analysis of tissue residues of melengestrol acetate and lasalocid sodium may be found in the *Food Additives Analytical Manual* on display in FDA's Freedom of Information Public Room (Parklawn Building, Room 12A30, 5600 Fisher's Lane, Rockville, MD 20857).

4. AGENCY CONCLUSIONS:

This ANADA filed under section 512(b)(2) of the Federal, Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that the combination of HEIFERMAX 500 and BOVATEC, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Blue Bird generic labeling is attached as follows:

Generic Labeling for ANADA 200-451:
Blue Bird labeling (Type C):
Heifer Supplement