

MAR 12 2007

Date of Approval: _____

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.

2007.200.451

FOIS 1

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

BULK

HEIFER SUPPLEMENT Medicated (Type C Medicated Feed) For Beef and Dairy Heifers

INDICATIONS

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

ACTIVE DRUG INGREDIENTS

Melengestrol acetate (0.0000276 – 0.00022%) 0.25 to 1.6 g/ton
Lasalocid (as lasalocid sodium).....100 to 1440 g/ton
(Final printed label must bear a single concentration of each drug.)

GUARANTEED ANALYSIS

Crude Protein, not less than	_____	%
Non-Protein Nitrogen (NPN) ¹ , not more than	_____	%
Crude Fat, not less than.....	_____	%
Crude Fiber, not more than	_____	%
Calcium, not less than.....	_____	%
Calcium, not more than.....	_____	%
Phosphorus, not less than.....	_____	%
Salt ² , not less than.....	_____	%
Salt ² , not more than.....	_____	%
Sodium ³ , not less than.....	_____	%
Sodium ³ , not more than.....	_____	%
Potassium, not less than	_____	%
Vitamin A ^{2, 4} , not less than	_____	I.U./lb
Dry Matter ⁵ , not less than	60%	
Dry Matter ⁵ , not more than.....	75%	
pH ⁵	4.5 to 6.0	

¹When added.

²If added.

³Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

⁴Other than precursors of Vitamin A.

⁵Applies only to liquid feeds.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

DIRECTIONS FOR USE

Add a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to a ration of nonmedicated feed. When fed to heifers at the rate of 0.5-2.0 pound(s) per head per day (specify one level), this medicated feed will provide 0.25-0.5 mg melengestrol acetate per head per day (specify one level) and 100-360 mg lasalocid per head per day (specify one level). 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.

MIXING DIRECTIONS

For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

For liquid feeds stored in mechanical, air, or agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

CAUTION

Melengestrol acetate is not effective in steers or spayed heifers.

Withdrawal periods of three to five days should be avoided to prevent the possibility that the heifers may come into estrus (heat) at the time of loading.

When mixing and handling lasalocid, use protective clothing, impervious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. Do not allow horses or other equines access to feed containing lasalocid. Ingestion of lasalocid by horses has been fatal. The safety of lasalocid in unapproved species has not been established. Mixing errors resulting in excessive concentrations of lasalocid could be fatal to cattle and sheep.

WARNING

A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

MANUFACTURED BY

Blue Bird Feed Company
Anytown, IN 11111

Expiration date _____
(Must be used within 60 days of manufacture)

Lot Number _____

NET WT _____