

Date of Approval: **FEB 29 2008**

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-284

ZILMAX plus MGA

(Zilpaterol Hydrochloride and Melengestrol Acetate)

Type A Medicated Articles

For Use in the Manufacture of Type B and C Medicated Feed
Heifers Fed in Confinement for Slaughter

For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 20 to 40 days on feed.

Sponsored by:

Intervet Inc.

NADA 141-284

FOIS

TABLE OF CONTENTS

I. GENERAL INFORMATION:..... 1

II. EFFECTIVENESS:..... 2

III. TARGET ANIMAL SAFETY:..... 3

IV. HUMAN FOOD SAFETY: 4

 A. Toxicology: 4

 B. Residue Chemistry: 4

 C. Microbial Food Safety: 5

 D. Analytical Method for Residues: 5

V. USER SAFETY: 5

VI. AGENCY CONCLUSIONS:..... 6

 A. Marketing Status: 6

 B. Exclusivity: 6

 C. Patent Information: 7

VII. ATTACHMENTS:..... 7

I. GENERAL INFORMATION:

- A. File Number:** NADA 141-280
- B. Sponsor:** Intervet Inc.
P.O. Box 318
29160 Intervet Lane
Millsboro, DE 19966
- Drug Labeler Code: 057926
- C. Proprietary Names:** ZILMAX plus MGA
- D. Established Names:** Zilpaterol hydrochloride and melengestrol acetate
- E. Pharmacological Categories:** Zilpaterol hydrochloride – Beta adrenergic agonist
Melengestrol acetate – Steroid hormone
- F. Dosage Forms:** Type A medicated articles to be used in the manufacture of Type B and C medicated feeds
- G. Amount of Active Ingredients:** Zilpaterol hydrochloride - 21.77 grams per pound (48 grams per kilogram)
Melengestrol acetate - 200 and 500 mg per pound
- H. How Supplied:** Zilpaterol hydrochloride – 22.05 lb (10 kg) bag
Melengestrol acetate – 50 lb bag (dry), 40 lb container (liquid)
- I. How Dispensed:** OTC
- J. Dosages:** Zilpaterol is fed at a concentration of 6.8 g of zilpaterol hydrochloride per ton of complete feed to provide 60 to 90 mg zilpaterol/head/day in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.
- 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/head/day in heifers being fed in confinement for slaughter.

- 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, increased carcass leanness, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 20 to 40 days on feed.

II. EFFECTIVENESS:

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on effectiveness grounds unless the FDA finds that the sponsor fails to demonstrate that:

- there is substantial evidence to indicate that any active ingredient/drug intended only for the same use as another active ingredient/animal drug in combination makes a contribution to the labeled effectiveness.
- each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population.
- where the combination contains more than one nontopical antibacterial active ingredient/animal drug, there is substantial evidence that each of the nontopical antibacterial active ingredients/animal drugs makes a contribution to the labeled effectiveness

Zilpaterol hydrochloride as provided by Intervet Inc., has previously been separately approved for use in cattle for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed (21 CFR 558.665(e)(2)). Melengestrol acetate as provided by Pfizer, Inc., has previously been separately approved for use for increased rate of weight gain,

improved feed efficiency, and suppression of estrus (heat) in heifers fed in confinement for slaughter (21 CFR 558.342(e)(1)). Effectiveness of zilpaterol hydrochloride and melengestrol acetate, with its approved uses and conditions of use, is demonstrated in Intervet Inc.'s approved NADA 141-258 for zilpaterol hydrochloride, and Pfizer, Inc.'s NADAs 039-402 and 034-254 for melengestrol acetate, to which Intervet Inc. has right of reference.

Zilpaterol hydrochloride and melengestrol acetate are each intended for a different use therefore the NADA need not demonstrate, by substantial evidence, that zilpaterol hydrochloride or melengestrol acetate, contributes to the labeled effectiveness of the combination. Zilpaterol hydrochloride and melengestrol acetate provide appropriate concurrent use because these drugs are intended to treat different conditions likely to occur simultaneously in heifers fed in confinement for slaughter during the last 20 to 40 days on feed. Zilpaterol hydrochloride is approved for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. Melengestrol acetate is approved for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

III. TARGET ANIMAL SAFETY:

In accordance with the FDCA, as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been approved separately for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on target animal safety grounds unless

- there is a substantiated scientific issue specific to an active ingredient or animal drug used in the combination that cannot adequately be evaluated based on the information contained in the application for the combination, and FDA finds that the application fails to show that the combination is safe, or
- there is a scientific issue raised by target animal observations contained in the studies submitted to the NADA for the combination, and FDA finds that the application fails to show that the combination is safe.

Zilpaterol hydrochloride as provided by Intervet Inc., has previously been separately approved for use in cattle for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed (21 CFR 558.665(e)(2)). Melengestrol acetate as provided by Pfizer, Inc., has previously been separately approved for use for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat) in heifers fed in confinement for slaughter (21 CFR 558.342(e)(1)).

Under the provisions of the Animal Drug Availability Act, this original approval allows for the combination of zilpaterol hydrochloride (as provided by Intervet Inc.) and melengestrol acetate (as provided by Pfizer, Inc.). Target animal safety of zilpaterol hydrochloride and melengestrol acetate, when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Intervet Inc.'s approved NADA 141-258 and Pfizer, Inc.'s NADAs 39-402 and 34-254 for melengestrol acetate, to which Intervet Inc. has right of reference. The Agency has found no substantiated scientific issue relating to the target animal safety of zilpaterol hydrochloride and melengestrol acetate when used in combination under this NADA and no scientific issue has been raised by target animal observations submitted as part of the NADA for this combination. Thus, pursuant to FFDCA, as amended by the Animal Drug Availability Act of 1996, no specific target animal safety studies are required for approval of NADA 141-284.

IV. HUMAN FOOD SAFETY:

In accordance with the FFDCA, as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been approved separately for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on human safety grounds unless FDA finds that the application fails to establish that:

- none of the active ingredients or animal drugs used in combination at the longest withdrawal for any of the active ingredients or animal drugs in the combination exceeds the established tolerance, or
- none of the active ingredients or animal drugs in combination interferes with the method of analysis for another active ingredient or drug in the combination.

A. Toxicology:

Safety of the individual drugs in this combination product has been established by data in NADA 141-258 for zilpaterol hydrochloride (FOI Summary dated August 10, 2006) and NADA 034-254 for melengestrol acetate (FOI Summary dated June 29, 1994).

B. Residue Chemistry:

1. Residue Chemistry Study:

Data demonstrating residue depletion and assay noninterference for the drugs of this combination have been summarized in the FOI Summary for the approval of NADA 141-276 dated January 10, 2008.

2. Target Tissue and Marker Residue Assignment:

The marker residue for zilpaterol is zilpaterol freebase and the target tissue in cattle is liver (NADA 141-258, *op. cit.*). No marker residue and target tissue is specified for melengestrol acetate.

3. Tolerance Assignments:

The tolerance for zilpaterol freebase is 12 ppb in cattle liver (21 CFR 556.765). The tolerance for MGA is 25 ppb in fat of cattle (21 CFR 556.380).

4. Withdrawal Period:

Melengestrol acetate is approved with a zero withdrawal period. The data in Study Number: 0238-0034-01 confirm that residues of this drug in the 4-way combination at zero withdrawal period are less than the applicable tolerance, thereby establishing depletion noninterference.

To ascertain the noninterference on the depletion of zilpaterol, the data for zilpaterol collected at 3 days of withdrawal were statistically analyzed using FDA's 99% tolerance limit with 95% confidence algorithm. The analysis showed that the derived tolerance limit was less than the tolerance of 12 ppb. These results support the assignment of a 3-day withdrawal period for zilpaterol when used in combination with melengestrol acetate.

C. Microbial Food Safety:

The Agency determined that an assessment of the microbial food safety associated with this application for the combination of zilpaterol hydrochloride and melengestrol acetate for use in heifers, approvable pursuant to the provisions of the Animal Drug Availability Act (1996), was not necessary at this time.

D. Analytical Method for Residues:

Refer to NADA 141-258 for zilpaterol (*op. cit.*) and to NADA 034-254 for melengestrol acetate (*op. cit.*) for the approved regulatory methods. The methods are available from the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to ZILMAX:

WARNING:

The active ingredient in Zilmax[®] is zilpaterol hydrochloride, a beta₂-adrenergic agonist. Not for use in humans. An anti-dust

process has been applied to the drug product, Zilmax[®], in order to greatly reduce inhalation risk. Extended handling tasks with the potential for dust generation require respiratory protection. Wear appropriate skin protection (e.g., impervious gloves, apron, overalls) if there is a potential for extended skin contact. Wear protective eye wear, if there is a potential for eye contact. If accidental eye contact occurs, immediately rinse with water and consult a physician.

The representative (blue bird) labeling for the Type B and Type C medicated feeds contains no information regarding safety to humans handling, administering, or exposed to MGA. This is based upon review of the Material Safety Data Sheets (MSDS) for MGA, as well as the MSDS for ZILMAX, and the individually approved blue bird labeling.

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514. The data demonstrate that ZILMAX plus MGA, when used according to the label, is safe and effective for increased rate of weight gain, improved feed efficiency, increased carcass leanness and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 20 to 40 days on feed. Additionally, data demonstrate that residues in food products derived from cattle fed in confinement for slaughter treated with ZILMAX plus MGA will not represent a public health concern when the product is used according to the label.

The drugs are to be fed in Type C medicated feeds in accordance with section II and III of the FOI Summary and the Blue Bird labeling that is attached to this document.

A. Marketing Status:

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the lay person have been provided. Label directions provide detailed instruction in plain language. The drug product is not a controlled substance. Thus, the drug product is assigned OTC status, and the labeling is adequate for the intended use.

B. Exclusivity:

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act.

C. Patent Information:

ZILMAX is under the following US patent numbers:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
4,900,735	December 11, 2008
5,731,028	June 6, 2016
7,207, 289	May 20, 2025

VII. ATTACHMENTS:

Final Printed Labeling:

Zilpaterol Type B Medicated Cattle Feed
Zilpaterol Liquid Type B Medicated Cattle Feed
Zilpaterol Type C Medicated Cattle Feed
Heifer Supplement Medicated (Type C Medicated Feed) for Beef and Dairy Heifers
Liquid Heifer Supplement Medicated (Type C Medicated Feed) For Beef and Dairy
Heifers

**Zilpaterol Finishing Cattle Feed
Type B Medicated Feed**

Do Not Feed Undiluted

Important: Must be thoroughly mixed into feed before use.

For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

ACTIVE DRUG INGREDIENT

Zilpaterol hydrochloride.....68 – 680 g/ton*

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

¹When added.

² If Added.

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

⁴ Other than precursors of Vitamin A.

INGREDIENTS

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

*Final printed label must bear a single drug concentration.

MIXING DIRECTIONS:

Thoroughly mix this Type B Medicated Feed into one ton of complete cattle feed according to the table below to obtain the proper concentration in the Type C Medicated Feed.

Concentration of Zilpaterol in Type B Medicated Feed grams/pound	Pounds Type B Medicated Feed To Add Per Ton of Type C Medicated Feed	Resulting Zilpaterol Concentration in Type C Medicated Feed ^a grams/ton
0.034	200	6.8
0.170	40	6.8
0.340	20	6.8

^a Based on 90% Dry Matter Basis

WARNING: The active ingredient in Zilmax[®] is zilpaterol hydrochloride, a beta₂-adrenergic agonist. Not for use in humans. An anti-dust process has been applied to the drug product, Zilmax[®], in order to greatly reduce inhalation risk. Extended handling tasks with the potential for dust generation require respiratory protection. Wear appropriate skin protection (e.g., impervious gloves, apron, overalls) if there is a potential for extended skin contact. Wear protective eyewear, if there is a potential for eye contact. If accidental eye contact occurs, immediately rinse with water and consult a physician.

► **WITHDRAWAL PERIOD:** 3 days ◀

CAUTION: Not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.

YOU MAY NOTICE: Animals receiving zilpaterol hydrochloride may exhibit increased respiratory rate as well as elevated levels of creatine phosphokinase (CPK) and creatinine.

MANUFACTURED BY

BLUE BIRD FEED MILL
Any town, USA 12345

Zilmax[®] is the trademark of Intervet.

Net Weight on Bulk Invoice

**Zilpaterol Finishing Cattle Feed
Liquid Type B Medicated Feed**

Do Not Feed Undiluted

Important: Must be thoroughly mixed into feed before use.

For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

ACTIVE DRUG INGREDIENT

Zilpaterol hydrochloride.....68 – 680 g/ton*

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, not less than	60%	
Dry Matter, not more than.....	75%	
pH	3.8 to 7.5	

¹When added.

² If Added.

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

⁴ Other than precursors of Vitamin A.

INGREDIENTS

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

*Final printed label must bear a single drug concentration.

MIXING DIRECTIONS

Thoroughly mix this Liquid Type B Medicated Feed into one ton of complete cattle feed according to the table below to obtain the proper concentration in the Type C Medicated Feed.

Concentration of Zilpaterol in Type B Medicated Feed grams/pound	Pounds Liquid Type B Medicated Feed To Add to Non-Medicated Feed to Make One Ton of Type C Medicated Feed	Resulting Zilpaterol Concentration in Type C Medicated Feed ^a grams/ton
0.034	200	6.8
0.170	40	6.8
0.340	20	6.8

^a Based on 90% Dry Matter Basis

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 other 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.

WARNING: The active ingredient in Zilmax[®] is zilpaterol hydrochloride, a beta₂-adrenergic agonist. Not for use in humans. An anti-dust process has been applied to the drug product, Zilmax[®], in order to greatly reduce inhalation risk. Extended handling tasks with the potential for dust generation require respiratory protection. Wear appropriate skin protection (e.g., impervious gloves, apron, overalls) if there is a potential for extended skin contact. Wear protective eyewear, if there is a potential for eye contact. If accidental eye contact occurs, immediately rinse with water and consult a physician.

► **WITHDRAWAL PERIOD:** 3 days ◀

CAUTION: Not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.

YOU MAY NOTICE: Animals receiving zilpaterol hydrochloride may exhibit increased respiratory rate as well as elevated levels of creatine phosphokinase (CPK) and creatinine.

MANUFACTURED BY

BLUE BIRD FEED MILL
Any town, USA 12345

Zilmax[®] is the trademark of Intervet.

Net Weight on Bulk Invoice

**Zilpaterol Finishing Cattle Feed
Type C Medicated Feed**

For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

ACTIVE DRUG INGREDIENT

Zilpaterol hydrochloride.....6.8 g/ton

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

¹When added.

²If Added.

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

⁴ Other than precursors of Vitamin A.

INGREDIENTS

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

FEEDING DIRECTIONS

Feed continuously to cattle fed in confinement for slaughter as the sole ration for last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol per head per day.

WARNING: The active ingredient in Zilmax[®] is zilpaterol hydrochloride, a beta₂-adrenergic agonist. Not for use in humans. An anti-dust process has been applied to the drug product, Zilmax[®], in order to greatly reduce inhalation risk. Extended handling tasks with the potential for dust generation require respiratory protection. Wear appropriate skin protection (e.g., impervious gloves, apron, overalls) if there is a potential for extended skin contact. Wear protective eyewear, if there is a potential for eye contact. If accidental eye contact occurs, immediately rinse with water and consult a physician.

► **WITHDRAWAL PERIOD:** 3 days ◀

CAUTION: Not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.

YOU MAY NOTICE: Animals receiving zilpaterol hydrochloride may exhibit increased respiratory rate as well as elevated levels of creatine phosphokinase (CPK) and creatinine.

MANUFACTURED BY
BLUE BIRD FEED MILL
Any town, USA 12345

Zilmax[®] is the trademark of Intervet.

Net Weight on Bulk Invoice

**THIS BLUEBIRD LABEL IS INTENDED FOR USE ONLY WITH
ZILPATEROL**

BAG OR BULK

**HEIFER SUPPLEMENT
Type C Medicated Feed**

For Beef and Dairy Heifers

INDICATIONS

Heifers Fed in Confinement for Slaughter: For Increased Rate of Weight Gain, Improved Feed Efficiency and Suppression of Estrus (Heat).

ACTIVE DRUG INGREDIENTS

Melengestrol acetate..... 0.125 - 1.0 mg/lb.*

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

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.

INGREDIENTS

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

* Final printed label on formulated Type C medicated feed must bear a single concentration of this drug

DIRECTIONS FOR USE

Must be top dressed or mixed with a complete ration containing zilpaterol (6.8 g/ton).

Feed at the rate of 0.5-2.0 pound(s) per head per day (specify one level) to provide 0.25-0.5 mg melengestrol acetate per head per day (specify one level). Feed melengestrol acetate in this combination for the final 20 to 40 days on feed.

CAUTION

Melengestrol acetate is not effective in steers and 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. You should consider feeding an approved medicated feed containing melengestrol acetate during the withdrawal time for this product to prevent heifers from coming into estrus at the time of loading.

MANUFACTURED BY

BLUE BIRD FEED MILL
Any town, USA 12345

Lot Number _____

Net Weight on Bulk Invoice

**THIS BLUEBIRD LABEL IS INTENDED FOR USE ONLY WITH
ZILPATEROL**

**LIQUID HEIFER SUPPLEMENT
Type C Medicated Feed**

For Beef and Dairy Heifers

Heifers Fed in Confinement for Slaughter: For increased Rate of Weight Gain, Improved Feed Efficiency and Suppression of Estrus (Heat).

ACTIVE DRUG INGREDIENTS

Melengestrol acetate..... 0.125 - 1.0 mg/lb.*

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
pH.....	4.0 to 8.0	

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.

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

Must be top dressed or mixed with a complete ration containing zilpaterol (6.8 g/ton).

Feed at the rate of 0.5-2.0 pound(s) per head per day (specify one level) to provide 0.25-0.5 mg melengestrol acetate per head per day (specify one level). Feed melengestrol acetate in this combination for the final 20 to 40 days on feed.

* Final printed label on formulated Type C medicated feed must bear a single concentration of this drug

MIXING DIRECTIONS

Mixing directions for liquid Type C feeds stored in recirculation tank systems are: "Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents from the bottom of the tank to the top. Recirculate daily, as directed in this paragraph even when the Type C feed is not used." Mixing directions for liquid Type C feeds stored in mechanical, air or other agitation-type tank systems are: "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 directed in this paragraph, even when the Type C feed is not used."

CAUTION:

Melengestrol Acetate is not effective in steers and 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. You should consider feeding an approved medicated feed containing melengestrol acetate during the withdrawal time for this product to prevent heifers from coming into estrus at the time of loading.

MANUFACTURED BY

BLUE BIRD FEED MILL
Any town, USA 12345

Lot Number _____

Net Weight on Bulk Invoice