Date of Approval: March 15, 2021

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-530

MGA® and Aureomycin®

(melengestrol acetate Type A medicated article) and
(chlortetracycline 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 and
replacement beef and dairy heifers

Original approval of an Animal Drug Availability Act of 1996 (ADAA) feed combination for the indications listed in Section I.L.

Sponsored by:

Zoetis Inc.

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I. GENERAL INFORMATION

A. File Number

NADA 141-530

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Names

MGA® and Aureomycin®

D. Drug Product Established Names

melengestrol acetate Type A medicated article and chlortetracycline Type A medicated article

E. Pharmacological Categories

MGA®: Steroid hormone
Aureomycin®: Antimicrobial

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): Melengestrol acetate at 200 mg per pound
MGA® 500 (liquid formulation): Melengestrol acetate at 500 mg per pound (as melengestrol acetate and its propylene glycol ketal)
Aureomycin® 50 Granular A: Chlortetracycline calcium complex equivalent to 50 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Meal: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 90 Granular: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Aureomycin® 100 Granular: Chlortetracycline calcium complex equivalent to 100 g chlortetracycline hydrochloride per lb.

[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: 50 lb. bag
MGA® 500: 40 lb. container (liquid)
Aureomycin® 50 Granular A: 50 lb. bag
Aureomycin® 90 Meal: 50 lb. bag
Aureomycin® 90 Granular: 50 lb. bag
Aureomycin® 100 Granular: 50 lb. bag and 2,000 lb. super sack

I. Dispensing Status

Veterinary feed directive (VFD)

J. Route of Administration

Oral

K. Species/Classes

Growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers

L. Indications and Dosage Regimens

1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

    a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) 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. 4,000 to 20,000 of g/ton chlortetracycline (as Aureomycin®) to provide 10 mg chlortetracycline per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

    Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone.

2. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

   a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to provide 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

   b. 4,000 to 20,000 of g/ton chlortetracycline (as Aureomycin®) to provide 10 mg chlortetracycline per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

   Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding.

3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the reduction of the incidence of liver abscesses in growing beef heifers fed in confinement for slaughter over 400 lbs.

   a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 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. 5.83 to 14 g/ton of chlortetracycline (as Aureomycin®) to provide 70 mg chlortetracycline per head per day for the reduction of the incidence of liver abscesses.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline.

4. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

   a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 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. 20 to 350 g/ton of chlortetracycline (as Aureomycin®) to provide 350 mg chlortetracycline per head per day for control of bacterial pneumonia associated with shipping fever complex caused by *Pastuerella* spp. susceptible to chlortetracycline.

The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline.

5. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

   a. 0.25 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 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. 500 to 4,000 g/ton of chlortetracycline (as Aureomycin®) to provide chlortetracycline at the rate of 10 mg per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone.

6. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

   a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

   b. 500 to 4,000 g/ton of chlortetracycline (as Aureomycin®) to provide 10 mg chlortetracycline per pound of body weight per day for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 5 days. After completing feeding this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding.

7. For suppression of estrus (heat), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

a. 0.5 to 2 g/ton melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

b. 20 to 350 g/ton of chlortetracycline (as Aureomycin®) to provide 350 mg chlortetracycline per head per day for control of bacterial pneumonia. associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.

The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

8. For suppression of estrus (heat), and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers over 700 pounds.

   a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

   b. 33.33 to 50 g/ton of chlortetracycline (as Aureomycin®) to provide 0.5 mg chlortetracycline per pound of body weight per day for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

9. For suppression of estrus (heat) and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers under 700 pounds.

   a. 0.5 to 2 g/ton of melengestrol acetate (as MGA®) to deliver 0.5 mg melengestrol acetate per head per day for suppression of estrus (heat).

   b. 50 to 350 g/ton of chlortetracycline (as Aureomycin®) to provide 350 mg chlortetracycline per head per day for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

   The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing chlortetracycline for not more than 24 days.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the ADAA of 1996, allows for drugs to be fed in combination in or on medicated feed without additional demonstration of their effectiveness or target animal safety when certain conditions are met. In those cases, the FD&C Act provides that effectiveness and target animal safety of each drug, demonstrated in its NADA at the time of the

approval, are adequate. The Agency has based its determination of the effectiveness and target animal safety of the combination of melengestrol acetate Type A medicated article and chlortetracycline Type A medicated article on the effectiveness and target animal safety of the previously separately approved conditions of use for MGA® and Aureomycin® for use in heifers fed in confinement for slaughter and heifers intended for breeding, and calves, beef and non-lactating dairy cattle, respectively, as these drugs or their active ingredients intended for use in combination in animal feeds have met the following criteria:

- there is substantial evidence to indicate that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the proposed 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 or animal drug, there is substantial evidence that each of the nontopical antibacterial active ingredients or animal drugs makes a contribution to the labeled effectiveness;
- there was not a substantiated scientific issue specific to an active ingredient or animal drug used in the combination that was not adequately evaluated based on the information contained in the application for the combination, and no data presented in the application raised a safety concern with the Agency; and
- there was not a scientific issue raised by target animal observations contained in the studies submitted to the NADA for the combination, and no data presented in the application raised a safety concern with the Agency.

Effectiveness and target animal safety of the individual drugs in this combination has been established by data in the following NADAs (refer to Table II.1):

Table II.1. Summary of effectiveness and target animal safety for the individual drugs subject to this combination.

Drug Product	Indications*	Approval Information
MGA® Sponsored by Zoetis Inc.	1. For use in feeds for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).[a] 2. For use in feeds for heifers intended for breeding for suppression of estrus (heat).[b]	NADA 039-402 [a](as published in 21 CFR 558.342) [b](refer to the FOI Summary, dated February 18, 1997)
Aureomycin®	1. For use in feeds for calves, beef and non-lactating dairy cattle for treatment of bacterial enteritis caused by	NADA 048-761 FOI Summary dated

Drug Product	Indications*	Approval Information
Sponsored by Zoetis Inc.	*Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline. 2. For use in feeds for growing cattle over 400 lbs. for the reduction of the incidence of liver abscesses. 3. For use in feeds for beef cattle and dairy replacement heifers for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline. 4. For use in feeds for beef cattle over 700 lbs for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline. 5. For use in feeds for beef cattle under 700 lbs for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	February 16, 1996

* The target animals listed in this table are as currently listed on the Type A medicated article labeling. For the current approval, the target animal terminology reflects current nomenclature as described in Guidance for Industry #191, Appendix III[2].

III. HUMAN FOOD SAFETY

With respect to the human food safety evaluation for these types of combination new animal drug approvals, the Agency evaluates whether any active ingredient or drug intended for use in the combination exceeds its established tolerance at the longest withdrawal time of any of the active ingredients or drugs in the combination, and

[2] http://cdms.fda.gov:8080/wtCDMS/drl/objectId/0900b9f1804d2778

whether any of the active ingredients or drugs of the combination interferes with the methods of analysis of another active ingredient or drug in the combination [section 512(d)(4)(A) of the FD&C Act]. Therefore, only additional residue chemistry data and assay noninterference information were needed to support approval of this ADAA feed-use combination. The Agency has based its determination of the human food safety of the combination of melengestrol acetate and chlortetracycline on the human food safety of the previously separately approved conditions of use for MGA® and Aureomycin® for use in heifers fed in confinement for slaughter and heifers intended for breeding and calves, beef and non-lactating dairy cattle, respectively, as these drugs or their active ingredients intended for use in combination in animal feeds have met the following criteria:

- 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, and
- none of the active ingredients or animal drugs in combination interferes with the method of analysis for another active ingredient or animal drug in the combination.

A. Microbial Food Safety

As noted, Section 512(d)(4)(A) of the FD&C Act, limits CVM's human food safety evaluation for these types of ADAA feed-use combination new animal drug approvals; therefore, microbial food safety was not assessed.

B. Toxicology

As noted, Section 512 (d)(4)(A) of the FD&C Act limits CVM's human food safety evaluation for these types of ADAA feed-use combination new animal drug approvals; therefore, toxicology assessment of these types of combination new animal drugs was not performed. Safety of the individual drugs in this combination has been established by data in the following NADAs (refer to Table III.1.):

Table III.1. Toxicology assessment of the individual drugs in this combination.

Drug Product	Approval Information
MGA®	NADA 034-254 (refer to the FOI Summary, dated June 29, 1994)
Aureomycin®	NADA 048-761 (as published in the FEDERAL REGISTER (61 FR 67453) on December 23, 1996)

C. Residue Chemistry

1. Summary of Residue Chemistry Studies

   a. Residue Depletion Study

   Title: Tissue Residue Study for the Combinations of Laidlomycin (Cattlyst®), Chlortetracycline (Aureomycin®), and Melengestrol Acetate (MGA®) or Lasalocid (Bovatec®), Chlortetracycline (Aureomycin®), or Melengestrol Acetate (MGA®) in Cattle Receiving Diets Containing These Drugs in Combination. (Study No. RC006-08LOCTxx)

   Study Dates: September 2008 to November 2008

   Study Location: Tulare, California

   Study Design:

   Objective: The objective of this Good Laboratory Practice (GLP) study was to demonstrate residue noninterference and assay noninterference for combination use of chlortetracycline, lasalocid, and melengestrol acetate or chlortetracycline, laidlomycin, and melengestrol acetate as Type C medicated feeds at the maximum approved doses for each ingredient. Tissue concentrations of the administered drugs were measured after 0-day withdrawal. Studies with 3-way combinations are used to support the withdrawal period of included 2-way combinations.

   Study Animals: Two control and eight beef crossbred heifers were used for the study.

   Drug Administration: The eight treated animals were divided between two groups. Control animals were provided a non-medicated feed throughout the study. Animals in the first test group were fed 150 mg/head/day laidlomycin and 0.5 mg/head/day melengestrol acetate for the entire 14-day treatment period and 10 mg/lb body weight/day chlortetracycline for the final 5 days of the treatment period. Animals in the second test group were fed 360 mg/head/day lasalocid and 0.5 mg/head/day melengestrol acetate for the entire 14-day treatment period and 10 mg/lb body weight/day chlortetracycline for the final 5 days of the treatment period.

   Measurements and Observations: Cattle were removed from medicated feed ~10-14 hours prior to slaughter. Liver, kidney, and fat tissues were collected. Liver tissue was analyzed for residues of laidlomycin and lasalocid. Kidney tissue was analyzed for residues of chlortetracycline. Fat was analyzed for residues of melengestrol acetate.

   Results: The results of analysis of chlortetracycline, lasalocid, laidlomycin, and melengestrol acetate are shown in Table III.1 below. All animals had residues for chlortetracycline, lasalocid, laidlomycin, and melengestrol acetate that were below their respective tolerances in all treatment groups.

Table III.1. Mean Residues for Chlortetracycline, Melengestrol Acetate, Lasalocid, and Laidlomycin (ppm)

Treatment	CTC[1] in Kidney	Melengestrol Acetate in Fat	Lasalocid in Liver	Laidlomycin in Liver
10 mg chlortetracycline/lb bw/day 0.5 mg melengestrol acetate/head/day 150 mg laidlomycin/head/day	4.365	BLOQ*	NA	BLOQ
10 mg chlortetracycline/lb bw/day 0.5 mg melengestrol acetate/head/day 360 mg lasalocid/head/day	2.125	BLOQ*	0.099	NA

[1] CTC = chlortetracycline
NA: Not applicable. The animals were not treated with the drug
BLOQ: Below the limit of quantitation. The limit of quantitation for the melengestrol acetate in fat assay was 9 ppb. The limit of quantitation for the laidlomycin assay was 0.05 ppm. The limit of quantitation for the lasalocid assay was 0.02 ppm

During the analysis, control tissue samples were fortified with chlortetracycline, lasalocid, laidlomycin, and melengestrol acetate at their respective tolerances, and analyzed with each analytical method. The results showed that assay non-interference has been demonstrated for each component of the combination in the analytical methods for the other components.

2. Target Tissue and Marker Residue

No reassessments for target tissues and marker residues were needed for this approval.

A target tissue and marker residue were not assigned for chlortetracycline in the approval under NADA 048-761 (as published in the FEDERAL REGISTER (61 FR 67453) on December 23, 1996).

The target tissue for melengestrol acetate is fat and the marker residue is melengestrol acetate (NADA 034-254, FOI Summary, dated June 29, 1994).

3. Tolerances

Tolerances for chlortetracycline in edible tissue of beef cattle and nonlactating dairy cattle are 2 ppm in uncooked muscle, 6 ppm in uncooked liver, and 12 ppm in uncooked fat and kidney (21 CFR 556.150 *per* FEDERAL REGISTER, (61 FR 67453) on December 23, 1996).

A tolerance of 0.025 ppm is established for melengestrol acetate in cattle fat (21 CFR 556.380 *per* FEDERAL REGISTER (59 FR 41241) on August 11, 1994).

4. Withdrawal Period

   Study RC006-08LOCTxx showed that residues of chlortetracycline and melengestrol acetate in cattle tissues were below their respective tolerances after a 0-day withdrawal period when chlortetracycline and melengestrol acetate were fed in combination. The data support assignment of a 0-day withdrawal period for cattle treated with 10 mg/lb body weight/day chlortetracycline and 0.5 mg/head/day melengestrol acetate.

D. Analytical Method for Residues

1. Determinative Method

   The microbiological method for determining chlortetracycline in cattle kidney is described in NADA 048-761 (FOI Summary dated February 16, 1996). The GC-MS method for determining melengestrol acetate in cattle fat is described in NADA 034-254 and NADA 039-402 (FOI Summaries dated June 29, 1994).

2. Confirmatory Method

   Confirmatory methods were not required for chlortetracycline and melengestrol acetate.

3. Availability of Method

   The validated analytical methods for analysis of residues of chlortetracycline and melengestrol acetate are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, 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 approval.

The combination labeling contains the following information regarding safety to humans handling, administering, or exposed to the Type C medicated feed:

User Safety Warnings: Not for use in humans. Keep out of reach of children.

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the FD&C Act and 21 CFR part 514. The data contained in the previously approved NADAs for MGA® and Aureomycin® demonstrate that, when they are used according to the label, they are safe and effective for the following indications:

1. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli*

and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

2. For suppression of estrus (heat), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

3. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the reduction of the incidence of liver abscesses in growing beef heifers fed in confinement for slaughter over 400 lbs.

4. For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp*.* susceptible to chlortetracycline in growing beef heifers fed in confinement for slaughter.

5. For suppression of estrus (heat), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp*.* susceptible to chlortetracycline in replacement dairy heifers less than 20 months of age and replacement beef heifers.

6. For suppression of estrus (heat), and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers over 700 pounds.

7. For suppression of estrus (heat) and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in replacement beef heifers under 700 pounds.

Additionally, data demonstrate that residues in food products derived from growing beef heifers fed in confinement for slaughter and replacement beef and dairy heifers administered MGA® and Aureomycin® will not represent a public health concern when the combination medicated feed is used according to the label.

A. Marketing Status

A valid VFD is required to dispense this drug. Any animal feed bearing or containing this drug will be fed to animals only by or on a lawful veterinary feed directive issued by a licensed veterinarian in the course of their professional practice. In addition, the veterinary feed directives issued for this drug are not refillable.

The decision to restrict this drug to use by or upon a lawful veterinary feed directive issues by a licensed veterinarian was based on the following factors: adequate directions cannot be written to enable lay persons to appropriately diagnose and subsequently use this drug product, and because restricting this drug product to use by or on the order of a licensed veterinarian is critical for assuring the safe and appropriate use of this drug product and to mitigate any potential for the development of bacterial resistance to antimicrobial drugs.

B. Exclusivity

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(ii) of the FD&C Act.

C. Patent Information

For current information on patents, see the Animal Drugs @ FDA database or the Green Book on the FDA CVM internet website.