Date of Approval: December 12, 2017

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-617

Deracin® plus Bovatec®

chlortetracycline plus lasalocid

Type A Medicated Articles for Use in the Manufacture of Type B and Type C Medicated Feeds

Cattle (fed in confinement for slaughter; pastured slaughter, stocker, feeder, dairy and beef replacement; beef; beef calves; non-lactating dairy)

Chlortetracycline
For treatment of bacterial enteritis caused by *Escherichia coli*, treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, and control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

Lasalocid
For improved feed efficiency, increased rate of weight gain, and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

Sponsored by:

Pharmgate LLC

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-617

B. Sponsor

Pharmgate LLC
1800 Sir Tyler Drive
Wilmington, NC 28405

Drug Labeler Code: 069254

C. Proprietary Name

Deracin® plus Bovatec®

D. Product Established Name

chlortetracycline plus lasalocid

E. Pharmacological Category

Chlortetracycline - Antimicrobial
Lasalocid - Ionophore

F. Dosage Form

Type A medicated articles for use in the manufacture of Type B (dry) and Type C (dry) medicated feeds.

G. Amount of Active Ingredient in Currently Marketed Products*

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 50, 90, or 100 g chlortetracycline hydrochloride per lb

Lasalocid 90.7 g/lb (20%) or 150 g/lb (33.1%) lasalocid sodium activity

*****The sponsors of these individual currently marketed Type A medicated articles may have approvals for other strengths of these products 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 the Type B and C medicated feed that is the subject of this approval.

H. How Supplied

Deracin® (chlortetracycline) – 50 lb bag
Bovatec® (lasalocid) – 50 lb bag

I. Dispensing Status

VFD

J. Dosage Regimen

Cattle fed in confinement for slaughter

1. For improved feed efficiency (lasalocid 10 to 30 g/ton), and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline (chlortetracycline 500 to 2000 g/ton): Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb of body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day.
2. For improved feed efficiency and increased rate of weight gain (lasalocid 25 to 30 g/ton), and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline (chlortetracycline 500 to 1200 g/ton): Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb of body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day.
3. For improved feed efficiency (lasalocid 10 to 30 g/ton), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (chlortetracycline 25 to 100 g/ton): Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg or more than 360 mg lasalocid per head daily.
4. For improved feed efficiency and increased rate of weight gain (lasalocid 25 to 30 g/ton), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (chlortetracycline 25 to 42.2 g/ton): Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg or more than 360 mg lasalocid per head daily.

Cattle fed in confinement for slaughter under 700 lbs

1. For improved feed efficiency (lasalocid 10 to 30 g/ton), and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline (chlortetracycline 25 to 100 g/ton): Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg or more than 360 mg lasalocid per head daily.
2. For improved feed efficiency and increased rate of weight gain (lasalocid 25 to 30 g/ton), and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline (chlortetracycline 25 to 42.2 g/ton): Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg or more than 360 mg lasalocid per head daily.

Pasture Cattle (slaughter, stocker, feeder, dairy and beef replacement heifers)

For increased rate of weight gain (lasalocid 30 to 600 g/ton), and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline (chlortetracycline 500 to 4000 g/ton): Feed continuously on a hand fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb of body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 lb of feed.

Pasture Cattle (slaughter, stocker, feeder, and beef replacement heifers)
For increased rate of weight gain (lasalocid 30 to 600 g/ton), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (chlortetracycline 25 to 700 g/ton): Feed continuously on a hand fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed.

Pasture Cattle over 700 lb (slaughter, stocker, feeder, beef replacement heifers)
For increased rate of weight gain (lasalocid 30 to 600 g/ton), and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline (chlortetracycline 25 to 1100 g/ton): Feed continuously on a hand fed basis 0.5 mg per lb of body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed.

Pasture cattle under 700 lbs (slaughter, stocker, feeder, beef replacement heifers)
For increased rate of weight gain (lasalocid 30 to 600 g/ton), and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline (chlortetracycline 25 to 700 g/ton): Feed continuously on a hand fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed.

Cattle weighing up to 800 lbs
For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* (lasalocid 30 to 181.8 g/ton), and for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline (chlortetracycline 500 to 4000 g/ton): Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb of body weight per day and 1 mg lasalocid per 2.2 lb body weight daily with a maximum of 360 mg of lasalocid per head per day.

Beef Cattle weighing up to 800 lbs
For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* (lasalocid 30 to 181.8 g/ton), and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella spp.* susceptible to chlortetracycline (chlortetracycline 25 to 2800 g/ton): Hand feed continuously at a rate of 350 mg chlortetracycline per head and 1 mg lasalocid per 2.2 lb body weight daily with a maximum of 360 mg of lasalocid per head per day.

Beef cattle under 700 lbs
For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* (lasalocid 30 to 181.8 g/ton), and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline (chlortetracycline 25 to 2800 g/ton): Hand feed continuously at a rate of 350 mg chlortetracycline per head and 1 mg lasalocid per 2.2 lb body weight daily with a maximum of 360 mg lasalocid per head per day.

K. Route of Administration

Oral, in feed

L. Species/Class

Cattle (fed in confinement for slaughter; pastured slaughter, stocker, feeder, dairy and beef replacement; beef; beef calves; non-lactating dairy).

M. Indications

Chlortetracycline

Dosage	Indications
0.5 mg per lb of body weight per day	Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.
0.5 – 2.0 mg per lb of body weight per day	Beef and Non- Lactating Dairy Cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline when delivered in a free-choice feed.
10 mg per lb of body weight per day	Calves, Beef, and Non-Lactating Dairy Cattle: Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.
350 mg per head per day	Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.
350 mg per head per day	Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

Lasalocid

Dosage	Indications
10 – 30 grams per ton of total ration (90% dry matter)	Feedlot cattle: For improved feed efficiency in cattle being fed in confinement for slaughter.
25 – 30 grams per ton of total ration (90% dry matter)	Feedlot cattle: For improved feed efficiency and increased rate of weight gain in cattle being fed in confinement for slaughter.
60 – 300 mg per head per day	Pasture Cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.
1 mg per 2.2 lb body weight per day	Cattle: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle up to 800 lbs.

N. Approved Original Generic Type A Medicated Article

Deracin®; chlortetracycline; ANADA 200-510; Pharmgate LLC

O. Reference Listed New Animal Drug

Aureomycin® plus Bovatec®; chlortetracycline plus lasalocid; NADA 141-250; Zoetis inc.

The individual Type A medicated articles approved for use in the manufacture of combination medicated feeds:
Aureomycin®; chlortetracycline; NADA 048-761; Pharmgate LLC
Bovatec®; lasalocid; NADA 096-298; Zoetis Inc.

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 (reference listed new animal drug). 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.

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 RLNAD 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). Chlortetracycline is codified under 21 CFR 558.128, and lasalocid is codified under 21 CFR 558.311. The combination of chlortetracycline and lasalocid is codified under 21 CFR 558.128(e)(4).

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

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

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms *per* kilogram of body weight *per* day. The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. Tolerances of 2 parts *per* million (ppm), 6 ppm, 12 ppm and 12 ppm are established for the sum of tetracycline residues in muscle, liver, fat and kidney, respectively, under 21 CFR §556.150.

The ADI for total residues of lasalocid is 10 micrograms *per* kilogram of body weight *per* day. The tolerance established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 0.7 ppm is

established for parent lasalocid (the marker residue) in liver (the target tissue), under 21 CFR §556.347.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate bioequivalence was granted for the Type A medicated article Deracin®, the withdrawal period for the combination Type B and C medicated feeds is that previously assigned to the RLNAD product.

When used together, chlortetracycline and lasalocid are approved with a zero-day withdrawal period.

C. Analytical Method for Residues:

The validated analytical methods for analysis of residues of chlortetracycline and lasalocid are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical methods, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Deracin® plus Bovatec®:

Not for Human Use

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Deracin® plus Bovatec®, when used according to the label, are safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with Deracin® plus Bovatec® will not represent a public health concern when the product is used according to the label.