Date of Approval: November 2, 2014

CORRECTED FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-510

DERACIN

(chlortetracycline)

Type A Medicated Article

Cattle, Swine, Sheep, Turkeys, Chickens, Ducks, and Psittacine Birds

For increased rate of weight gain, improved feed efficiency, and the control of various diseases and bacterial infections

Sponsored by:

Pharmgate LLC

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I. GENERAL INFORMATION

A. File Number

ANADA 200-510

B. Sponsor

Pharmgate LLC
161 North Franklin Turnpike, suite
2C Ramsey, NJ 07446

Drug Labeler Code: 069254

C. Proprietary Name

DERACIN

D. Drug Product Established Name

Chlortetracycline

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Type A medicated article

G. Amount of Active Ingredient

50, 90, 100 g/lb

H. How Supplied

50 lb bag

I. Dispensing Status

OTC

J. Dosage Regimen

See Indications for more information

K. Route of Administration

Oral, in feed

L. Species/Class

Cattle, swine, sheep, turkeys, chickens, ducks, and psittacine birds

M. Indications

Cattle

Indications	**Dosage Regimen** **mg per lb body weight per day**
Calves (up to 250 lb): Increased rate of weight gain and improved feed efficiency.	0.1
Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	0.5
Beef and Non-Lactating Dairy Cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	0.5 – 2.0 For use in free-choice feeds. A feed mill license is required when the free-choice feed is manufactured using a proprietary formula and/or specifications.
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.	10 Feed for not more than 5 days. The appropriate amount of DERACIN containing feed supplement may be mixed in the cattle's daily ration or administered as a top-dress. If the DERACIN containing feed supplement is administered as a top dress, it must be spread uniformly on top of the ration and sufficient space must be provided so that all cattle can eat at the same time.

Swine

Indications	**Dosage Regimen** **mg per lb body weight per day**
Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	10 Note: This drug level is equivalent to approximately 400 grams per ton, depending on feed consumption and body weight. Feed for not more than 14 days.

Turkeys

Indications	**Dosage Regimen** **mg per lb body weight per day**
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral	25 Feed continuously for 7 to 14 days.

enteritis) susceptible to chlortetracycline.	

Cattle

Indications	**Dosage Regimen mg per head per day**
Calves (250-400 lb): Increased rate of weight gain and improved feed efficiency.	25 - 70
Growing Cattle (over 400 lb): Increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	70
Beef Cattle and Dairy Replacement Heifers: Control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	350
Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	350

Sheep

Indications	**Dosage Regimen mg per head per day**
Breeding Sheep: Reduction in the incidence of (vibrionic) abortions caused by *Campylobacter fetus* infection susceptible to chlortetracycline.	80

Swine

Indications	**Dosage Regimen g per ton in complete feed**
Increased rate of weight gain and improved feed efficiency.	10 - 50
Reduction in incidence of cervical lymphadenitis (jowl abscesses) caused by Group E. *Streptococci* susceptible to chlortetracycline.	50 - 100
Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	400 Feed continuously for not more than 14 days.

Sheep

Indications	**Dosage Regimen g per ton in complete feed**
Increased rate of weight gain and improved feed efficiency.	20 - 50

Ducks

Indications	**Dosage Regimen g per ton in complete feed**
Control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.	200 – 400 Feed in complete ration to provide from 8 to 28 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.

Chickens

Indications	**Dosage Regimen g per ton in complete feed**
Increased rate of weight gain and improved feed efficiency.	10 - 50
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	100 – 200 Feed continuously for 7 to 14 days.
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	200 – 400 Feed continuously for 7 to 14 days.
Reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline.	500 Feed for 5 days.

Turkeys

Indications	**Dosage Regimen g per ton in complete feed**
Increased rate of weight gain and improved feed efficiency.	10 - 50
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	200 Feed continuously for 7 to 14 days.
Control of hexamitiasis caused by *Hexamita meleagrides* susceptible to Chlortetracycline.	400 Feed continuously for 7 to 14 days.
Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.	400

Psittacine Birds

Indications	**Dosage Regimen mg per g feed**
Treatment of psittacine birds (parrots, macaws, cockatoos) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	10 Feed continuously for 45 days. Each bird should consume an amount of medicated feed equal to one-fifth of its body weight daily. During treatment, parrots, macaws, and cockatoos should be kept individually or in pairs in clean cages.

N. Reference Listed New Animal Drug

AUREOMYCIN; chlortetracycline; NADA 048-761; 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 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.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), 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 demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Pharmgate LLC was granted a waiver from the requirement to demonstrate bioequivalence for the generic product DERACIN (chlortetracycline) Type A medicated article. The generic product is administered as medicated feed, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD, AUREOMYCIN (chlortetracycline) Type A medicated article, sponsored by Zoetis Inc. under NADA 048-761, was approved for use in cattle, swine, sheep, turkeys, chickens, ducks, and psittacine birds. The RLNAD was originally approved on October 21, 1977; and the most recent significant supplement (R-0282) was approved on August 1, 2007, for revised Type A medicated article labeling.

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

Because a waiver from the requirement to demonstrate bioequivalence was granted, the tolerances for residues and the withdrawal times previously established for the RLNAD apply to the generic product.

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product.

Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, of 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney; a tolerance is established for residues of chlortetracycline in eggs of 0.4 ppm, under 21 CFR 556.150.

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.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product.

The RLNAD was approved with a zero-day withdrawal period under 21 CFR 558.128.

DERACIN labeling carries the following warnings:

A withdrawal period has not been established for this product in pre- ruminating calves.
Do not use in calves to be processed for veal.
Do not feed to turkeys producing eggs for human consumption. Do not feed to ducks producing eggs for human consumption.

C. Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus* var *mycoides* (ATCC 11778). The method is found in Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols, Revised October 1968, Reprinted December 1974, Nation Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204. The method is on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY

CVM did not require user safety studies for this approval.

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, when used according to the label, is safe and effective.

VIII. APPENDIX

The RLNAD indications were in error at the time of the original ANADA approval, thus, a correction to the generic Freedom of Information (FOI) summary, Section I.M., Indications, was required.

The revised text is: “Beef Cattle and Dairy Replacement Heifers: Control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline."

The original text was: "Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline."