Date of Approval: January 29, 2018

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-622

Deccox® plus Deracin®

decoquinate plus chlortetracycline

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

Cattle (calves, beef, and non-lactating dairy)

Decoquinate
For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

Chlortetracycline
For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

Sponsored by:

Pharmgate LLC

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-622

B. Sponsor

Pharmgate LLC
1800 Sir Tyler Drive
Wilmington, NC 28405

Drug Labeler Code: 069254

C. Proprietary Name

Deccox® plus Deracin®

D. Product Established Name

decoquinate plus chlortetracycline

E. Pharmacological Category

Decoquinate: anticoccidial
Chlortetracycline: antimicrobial

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*

Decoquinate 27.2 g per lb

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

*****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 C medicated feed that is the subject of this approval.

H. How Supplied

Deccox® (decoquinate) – 50 lb bag
Deracin® (chlortetracycline) – 50 lb bag

I. Dispensing Status

VFD

J. Dosage Regimen

Calves, beef, and non-lactating dairy cattle - For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* (decoquinate 12.9 to 90.8 g/ton); 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 at a rate of 1 g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis.

Calves, beef, and non-lactating dairy cattle - For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* (decoquinate 90.9 to 535.7 g/ton); for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline (chlortetracycline 4000 to 20,000 g/ton): Administer as a top dress supplement or mix into the daily ration to provide 22.7 mg decoquinate per 100 lb of body weight per day and 1 g chlortetracycline per 100 lb body weight/day for not more than 5 days.

K. Route of Administration

Oral, in feed

L. Species/Class

Cattle (calves, beef, and non-lactating dairy)

M. Indications

Decoquinate

Dosage	Indications
22.7 mg per 100 lbs (0.5 mg per kg) of body weight per day	Cattle: For the prevention of coccidiosis in ruminating and non-ruminating calves (including veal calves) and cattle caused by *Eimeria bovis* and *E. zuernii*.

Chlortetracycline

Dosage	Indications
10 mg per lb of body weight per day	Calves, Beef, and Non-Lactating Dairy Cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

N. Approved Original Generic Type A Medicated Article

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

O. Reference Listed New Animal Drug

Deccox® plus Aureomycin®; decoquinate plus chlortetracycline; NADA 141-185; Zoetis Inc.

The individual Type A medicated articles approved for use in the manufacture of combination medicated feeds:

Deccox®; decoquinate; NADA 039-417; Zoetis Inc.
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 (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). Decoquinate is codified under 21 CFR 558.195. Chlortetracycline is codified under 21 CFR 558.128. The combination of decoquinate and chlortetracycline 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 decoquinate is 75 micrograms *per* kilogram of body weight *per* day. The tolerances established for the feed use of the RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 1 part *per* million (ppm) is established for residues of decoquinate in skeletal muscle, and 2 ppm in other tissues, under 21 CFR §556.170.

The 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 of the RLNAD apply to the generic feed use combination new animal drug product. Tolerances of 2 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.

B. Withdrawal Periods:

Because a waiver from the requirement to perform an *in vivo* bioequivalence study 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, decoquinate and chlortetracycline are approved with a zero-day withdrawal period.

C. Analytical Method for Residues:

The validated analytical methods for analysis of residues of decoquinate and chlortetracycline 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 Deccox® plus Deracin®:

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 Deccox® plus Deracin®, when used according to the label, are safe and effective.

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