Date of Approval: August 9, 2018

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200630

CocciAid™

(amprolium)

9.6% Oral Solution

Growing chickens, turkeys, and laying hens

CocciAid™ (amprolium) 9.6% Oral Solution is intended for the treatment of coccidiosis in growing chickens, turkeys, and laying hens.

Sponsored by:

Aurora Pharmaceutical, LLC

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-630

B. Sponsor

Aurora Pharmaceutical, LLC
1196 Highway 3 South
Northfield, MN 55057-3009

Drug Labeler Code: 051072

C. Proprietary Name

CocciAid™

D. Product Established Name

amprolium

E. Pharmacological Category

Anticoccidial

F. Dosage Form

Oral Solution

G. Amount of Active Ingredient

96 mg/mL (9.6%)

H. How Supplied

1 Gallon (128 fl oz) (3.785 L)

I. Dispensing Status

OTC

J. Dosage Regimen

Give amprolium at the 0.012% level (8 fl oz per 50 gallons) as soon as coccidiosis is diagnosed and continue for 3 to 5 days. (In severe outbreaks, give amprolium at the 0.024% level.) Continue with 0.006% amprolium medicated water for an additional 1 to 2 weeks.

K. Route of Administration

Oral

L. Species/Class

Growing chickens, turkeys, and laying hens

M. Indications

CocciAid™ (amprolium) 9.6% Oral Solution is intended for the treatment of coccidiosis in growing chickens, turkeys, and laying hens. If no improvement is noted within 3 days, have the diagnosis confirmed and follow the instructions of your veterinarian or poultry pathologist. Losses may result from intercurrent disease or other conditions affecting drug intake which can contribute to the virulence of coccidiosis under field conditions.

N. Reference Listed New Animal Drug

Amprol® 9.6% Oral Solution; amprolium; NADA 013-149; Huvepharma EOOD

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 (RLNAD)). 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 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 period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of performing an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Aurora Pharmaceutical, LLC, was granted a waiver from the requirement to perform an *in vivo* bioequivalence study for the generic product CocciAid™ (amprolium) 9.6% oral solution. The generic drug product is an oral solution, 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 is Amprol (amprolium) 9.6% oral Solution, sponsored by Huvepharma EOOD, under NADA 013-149 and, was approved for use in growing chickens on June 20, 1962; supplemental approval was granted for turkeys and laying hens on August 12, 1964.

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 growing chickens, turkeys, and laying hens:

A. Acceptable Daily Intake and Tolerances for Residues:

An acceptable daily intake (ADI) is not codified for amprolium in 21 § CFR 556.50.

The tolerances established for the RLNAD apply to the generic product. The tolerances for residues of amprolium (1-(4-amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride) in the edible tissues and in eggs of chickens and turkeys are 1 ppm in liver and kidney, 0.5 ppm in muscle, 8 ppm in egg yolks, and 4 ppm in whole eggs (21 § CFR 556.50).

B. Withdrawal Period:

Because a waiver from the requirement to perform an *in vivo* bioequivalence study was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 0 days has been established for amprolium in growing chickens, turkeys, and laying hens.

C. Regulatory Method for Residues:

The validated regulatory analytical method for the detection of residues of amprolium is a fluorimetric test. A description of the regulatory method is filed in the Food Additives Analytical Manual on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

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 CocciAid™:

- WARNING: Keep this and all drugs out of reach of children. NOT FOR HUMAN USE.
- PRECAUTIONS: FOR ORAL USE IN ANIMALS ONLY. MAY CAUSE EYE IRRITATION. For irritation, flush with plenty of water; get medical attention.

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 CocciAid™ (amprolium) 9.6% Oral Solution, when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with CocciAid™ (amprolium) 9.6% Oral Solution will not represent a public health concern when the product is used according to the label.