

Date of Approval: May 8, 2024

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-780

CocciAid® for Calves

(amprolium)

Oral solution

Beef and dairy calves

An aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves.

Sponsored by:

Aurora Pharmaceutical, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-780

B. Sponsor

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

Drug Labeler Code: 051072

C. Proprietary Name

CocciAid® for Calves

D. Drug 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 bottle

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Treatment Protocol: 10 mg/kg per day for 5 days in drinking water or as a drench.

Prevention Protocol: 5 mg/kg per day for 21 days in drinking water or as a drench.

K. Route of Administration

Oral

L. Species/Class

Beef and dairy calves

M. Indication

An aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves.

N. Reference Listed New Animal Drug (RLNAD)

CORID®; amprolium; NADA 013-149; Huvepharma EOOD

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). 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. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (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, Inc., was granted a biowaiver for the generic product CocciAid® for Calves (amprolium) 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 CORID® (amprolium) oral solution, sponsored by Huvepharma EOOD, under NADA 013-149, and was approved for use in beef and dairy calves on June 20, 1962.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

An acceptable daily intake (ADI) is not cited for total residues of amprolium. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.5 parts per million (ppm) is established for amprolium in liver, kidney, and muscle and 2.0 ppm in fat, under 21 CFR 556.50.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 24 hours has been established for amprolium in calves. A withdrawal period has not been established for this product in pre-ruminating calves.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of amprolium is 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

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to CocciAid® for Calves:

USER SAFETY WARNINGS: NOT FOR HUMAN USE. Keep this and all drugs out of the reach of children.

PRECAUTIONS: FOR ORAL USE IN ANIMALS ONLY. MAY CAUSE EYE IRRITATION. For irritations, flush with plenty of water; get medical attention.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that CocciAid® for Calves, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef and dairy calves treated with CocciAid® for Calves will not represent a public health concern when the product is used according to the label.