Date of Approval: June 29, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 013-149

CORID®

(amprolium oral solution)

Concentrated solution

Calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age

Addition of cattle classes other than calves and assignment of a zero-day withdrawal period

Sponsored by:

Huvepharma EOOD

Executive Summary

CORID® (amprolium oral solution) was previously approved for use as an aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves with a 24-hour withdrawal period.

This supplement adds additional cattle classes to the CORID® (amprolium oral solution) label and assigns a zero-day withdrawal period in treated cattle. FDA found that the sponsor's existing effectiveness and target animal safety data supported the addition of the other cattle classes to include calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age.

The sponsor conducted a tissue residue depletion study to establish that residues of amprolium were below the established tolerance for the target tissue (liver) thereby supporting a zero-day withdrawal period in treated cattle.

Based on the data available to FDA, the supplemental application is approved.

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I. GENERAL INFORMATION

A. File Number

NADA 013-149

B. Sponsor

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Drug Labeler Code: 016592

U.S. Agent Name and Address:

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C. Proprietary Name

CORID®

D. Drug Product Established Name

amprolium oral solution

E. Pharmacological Category

Anticoccidial

F. Dosage Form

Concentrated solution

G. Amount of Active Ingredient

9.6% (96 mg amprolium/mL)

H. How Supplied

16-oz and 1-gal bottles

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

5-Day Treatment Protocol: 10 mg amprolium/kg (10 mg/2.2 lb) body weight (BW) per day in drinking water or as a drench

21-Day Prevention Protocol: 5 mg amprolium/kg (5 mg/2.2 lb) body weight (BW) per day in drinking water or as a drench

K. Route of Administration

Oral

L. Species/Classes

Calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age.

M. Indication

An aid in the prevention and treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves, growing beef steers and heifers fed in confinement for slaughter, growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers under one year of age. Not for use in veal calves.

N. Effect of Supplement

This supplement provides for the addition of cattle classes other than calves and assignment of a zero-day withdrawal period.

II. EFFECTIVENESS

A. Dosage Characterization

This supplemental approval does not change the previously approved dosage.

B. Substantial Evidence

The Food and Drug Administration (FDA) did not require effectiveness studies for this supplemental approval. FDA found that the effectiveness of CORID® that supported the inclusion of older cattle classes was established by data previously submitted in NADA 013-149.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this supplemental approval. FDA found that the target animal safety of CORID® that supported the inclusion of older cattle classes was established by data previously submitted in NADA 013-149.

IV. HUMAN FOOD SAFETY

A. Microbial Food Safety

This drug is not an antimicrobial. Therefore, the Agency determined that a microbial food safety assessment is not required.

B. Toxicology

Reassessment of the toxicological information was not needed for this supplemental approval. The safety of CORID® (amprolium) has been established by data in NADA 012-350 for amprolium (38 FR 34996, dated December 21, 1973).

C. Residue Chemistry

1. Summary of Residue Chemistry Studies

   a. Total Residue and Metabolism Studies

      CVM did not require total residue and metabolism studies for this supplemental approval. The safety of CORID® (amprolium) has been established by the data in NADA 012-350 for amprolium (38 FR 34996, dated December 21, 1973).

   b. Comparative Metabolism Study

      CVM did not require comparative metabolism studies for this supplemental approval. The safety of CORID® (amprolium) has been established by the data in NADA 012-350 for amprolium (38 FR 34996, dated December 21, 1973).

   c. Study to Establish Withdrawal Period

      (1) Tissue Residue Depletion Study

      Title: Residue Depletion in Cattle Fed in Confinement for Slaughter Following Oral Administration of CORID® (amprolium) for 5 Days. (Study No.: AM-RSCB-1803)

      Study Dates: August 13, 2019 to March 16, 2020

      Study Locations: Parma, ID (in-life); Fresno, CA (analytical laboratory (tissues)); New Ulm, MN (analytical laboratory (feed))

      Objective: To determine whether residues of amprolium were below the codified tolerance (0.5 ppm) at practical zero-day withdrawal in the livers of cattle fed in confinement for slaughter following *ad libitum* oral administration of amprolium (CORID® 9.6% Oral Solution) for five consecutive days.

      Study Animals: Ten calves (5 heifers and 5 steers) between 312 and 361 days of age, weighing between 313 and 354 kg were used.

      Experimental Design: In this GLP study, calves were administered amprolium (CORID® 9.6% Oral Solution) in medicated water at an approximate dose rate of 15 mg/kg of body weight *per* day (1.5X dose) for five consecutive days. Calves were slaughtered on the fifth day within 6 to 12 hours withdrawal. Livers were collected from each animal and analyzed for amprolium using a validated analytical method. The sponsor provided a justification for why this route of administration, dose, and duration (i.e., medicated water at 15 mg/kg BW for 5 days) represents a worst-case scenario to address Agency concerns for the human food safety of

amprolium residues. In addition, the sponsor provided data from previous approvals of amprolium to justify analysis of amprolium in cattle liver only.

Results: Concentrations for amprolium were measured in liver in duplicate. Results are summarized in Table IV.1 below. All samples analyzed were below the codified tolerance for amprolium in cattle liver.

Table IV.1. Concentrations of amprolium (ppm) in cattle liver

Withdrawal	Rep 1	Rep 2	Mean
0	0.118	0.115	0.1165
0	0.0444	0.0582	0.0513
0	0.0873	0.0821	0.0847
0	0.112	0.113	0.1125
0	0.134	0.175	0.1545
0	0.139	0.141	0.140
0	0.234	0.234	0.234
0	0.0968	0.125	0.1109
0	0.129	0.134	0.1315
0	0.139	0.141	0.140
Total Mean	**0.1234**	**0.1318**	**0.1276**
SD*	-	-	**0.0479**
***k* factor (n = 10)**	-	-	**4.433**
UTL†	-	-	**0.339**

* SD refers to standard deviation of the mean
† Upper tolerance limit

A single-timepoint UTL (99th percentile of the population and the 95 percent confidence level) was calculated using the data at the practical zero withdrawal timepoint. Using a *k* factor of 4.433 (n = 10), an upper tolerance limit of 0.34 ppm was calculated, which is below the 0.5 ppm tolerance. Therefore, the data support assignment of a zero-day withdrawal period.

2. Target Tissue and Marker Residue

No marker residue or target tissue is codified under 21 CFR §556.50. Data from previous approvals of amprolium were used to support a justification to only analyze amprolium residues in cattle liver for determination of a withdrawal period.

3. Tolerances

The tolerances for amprolium in cattle tissues are 0.5 ppm in liver, kidney, and muscle, and 2.0 ppm in fat (21 CFR §556.50).

4. Withdrawal Period

Based on a cattle liver tolerance of 0.5 ppm, data from Study Number AM-RSCB-1803 summarized above support assignment of a zero-day withdrawal period for the use of amprolium when used according to label directions.

D. Analytical Method for Residues

1. Description of Analytical Method

   The analytical method for determination of amprolium residues in bovine liver tissue is an adaptation of the Official Method #383 (Merck, Sharp & Dohme – March 13, 1978) originally developed for amprolium analysis in chicken tissues. The method utilizes fluorescence detection.

2. Availability of the Method

   The validated analytical method for analysis of residues of amprolium is on file at the Center for Veterinary Medicine, CPK1, 5001 Campus Drive, College Park, MD 20740.

   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.

V. USER SAFETY

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

Not for human use. Keep this and all drugs out of the reach of children.

VI. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR part 514. The data demonstrate that CORID®, when used according to the label, is safe and effective for the effect of the supplement in the General Information Section above. Additionally, data demonstrate that residues in food products derived from species treated with CORID® will not represent a public health concern when the product is used according to the label.

A. Marketing Status

This product can be marketed over the counter (OTC) because the approved labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.

B. Exclusivity

CORID®, as approved in our approval letter, does not qualify for marketing exclusivity under section 512(c)(2)(F) of the FD&C Act.

C. Supplemental Applications

This supplement is a Category II supplement as defined in (21 CFR 514.106(b)(2)). This supplemental approval required a reevaluation of certain safety or effectiveness data in the application.

D. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.