

Date of Approval: May 23, 2011

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION

ANADA 200-464

AMPROMED For Calves
(amprolium)
20% Soluble Powder

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

Sponsored by:

Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

- A. File Number:** ANADA 200-464
- B. Sponsor:** Cross Vetpharm Group Ltd.
Broomhill Rd., Tallaght
Dublin 24, Ireland
- Drug Labeler Code: 061623
- U.S. Agent:
Linda M. Duple
Bimeda, Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557
- C. Proprietary Name:** AMPROMED For Calves
- D. Established Name:** Amprolium
- E. Pharmacological Category:** Anticoccidial
- F. Dosage Form:** Soluble powder
- G. Amount of Active Ingredient:** 200 mg/g (20%)
- H. How Supplied:** 10 oz packet and 25 lb pail
- I. How Dispensed:** OTC
- J. Dosages:** 5-Day Treatment Protocol
Daily Dosage: 10 mg/kg
(10 mg per 2.2 lb body weight) 1oz = 3 ½
tablespoonfuls
- 21-Day Prevention Protocol
Daily Dosage: 5 mg/kg
(5 mg per 2.2 lb body weight) 1oz = 28.35 grams
- K. Route(s) of Administration:** Oral
- L. Species/Class:** Cattle/calves

- M. Indications:** As 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 033-165; Huvepharma AD.

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 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 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, Cross Vetpharm Group Ltd., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product AMPROMED (amprolium) For Calves 20% soluble powder. The generic product is administered soluble powder, 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 absorption of the active ingredient. The RLNAD is CORID (amprolium) 20% soluble powder, sponsored by Huvepharma AD, under NADA 033-165, and was approved for use in calves on November 4, 1966.

III. HUMAN FOOD SAFETY:

The following are assigned to this product for calves:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance of 2.0 parts per million (ppm) in uncooked fat, 0.5 ppm in uncooked muscle tissue, liver, and kidney, is established for amprolium hydrochloride under 21 CFR 556.50.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

A withdrawal period of 24 hours has been established for amprolium hydrochloride in pre-ruminating calves.

- **Regulatory Method for Residues:**

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

IV. USER SAFETY:

Human warnings are provided on the product label as follows: “KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.”

V. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfy the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that AMPROMED For Calves, when used according to the label, is safe and effective as an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves.