

Date of Approval: May 23, 2011

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-488

AMPROMED P For Poultry

(amprolium)

20% Soluble powder

Growing chickens, turkeys, and laying hens

Indications: Intended for the treatment of coccidiosis in growing chickens, turkeys, and laying hens.

Sponsored by:

Cross Vetpharm Group Ltd.

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**I. GENERAL INFORMATION:**

- A. File Number:** ANADA 200-488
- 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 P For Poultry
- 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 pouches and 25 lb pail
- I. How Dispensed:** OTC
- J. Dosages:** For use in automatic water proportioners that meter 1 fluid ounce of stock solution per gallon of drinking water.
- To prepare dosage level of**
- |  |                   |
|--|-------------------|
| Dissolve AMPROMED P For Poultry 20% soluble powder in one gallon of water. (Makes 1 gallon of stock solution.) |                   |
| 0.024%   | 20 oz in 1 gallon |
| 0.012%   | 10 oz in 1 gallon |
| 0.006%   | 5 oz in 1 gallon  |

**To prepare 50 Gallons of Medicated Water:**

DOSAGE LEVEL	MIXING DIRECTIONS
0.024%	Dissolve 8 ounces of AMPROMED P For Poultry 20% soluble powder in about 5 gallons of water in a 50-gallon medicated barrel. Stir, then add water to the 50-gallon mark. Stir thoroughly.
0.012%	Follow same directions as above but use 4 ounces of AMPROMED P For Poultry 20% soluble powder
0.006%	Follow same directions as above but use 2 ounces of AMPROMED P For Poultry 20% soluble powder

**Note:** Make drinking water daily. Stock solutions for proportioners may be stored in a clean, closed labeled container for up to 3 days.

**K. Route of Administration:**

Oral

**L. Species/Classes:**

Growing chickens, turkeys, and laying hens

**M. Indication:**

Intended for the treatment of coccidiosis in growing chickens, turkeys and laying hens.

**N. Reference listed new animal drug (RLNAD):**

AMPROL 128; 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 P (amprolium) For Poultry, 20% soluble powder. The generic product is administered orally, 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 AMPROL 128 (amprolium), 20% soluble powder, sponsored by Huvepharma AD, under NADA 033-165, and was approved for use in growing chickens, turkeys and laying hens on November 4, 1966.

**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:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance, in the edible tissues and eggs of chickens and turkeys, of 1 part per million (ppm) in the uncooked liver and kidney; 0.5 ppm in uncooked muscle tissue; and in eggs, 8 ppm in egg yolks and 4 ppm in whole egg under 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 0 days has been established for amprolium hydrochloride in chickens and turkeys.

- **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.

## **VI. USER SAFETY:**

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

## **VII. 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 P For Poultry, when used according to the label, is safe and effective for the treatment of coccidiosis in growing chickens, turkeys, and laying hens.