Approval Date: September 6, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-389

Amprolium 9.6% Oral Solution (amprolium)

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

Sponsored by:

IVX Animal Health, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-389
b. Sponsor:	IVX Animal Health, Inc. 3915 South 48th Street Ter. St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Amprolium
d. Proprietary Name:	Amprolium 9.6% Oral Solution
e. Dosage Form:	Oral Solution
f. How Supplied:	32 fl. oz. (1 quart bottle) (946 mL) 64 fl. oz. (half gallon) (1.89 L) 128 fl oz. (1 gal) (3.785 L)
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	9.6% amprolium
i. Route of Administration:	Oral
j. Species/Class:	Calves
k. Recommended Dosage:	In drinking water for *treatment*: Add Amprolium 9.6% Oral Solution to drinking water at the rate of 16 fl oz/100 gallons. This will provide an intake of approximately 10 mg amprolium/kg (2.2 lb) body weight. Offer as the only source of drinking water for 5 days. In drinking water for *prevention*: Add Amprolium 9.6% Oral Solution to drinking water at the rate of 8 fl oz/100 gallons. This will provide an intake of approximately 5 mg amprolium/kg (2.2 lb). Offer as the only source of drinking water for 21 days.

As a drench for *treatment*: Add 3 fl oz Amprolium 9.6% Oral Solution to 1 pint of water and, with a dose syringe, give 1 fl oz of this solution for each 100 lb (45 kg) body weight. This will provide a dose of approximately 10 mg amprolium/kg (2.2 lb). Give daily for 5 days.

As a drench for *prevention*: Add 1-½ fl oz of Amprolium 9.6% Oral Solution to 1 pint of water and, with a dose syringe, give 1 fl oz of this solution for each 100 lb (45 kg) body weight. This will provide a dose of approximately 5 mg amprolium/kg (2.2 lb). Give daily for 21 days.

Make drinking water fresh daily. Drench solutions may be stored in a clean, closed, labeled container for up to 3 days.

l. Pharmacological Category:	Coccidiostat
m. Indications:	As an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* in calves
n. Pioneer Product:	CORID9.6% Oral Solution; amprolium; Merial, Ltd., NADA 013-149

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

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 (pioneer product). 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 pioneer, 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, IVX Animal Health, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Amprolium 9.6% Oral Solution. The generic product is administered as an oral solution, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, CORID 9.6% Oral Solution the subject of Merial Ltd., NADA 013-149, was approved on June 20, 1962.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance 2.0 parts per million in uncooked fat and 0.5 part per million in uncooked muscle tissue, liver, and kidney in calves are established for amprolium 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 (21 CFR 520.100).

  The withdrawal time is 24 hours before slaughter.

- **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.

4. AGENCY CONCLUSIONS:

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Amprolium 9.6% Oral Solution, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:
Generic Labeling for ANADA 200-389:
Product label 32 fl. oz. (946 mL)
Product label 64 fl. oz. (1.89 L)
Product label 128 fl. oz. (3.785 L)

Pioneer Labeling for NADA 013-149:
Product label 1 gal. (3,785 mL)