Approval Date: February 12, 2009

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-463

Amprolium-P 9.6% Oral Solution (amprolium)

The treatment of coccidiosis in growing chickens, turkeys and laying hens.

Sponsored by:

IVX Animal Health, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-463
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-P 9.6% Oral Solution
e. Dosage Form:	Oral solution
f. How Supplied:	32 fl oz (946 mL) 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:	Growing chickens, turkeys and laying hens
k. Recommended Dosage:	Give amprolium at the 0.012% level (8 fl oz per 50 gallons) as soon as coccidiosis is diagnosed and continue for 3 to 5 days. (In severe outbreaks, give amprolium at the 0.024% level.) Continue with 0.006% amprolium medicated water for an additional 1 to 2 weeks. No other source of drinking water should be available to the birds during this time. Use as the source of amprolium. Make drinking water fresh daily. Stock solutions for proportioners may be stored in a clean, closed labeled container for up to 3 days.
l. Pharmacological Category:	Coccidiostat

m. Indications:	The treatment of coccidiosis in growing chickens, turkeys and laying hens.
n. Pioneer Product:	AMPROL 9.6% Oral Solution; amprolium; NADA 013-149; Huvepharma, AD

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-P (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, AMPROL (amprolium) 9.6% Oral Solution the subject of Huvepharma, AD, 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. Tolerances are established as follows for residues of amprolium (1-(4-amino-2n-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride) under 21 CR 556.50:
  (a) In edible tissues and in eggs of chickens and turkeys:
    (1) 1 part per million in uncooked liver and kidney.
    (2) 0.5 part per million in uncooked muscle tissue.
    (3) In eggs:
      (i) 8 parts per million in egg yolks.
      (ii) 4 parts per million in whole egg.

- **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).

  No withdrawal time 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 original 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-P 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 200-463:
Product label 32 fl oz (946 mL)
Product label 128 fl oz (3.785 L)

Pioneer Labeling for NADA 013-149:
Product label 16 fl oz (473 mL)