Date of Approval: July 25, 2003

FREEDOM OF INFORMATION SUMMARY

AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-304

PRITOX™
(37.5% w/w Copper Naphthenate)

Equine Antimicrobial

As an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.

Sponsored by:

First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-304
b. Sponsor:	First Priority, Inc. 1585 Todd Farm Drive Elgin, IL 60123 Drug Labeler Code: 058829
c. Established Name:	Copper naphthenate solution
d. Proprietary Name:	Pritox™
e. Dosage Form:	Solution
f. How Supplied:	8 oz (236 mL) & 16 oz (473 mL) cylinders
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	37.5 % w/w copper naphthenate
i. Route of Administration:	Topical
j. Species/Class:	Ponies & horses
k. Recommended Dosage:	Clean the hoof thoroughly, removing debris and necrotic material prior to application of Pritox™. Apply daily to affected hoofs until fully healed.
l. Pharmacological Category:	Antimicrobial
m. Indications:	As an aid in treating horses and ponies with thrush due to organisms susceptible to copper naphthenate.
n. Pioneer Product:	Kopertox™; copper naphthenate; NADA 012-991; Fort Dodge Animal Health

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 (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter), 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. The requirements for the *in vivo* blood level bioequivalence study may be waived for certain generic products. Upon approval, an ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. ANADAs for drug products for food-producing animals will generally be required to include *in vivo* bioequivalence and tissue residue studies. If a waiver of the *in vivo* bioequivalence and/or tissue residue study is granted for a food animal product, then the withdrawal period established for the pioneer product will be assigned to the generic product. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on August 16, 1999, from the requirement for an *in vivo* bioequivalence study for the generic product, Pritox™ (copper naphthenate). The generic and pioneer products contain the same active ingredient in the same concentration and are topical solutions for application to hoofs of horses and ponies as an aid in treating thrush due to organisms susceptible to copper naphthenate. The pioneer product Kopertox™ (copper naphthenate), the subject of Fort Dodge Animal Health (NADA 012-991), was approved on May 8, 1962.

3. HUMAN SAFETY:

This drug is indicated for use only in horses and ponies, which are non-food animals. Since this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human warning statements are provided on the product label as follows: "**KEEP OUT OF REACH OF CHILDREN AND PETS**." "**CAUTION: Do not use on animals intended for food production.**" "**Not for use on horses intended for food.**" "**CAUTION: COMBUSTIBLE MIXTURE Use in a well-ventilated place. Avoid fire, flame, sparks or heaters. If swallowed, do not induce vomiting, call physician immediately Avoid breathing vapor. Avoid contact with skin and eyes.**"

4. AGENCY CONCLUSIONS:

This ANADA filed 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 Pritox™, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Pioneer Labeling for NADA 012-991:
Kopertox™ (37.5 % copper naphthenate in a suitable solvent)
1 – Container Label 16 oz (473 mL); 1 – Container Label 8 oz (236 mL)

Generic Labeling for ANADA 200-304:
Pritox™ (37.5 % copper naphthenate in a suitable solvent)
1 – Cylinder Label 16 oz (473 mL); 1 – Cylinder Label 8 oz (236 mL)