Approval Date: November 14, 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-362

PRICONAZOLE Lotion, 1% and Spray, 1%
(miconazole nitrate)

Indications for use: for the topical treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

Sponsored by:

First Priority, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-362
b. Sponsor:	First Priority, Inc. 1585 Todd Farm Dr. Elgin, IL 60123 Drug Labeler Code: 058829
c. Established Name:	Miconazole nitrate
d. Proprietary Name:	PRICONAZOLE Lotion, 1% PRICONAZOLE Spray, 1%
e. Dosage Form:	Liquid and Spray
f. How Supplied:	Lotion, 1%: 30 mL and 60 mL bottles Spray, 1%: 120 mL and 240 mL bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Lotion: 1.15% of miconazole nitrate (equivalent to 1% of miconazole base by weight). Spray: 1.15% of miconazole nitrate (equivalent to 1% of miconazole base by weight).
i. Route of Administration:	Topical
j. Species/Class:	Dogs and cats
k. Recommended Dosage:	Apply a light covering to affected areas, once daily for 2 to 4 weeks.
l. Pharmacological Category:	Antifungal
m. Indications:	PRICONAZOLE (miconazole nitrate) Lotion, 1% and Spray, 1% are indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

n. Pioneer Product: CONOFITE Lotion 1% and Spray, 1%; miconazole nitrate, NADA 095-184; Schering-Plough Animal Health Corp.

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 shows 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, First Priority, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product PRICONAZOLE (miconazole nitrate) Lotion, 1% and Spray, 1%. The generic product is administered as a topical spray or lotion, 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, CONOFITE (miconazole nitrate) Lotion, 1% and Spray, 1%, the subject of Schering-Plough Animal Health Corp. (NADA 095-184), was approved on September 30, 1974.

3. HUMAN SAFETY:

This drug is indicated for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in 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 labeling as follows: **"Keep out of the reach of children.**

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that PRICONAZOLE (miconazole nitrate) Lotion, 1% and Spray, 1%, when used under their proposed conditions of use, they are 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 200-362:
PRICONAZOLE Lotion, 1% (miconazole nitrate) 30 mL (1 fl. oz.) label
PRICONAZOLE Lotion, 1% (miconazole nitrate) 60 mL (2 fl. oz.) label
PRICONAZOLE Spray, 1% (miconazole nitrate) 120 mL (4 fl. oz.) label
PRICONAZOLE Spray, 1% (miconazole nitrate) 240 mL (16 fl. oz.) label
PRICONAZOLE Lotion, 1% and Spray, 1% (miconazole nitrate) Package Insert

Pioneer Labeling for NADA 95-184:
CONOFITE Lotion, 1% (miconazole nitrate) 30 mL label
CONOFITE Spray, 1% (miconazole nitrate) 60 mL label
CONOFITE Lotion, 1% and Spray, 1% (miconazole nitrate) Package Insert