Date of Approval: August 20, 2003

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-352

PRIMEX Canine-2X and PRIMEX Canine (pyrantel pamoate)

Anthelmintic Suspension

For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

Sponsored by:

First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-352
b. Sponsor:	First Priority, Inc. 1585 Todd Farm Drive Elgin, IL 60123-1146 Drug Labeler Code: 058829
c. Established Name:	Pyrantel pamoate
d. Proprietary Names:	PRIMEX Canine-2X and PRIMEX Canine
e. Dosage Form:	Suspension
f. How Supplied:	PRIMEX Canine-2X: 60 mL and 473 mL containers PRIMEX Canine: 60 mL containers
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	PRIMEX Canine-2X: 4.54 milligrams of pyrantel base as pyrantel pamoate per mL. PRIMEX Canine: 2.27 milligrams of pyrantel base as pyrantel pamoate per mL.
i. Route of Administration:	Oral
j. Species/Class:	Dogs and puppies
k. Recommended Dosage:	PRIMEX Canine-2X: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight. PRIMEX Canine: Administer 1 full teaspoon (5 mL) for each 5 lb of body weight.
l. Pharmacological Category:	Anthelmintic
m Indications:	For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala)* in dogs and puppies. To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

n. Pioneer Product: NEMEX-2 and RFD (pyrantel pamoate); NADA 100-237; Pfizer, Inc.

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) 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, First Priority, Inc. was granted a waiver on July 3, 2001, from the requirement for an *in vivo* bioequivalence study for the generic products PRIMEX Canine-2X and PRIMEX Canine (pyrantel pamoate). The generic products are administered as an oral suspension, contain the same active ingredient in the same concentration and dosage form as the pioneer products, and contain no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer products NEMEX-2 and RFD (pyrantel pamoate), manufactured by Pfizer, Inc. (NADA 100-237), were approved on June 3, 1977.

3. HUMAN FOOD SAFETY:

This drug is intended for use in dogs and puppies, which are non-food animals. Because 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 food safety and human exposure warnings are provided on the product label as follows: "**For Animal Use Only • Keep Out of Reach of Children**."

4. AGENCY CONCLUSIONS:

This 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 PRIMEX Canine-2X and PRIMEX Canine, when used under their proposed conditions of use, are safe and effective when used for their labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-352:
PRIMEX Canine-2X (pyrantel pamoate), 4.54 mg/mL
1 – 60 mL and 1 – 473 mL container labels with accompanying insert
1 – 60 mL box label
PRIMEX Canine (pyrantel pamoate), 2.27 mg/mL.
1 – 60 mL container label with accompanying insert
1 – 60 mL box label

Pioneer Labeling for NADA 100-237:
Pfizer Inc.'s NEMEX-2 (pyrantel pamoate), 4.54 mg/mL
1 – 60 mL and 1 – 473 mL container labels with accompanying insert
1 – 60 mL box label
Pfizer's RFD (pyrantel pamoate), 2.27 mg/mL
1 – 60 mL container label with accompanying insert
1 – 60 mL box label