

Date of Approval: August 19, 2003

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION (ANADA)**

ANADA 200-353

PRIMEX Equine
(50 mg of pyrantel base as pyrantel pamoate per mL)

Anthelmintic Suspension

For the removal and control of mature large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pin worms (*Oxyuris equi*); large roundworms (*Parascaris equorum*) and small strongyles in horses and ponies.

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-353
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146

Drug Labeler Code: 058829
- c. Established Name: Pyrantel pamoate
- d. Proprietary Name: PRIMEX Equine
- e. Dosage Form: Suspension
- f. How Supplied: 32 fl. oz. (960 mL) bottle
- g. How Dispensed: Rx
- h. Amount of Active Ingredient: 50 milligrams of pyrantel base as pyrantel pamoate per mL.
- i. Route of Administration: Oral
- j. Species/Class: Horses and ponies
- k. Recommended Dosage: Administer 3 mg pyrantel base per pound of body weight (6 mL PRIMEX Equine per 100 lb body weight).
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the removal and control of mature large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pin worms (*Oxyuris equi*); large roundworms (*Parascaris equorum*) and small strongyles in horses and ponies.
- n. Pioneer Product: STRONGID T (pyrantel pamoate); NADA 91-739; 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 from the requirements for an *in vivo* bioequivalence study for the generic product PRIMEX Equine (pyrantel pamoate). The generic product is administered as an oral suspension, contains the same active ingredient 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 STRONGID T (pyrantel pamoate), NADA 91-739, was approved on October 19, 1973.

3. HUMAN FOOD SAFETY:

This drug is indicated for use only in horses and ponies, 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 warning statements are provided on the product label as follows: **“For Animal Use Only • Keep Out of Reach of Children.” “Not For Horses Or Ponies Intended For Food.”**

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 PRIMEX Equine, 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 indicated below:

Generic Labeling for ANADA 200-353:

PRIMEX Equine, 50 mg of pyrantel base as pyrantel pamoate per mL
1 – 32 fl oz (960 mL) container label with accompanying package insert.

Pioneer Labeling for NADA 91-739:

Pfizer Inc.'s STRONGID T, 50 mg of pyrantel base as pyrantel pamoate per mL.
1 – Quart (946 mL) container label with accompanying package insert.