

Date of Approval: November 3, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-445

For Over-The-Counter Use of
PRIMEX Equine Liquid Wormer
(pyrantel pamoate)

Equine Anthelmintic

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

Sponsored by:

First Priority, Inc.

1. GENERAL INFORMATION:

- a. ANADA Number: ANADA 200-445
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Dr.
Elgin, IL 60123

Drug Labeler Code: 058829
- c. Established Name: Pyrantel pamoate
- d. Proprietary Name: PRIMEX Equine Liquid Wormer
- e. Dosage Form: Suspension
- f. How Supplied: 16 fl oz (473 mL) bottle
32 fl oz (946 mL) bottle
- g. How Dispensed: OTC
- 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 infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*) and small strongyles in horses and ponies.
- n. Pioneer Product: PAMOBAN Horse Wormer; 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) 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 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 Guidance, revised 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 PRIMEX (pyrantel pamoate) Equine Anthelmintic Suspension. The generic product is administered as an oral suspension, contains similar 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 PAMOBAN (pyrantel pamoate) Horse Wormer (OTC), the subject of Pfizer, Inc., NADA 091-739, was approved on July 6, 1976.

3. HUMAN SAFETY:

This drug is intended for use in horses, 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 Warnings are provided on the product label as follows: **“Keep Out of Reach of Children”** and **“For Animal Use Only”**

4. AGENCY CONCLUSIONS:

This ANADA filed 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 Liquid Wormer, 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 200-445:

PRIMEX Equine Liquid Wormer product label (473 mL)

PRIMEX Equine Liquid Wormer product label (946 mL)

PRIMEX Equine Liquid Wormer package insert

Pioneer Labeling for NADA 091-739:

PAMOBAN Horse Wormer

Bottle label (60 mL)

Box label