Date of Approval: August 19, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-246

For Over-The-Counter Use of

Pyrantel Pamoate Equine Anthelmintic Suspension

(pyrantel pamoate)

50 mg pyrantel base as pyrantel pamoate per mL

Equine Anthelmintic

Indications for use: 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:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-246
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th Street Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Pyrantel pamoate
d. Proprietary Name:	Pyrantel Pamoate Equine Anthelmintic Suspension
e. Dosage Form:	Liquid Suspension
f. How Supplied:	16 oz and 32 oz HDPE bottles
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each mL contains 50 mg pyrantel base as pyrantel pamoate
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 Pyrantel Pamoate per 100 lb body weight]. Administer by means of a dose syringe or by mixing into the feed. It is recommended that severely debilitated animals not be treated with this preparation.
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 091-739; Pfizer, Inc.

o. Effect of Supplement:	Pyrantel Pamoate Equine Anthelmintic Suspension for horses is a supplement to the original ANADA 200-246 for the prescription product Anthelban V (pyrantel pamoate). This supplement provides for the over-the-counter use of Pyrantel Pamoate Equine Anthelmintic Suspension, an identical formulation to Anthelban V labeled for the same conditions of use, except administration by stomach tube.

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. 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, Phoenix Scientific, Inc. was granted a waiver on June 25, 1997, from the requirement of an *in vivo* bioequivalence study for Anthelban V (JINAD 10038 A0001). The waiver applies equally to the OTC label for the identical formulation, Pyrantel Pamoate Equine Anthelmintic Suspension. This product is a generic copy of Pfizer Inc.'s Pamoban™ Horse Wormer (OTC), NADA 091-739 (50 mg/mL pyrantel base as pyrantel pamoate). The generic and pioneer products contain the same active ingredients and are liquid suspensions intended for use in horses by the oral route of administration. The pioneer product, Pamoban™ Horse Wormer (OTC), sponsored by Pfizer Inc. (NADA 091-739), was approved on July 6, 1976.

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.

Labeling contains adequate caution/warning statements. Human Warnings are provided on the product label as follows: "Keep out of reach of children." "Not for horses or ponies intended for food."

4. AGENCY CONCLUSIONS:

This abbreviated new animal drug application (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 Pyrantel Pamoate Equine Anthelmintic Suspension, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Pioneer Labeling for NADA 091-739:
Pamoban™ Horse Wormer (50 mg/mL pyrantel base as pyrantel pamoate)
1 – Bottle Label (60 mL); 1 – Box Label

Generic Labeling for ANADA 200-246:
Pyrantel Pamoate Equine Anthelmintic Suspension (50 mg/mL pyrantel base as pyrantel pamoate)
1 – Package Insert; 1 – Bottle Label (946 mL); 1 – Bottle Label (473 mL)