Date of Approval: January 22, 2003

FREEDOM OF INFORMATION (FOI) SUMMARY

Pyrantel Pamoate Paste

Equine Anthelmintic Paste

ANADA 200-342

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

St. Joseph, MO 64503

1. GENERAL INFORMATION

ANADA :	200-342
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace St. Joseph, MO 64503 Drug Labeler Code 059130
Generic Name:	Pyrantel Pamoate Paste
Trade Name:	Pyrantel Pamoate Paste
Dosage Form:	Oral Paste
How Supplied:	15.9 mL in 36 mL syringe
How Dispensed:	OTC
Amount of Active Ingredients:	19.13%
Route of Administration	Oral
Species:	Horses
Labeled Dosage:	3 mg pyrantel base per pound of body weight
Indications for Use:	Pyrantel Pamoate Paste is indicated for the removal and control of mature infections of the following parasites: **Large Strongyles**: *Strongylus vulgaris* *S. edentatus S. equinus* **Small Strongyles** **Pinworms** *Oxyuris equi* **Large Roundworms** *Parascaris equorum*
Pioneer Product: (Listed Product):	Strongid® Paste (Pyrantel Pamoate) NADA 129-831 (Pfizer Animal Health)

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 grants a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline October 2000).

This ANADA approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

Bioequivalence Study
PSI -0690-00E-005

Title:	Controlled Bioequivalence Study of Generic Pyrantel Pamoate Paste (PSI) and Strongid® Paste in Horses
Study Location(s):	East Tennessee Clinical Research, Inc. 1717 Western Avenue Knoxville, Tennessee 37921 Copper Ridge Farm 80 Copper Ridge Farm Road Rockwood, Tennessee 37854

Summary: Animals with historical evidence of naturally acquired infections of *Strongylus edentatus* and *Cyathostomum catinatum* were observed and acclimated for 14 days prior to study start. After meeting entrance criteria, 36 horses were ranked in decreasing order by body weight. Each three consecutive horses comprised a replicate set (for a total of 12 replicates). Within each replicate, treatments were assigned completely at random and were equally represented. Animals assigned to treatment group 1 received the test article (PSI generic

pyrantel pamoate paste) at 6.6 mg pyrantel base per kilogram body weight. Animals assigned to treatment group 2 received the positive control (Pfizer Strongid® Paste) at 6.6 mg/kg. Animals assigned to treatment group 3 were untreated controls.

Clinical observations were conducted prior to treatment and between 6-8 hours after treatment on day 0. Thereafter, observations for general health and adverse events were conducted once daily until necropsy on Days 10, 11 and 12. The various organs of the large intestine were separated, opened longitudinally, and the contents were collected in a large container. All attached parasites (e.g., large strongyles) were collected and placed in labeled containers of 10% formalin. The contents of the organs and washings were combined and mixed thoroughly. Duplicate 10% and duplicate 1% aliquots of intestinal contents were collected and preserved with formalin for enumeration of adult *Strongylus edentatus* and *Cyathostomum catinatum*, respectively.

Adult *S. edentatus* were found in all 12 horses of treatment group 3 (untreated controls). The percent efficiency of the treatment group 1 (test article) was calculated as 90%, and the percent efficiency of treatment group 2 (positive control) was calculated as 92%.

Adult *C. catinatum* were found in 11 of 12 horses of treatment group 3 (untreated controls). The percent efficiency of the treatment group 1 (test article) was calculated as 99.9%, and the percent efficiency of treatment group 2 (positive control) was calculated as 100%.

As both the test article (PSI Pyrantel Paste) and the positive control (Pfizer Strongid® Paste) were found to be greater than or equal to 90% effective against both *S. edentatus* and *C. catinatum*, no further statistical evaluation was necessary. Phoenix Scientific Inc.'s Pyrantel Pamoate Paste and Pfizer's Strongid® Paste are considered bioequivalent when administered as an intended oral dosage of 6.6 mg pyrantel base per kg body weight under controlled conditions.

3. HUMAN SAFETY

Human Safety Relative to Food Consumption:

None required as Pyrantel Pamoate Paste is intended for use only in horses. The labeling includes the statement, **"WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD".**

Human Safety Relative to Possession, Handling, and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Pyrantel Pamoate Paste, were established by demonstration of bioequivalence to the pioneer product, Strongid® Paste (NADA 129-831, Pfizer).

This generic product and the pioneer product have identical labeling indications for use in horses. The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active ingredients.

This ANADA satisfies the requirements of section 512(n) of the Act and demonstrates that Pyrantel Pamoate Paste is safe and effective for its labeled indications when used under its proposed conditions of use.

5. Attachments:

1. **Generic labeling:**
   Package Insert-onsert
   Syringe Label-18.8g (15.0mL)
   Display Label-6x18.8g (15.9mL)

2. **Pioneer Labeling**
   Package Insert
   Syringe Label-20 mL (23.6g)
   Carton Label