Date of Approval: June 18, 1998

FREEDOM OF INFORMATION (FOI) SUMMARY

Anthelban V (pyrantel pamoate)

Equine Anthelmintic Suspension

ANADA 200-246

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

P.O. Box 6457

St. Joseph, MO 64506-0457

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

ANADA Number:	200-246
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace P.O. Box 6457 St. Joseph, MO 64506-0457
Generic Name:	Pyrantel Pamoate USP
Trade Name:	Anthelban V (pyrantel pamoate)
Dosage Form:	Oral Suspension
How Supplied:	16 oz and 32 oz HDPE bottles
How Dispensed:	Rx
Amount of Active Ingredients:	Each mL contains: 50 mg Pyrantel(base) as Pyrantel Pamoate
Route of Administration:	Oral
Species:	Equine (ONLY)

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.

Labeled Dosage:

Administer 3 mg pyrantel base per pound of body weight (6 mL Anthelban V (pyrantel pamoate) per 100 lb body weight). It is recommended that severely debilitated animals not be treated with this preparation.

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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Approval of an ANADA requires that the sponsor show that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Phoenix Scientific Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Pyrantel Pamoate Oral Suspension. The generic product is administered as an oral suspension and contains the same active and inactive ingredients in the same concentration as the pioneer product.

3. HUMAN FOOD SAFETY

The product is labeled for use in horses only. The label includes the statement: WARNING NOT FOR HORSES OR PONIES INTENDED FOR FOOD.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSION:

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 Anthelban V (pyrantel pamoate oral suspension) when used under its proposed conditions of use, is safe and effective for the labeled indications.

Atachment: Generic and pioneer labeling