FREEDOM OF INFORMATION (FOI) SUMMARY

Continuex™ (pyrantel tartrate)

ANADA 200-282

Farnam Companies, Inc.

301 W. Osborn Road

Phoenix, AZ 85013-3928

Date of Approval: September 26, 2000

Freedom of Information Summary

I. GENERAL INFORMATION

ANADA Number: **200-282**

Sponsor: Farnam Companies, Inc.
301 W. Osborn Road
Phoenix, AZ 85013-3928

Generic Name: Pyrantel tartrate

Trade Name: Continuex™

Marketing Status: OTC

Species: Equine

II. Indications for Use

For the prevention of *Stongylys vulgaris* larval infections in horses.

For control of the following parasites in horses:

LARGE STRONGYLES (adults) *S. vulgaris, S. edentatus, Triodontophorus* spp
SMALL STRONGYLES (adult and forth-stage larvae) *Cyathostomum* spp. *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.
PINWORMS (adult and fourth-stage larvae) *Oxyuris equi*
ASCARIDS (adule and fourth-stage larvae) *Parascaris equorum*

Pioneer Product: Strongid 48 (pyrantel tartrate), Pfizer, Inc. (NADA 140-819)

III. Dosage Form:

Pyrantel tartrate is a Type A Medicated Article [concentration of 10.6% (48 grams per pound)] as pyrantel tartrate. To be used in formulating Type B medicated feeds (finished formulation) which are pelleted [concentration of 2.11% (9.6 grams per pound)].

Route of Administration

To be administered orally in the feed as either a top dress or mixed in the horses daily grain ration.

Recommended Dosage

Pyrantel tartrate is to be administered on a daily basis at the rate of 1.2 mg/lb (2.64 mg/kg) body weight daily. The duration of administration is for the period during which the animal is at risk of exposure to internal parasites.

IV. 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. An ANADA relies on the target animal safety, drug effectiveness and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will be required to include bioequivalence and residue studies. A tissue residue study will generally be required to accompany a clinical end-point, pharmacologic end-point, or blood level bioequivalence study that can not quantify the concentration of the drug in the blood through out the established withdrawal peroid. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalency study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalency Guideline, April 1996).

Based on the formulation characteristics of the generic product, Farnam Companies, Inc. was granted a waiver April 1, 1998, from conducting an in vivo bioequivalence study with pyrantel tartrate.

IV. HUMAN FOOD SAFETY

The drug is labeled: "Not for use in horses intended for food." Data on human food safety were not required for approval of this Abbreviated New Animal Drug Application.

V. AGENCY CONCLUSIONS

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 Continuex (pyrantel tartrate medicated feed) when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachment: Generic and pioneer labeling.

Type A

Type B