Date of Approval: October 16, 2002

FREEDOM OF INFORMATION SUMMARY

Original ANADA 200-176

PRAZITECH™ Injection

(Dogs and cats)

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-176
Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th ST. Terrace St. Joseph, MO 64503
Generic Name:	Praziquantel
Trade Name:	PRAZITECH™ Injection
Dosage Form:	Injectable
How Supplied:	10 & 50 mL bottles
How Dispensed:	Rx
Amount of Active Ingredients:	56.8 mg/mL praziquantel
Route of Administration:	IM or SC
Species:	Dogs and cats
Pharmacological Category:	Cestocide

Indication and Dosage:

Dogs: 5 lbs. and under-0.3 mL
6-10 lbs-0.5 mL
11-25 lbs. -1.0 mL
Cats: Under 5-lbs. -0.2 mL
5-10 lbs-0.4 mL
11 lbs. and over 0.6 mL maximum

	Praziquantel Injection is indicated for the removal of the following canine and/or feline cestodes. Dogs: *Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus* and *Echincocccus multilocularis*. Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.
Pioneer Product/ Listed Product:	Droncit® Injectable NADA 111-607 Bayer Corporation

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 data 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 Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for PRAZITECH™ Injection (praziquantel). The generic and pioneer products are solutions that contain the same active and inactive ingredients in the same concentrations.

3. HUMAN SAFETY:

PRAZITECH™ Injection is intended for use only in dogs and cats, 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.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application 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 PRAZITECH™, when used under the proposed conditions of use, is safe and effective for the labeled indications.

5. LABELING:

Attachments: Pioneer Labeling:

Package Insert for Droncit®
10 mL & 50 mL bottle labels

Generic Labeling:

Package Insert for PRAZITECT™
10 mL & 50 mL bottle labels

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.