

Date of Approval: September 15, 2004

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-265

Prazi-C Tablets
(praziquantel)
34 mg/tablet

OTC Cestocide for use in Dogs and Puppies

For the removal of the *Dipylidium caninum* and *Taenia pisiformis*.

Sponsored by:
Phoenix Scientific, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-265
- b. Sponsor: Phoenix Scientific, Inc.
3915 South 48th St. Terrace
St. Joseph, MO 64503

Drug Labeler Code: 059130
- c. Established Name: Praziquantel
- d. Proprietary Name: Prazi-C Tablets
- e. Dosage Form: Tablets
- f. How Supplied: 5, 10, or 50 tablets in HDPE bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 34 mg of praziquantel per tablet
- i. Route of Administration: Oral
- j. Species/Class: Dogs and puppies
- k. Recommended Dosage: Tablets may be administered directly per os or crumbled and mixed with feed:

5 lbs. & under	0.5 tablet
6-10 lbs.	1 tablet
11-15 lbs.	1.5 tablets
16-30 lbs.	2 tablets
31-45 lbs.	3 tablets
46-60 lbs.	4 tablets
Over 60 lbs.	5 tablets max

Not intended for use in puppies less than 4 weeks of age. FASTING IS NEITHER NECESSARY NOR RECOMMENDED.

- l. Pharmacological Category: Anthelmintic (cestocide)

- m. Indications: For the removal of *Dipylidium caninum* and *Taenia pisiformis*.
- n. Pioneer Product: TAPE WORM TABS; praziquantel; NADA 111-798; Bayer HealthCare LLC, Animal Health Division
- o. Effect of Supplement: This supplement provides for OTC marketing of Prazi-C (praziquantel) Tablets in 5, 10, and 50-tablet container sizes for use in the removal of the tapeworms, *Dipylidium caninum* and *Taenia pisiformis*, from dogs and puppies. The OTC pioneer product is marketed in 5-tablet container sizes only. The prescription praziquantel product includes additional labeling claims for use by or on the order of a licensed veterinarian, for removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

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) 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.

To show that this generic product is safe and effective for its intended use, an *in vivo* blood level bioequivalence study was conducted. The study objective to determine the bioequivalence of generic and pioneer praziquantel tablets by serum bioequivalence was achieved. Refer to the original FOI Summary dated August 28, 2003, for more detail.

3. HUMAN SAFETY:

This drug is indicated for use only in dogs and puppies, 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.

Human warning statements are provided on the product labeling as follows: **“Keep out of the reach of children. Not for human use.”**

4. AGENCY CONCLUSIONS:

This 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 Prazi-C Tablets, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-265:

Prazi-C Tabs (praziquantel)

1 – 5 tablet container and carton label; 1 – 10 tablet container label and carton label; 1 – 50 tablet container label and carton label; 1 – package insert

Pioneer Labeling for NADA 111-798:

TAPE WORM TABS (praziquantel)

1 – 5 tablet container label and display card label (inside and outside); 1 – display carton designed to hold 6 containers (front, side and back, top)