Date of Approval: August 28, 2003

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-265

Praziquantel Tablets
(praziquantel)
34 mg/tablet

Cestocide for Dogs and Puppies

For the removal of the following cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis.*

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-265
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th Street Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Praziquantel
d. Proprietary Name:	Praziquantel Tablets
e. Dosage Form:	Tablets
f. How Supplied:	50, 150, or 500 tablets in HDPE bottles
g. How Dispensed:	Rx
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*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.
n. Pioneer Product:	DRONCIT Canine Cestocide Tablets (praziquantel); NADA 111-798; Bayer HealthCare LLC, Animal Health Division

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* bioequivalence study was conducted. A summary of this study follows:

Title: Serum Bioequivalence of Generic and Pioneer Praziquantel Oral Tablets in the Dog.

Study Location: CAVL, Inc.
9602 S. Washington Street
RR 7, Box 594
Amarillo, TX 79118

Trial Design: Two Period Crossover

This study used twenty-four, 12 male and 12 female, healthy mixed breed dogs, between 1 and 3 years of age at the time of selection for the study and weighing from 31 to 45 lb. Dogs were segregated by sex and ranked by initial body weight (highest to lowest) within each sex. Three blocks were constructed around the ranked order of animals. Each block contained 4 males and 4 females.

Treatment consisted of a single administration of three (3) 34 mg tablets (102 mg) of generic and pioneer praziquantel per os. Using a two period crossover experimental design, each group of 12 dogs for period 1 received either the sponsor's test formulation or the reference formulation product. There was a 48 hour washout interval between the two periods of the crossover design. After the washout interval (period 2) the groups switched products.

Blood samples for each animal, for each period of the study were taken at the following times, 0 hour and (hours after drug administration); 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 5, 6, 8, 12, and 24 hours (17 samples/animal/treatment period). Approximately 48 hours after the first treatment, animals were dosed with the alternate product and the blood collections repeated

during the second treatment period. Serum samples were submitted to the designated laboratory for praziquantel analysis at the completion of the study. Each sample was analyzed on an HPLC system equipped with an ultraviolet detector. The results were calculated using a linear regression analysis.

The following table reflect the data of the assayed praziquantel serum levels in the blood of the test animals from the 0 hour sample through the 24 hour sample as statistically analyzed with an analysis of variance procedure following the 1996 Bioequivalence Guideline.

Variable	Phoenix mean	Bayer Mean	Lower	Upper
Log_e (Area under Curve)	7.452	7.449	-7.5%	8.76%
Log_e (Maximum Concentration)	6.33	6.22	-0.09%	25.42%

Both variables, the logarithmic area under the curve and logarithmic maximum concentration, satisfied the bioequivalence criteria. Therefore, the study objective to determine the bioequivalence of generic and pioneer praziquantel tablets by serum bioequivalence was achieved.

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 Praziquantel 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:

<u>Generic Labeling for ANADA 200-265:</u>
Praziquantel Tablets (praziquantel)
1 – 50 tablet container label; 1 – 150 tablet container label; 1 – 500 tablet container label
1 – package insert

Pioneer Labeling for NADA 111-798:
DRONCIT Canine Cestocide Tablets (praziquantel)
1 – 50 tablet container label; 1 – 150 tablet container label
1 – package insert