Date of Approval: July 1, 2016

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-501

Praziquantel Injection

Praziquantel

Dogs and Cats

Praziquantel Injection is indicated for the removal of the following canine and/or feline cestodes: Dogs: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*. Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.

Sponsored by:

Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-501

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24
Ireland

Drug Labeler Code: 061623

US Agent Name and Address:

Jodi Beaudry
Bimeda Inc.
291 Forest Prairie Rd.
Le Sueur, MN 56058

C. Proprietary Name

Praziquantel Injection

D. Product Established Name

praziquantel

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

56.8 mg/mL

H. How Supplied

50 mL vials packaged individually

I. Dispensing Status

Rx

J. Dosage Regimen

Praziquantel may be administered by either the subcutaneous or intramuscular route to dogs and cats. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dose. The optimum

dosage for each individual animal will be achieved by utilizing the following dosage schedule:

DOGS AND PUPPIES†

Dogs:
5 lbs. and under—0.3 mL
6-10 lbs.—0.5 mL
11-25 lbs.—1.0 mL
Over 25 lbs.—0.2 mL/5 lbs. body weight to a maximum of 3 mL

†Not intended for use in puppies less than four (4) weeks of age.

CATS AND KITTENS††

Cats:
Under 5 lbs.—0.2 mL
5-10 lbs.—0.4 mL
11 lbs. and over—0.6 mL maximum

††Not intended for use in kittens less than six (6) weeks of age.

K. Route of Administration

Injection (subcutaneous or intramuscular)

L. Species/Class

Dogs (4 weeks of age and greater) and cats (6 weeks of age and greater)

M. Indication(s)

Praziquantel Injection is indicated for the removal of the following canine and/or feline cestodes: Dogs: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*. Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.

N. Reference Listed New Animal Drug

DRONCIT 5.68% Injectable Solution; praziquantel; NADA 111-607; Bayer HealthCare LLC, Animal Health Division

II. BIOEQUIVALENCE:

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 (reference listed new animal drug (RLNAD)). 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.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, 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 period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product, Praziquantel Injection. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is DRONCIT (praziquantel) 5.68% Injectable Solution, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 111-607 and was approved for use in dogs and cats on February 3, 1981.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs and cats, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Praziquantel Injection:

NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Praziquantel Injection, when used according to the label, is safe and effective.