§ 520.1870 Praziquantel tablets.

(a) Specifications. Each tablet contains:

(1) 34 milligrams (mg) praziquantel.
(2) 11.5 or 23 mg praziquantel.

(b) Sponsors. See sponsors in §510.600(c) of this chapter:

(1) No. 000859 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section, as in paragraph (c)(2) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section.

(c) Conditions of use—

(1) Dogs—

(i) Amount. 5 pounds (lb) and under, 1/2 tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1 1/2 tablets (51 mg); 16 to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.

(ii) Indications for use—

(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(B) For removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(iii) Limitations—

(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cats—

(i) Indications for use. For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(ii) Dosage. Cats 4 pounds and under, 11.5 mg; 5 to 11 pounds, 22 mg; over 11 pounds, 34.5 mg.

(iii) Limitations. Administer directly by mouth or crumbled and in feed. Not intended for use in kittens less than 1 month of age or weighing less than 1.5 pounds. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. Consult your veterinarian before giving to sick or pregnant animals.

(2) Dogs—

(i) Amount. Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) Indications for use. For the treatment and control of roundworms.