Food and Drug Administration, HHS

per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses. 1

- (3) Not for use in horses intended for food. ¹
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. ¹

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§520.804 Enalapril tablets.

- (a) *Specifications*. Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.
- (b) Sponsor. See 050604 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.
- (ii) Indications for use. Treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.
- (iii) Limitations. Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvular disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

 $[59~\mathrm{FR}~17694,~\mathrm{Apr.}~14,~1994,~\mathrm{as}~\mathrm{amended}~\mathrm{at}~62~\mathrm{FR}~63270,~\mathrm{Nov.}~28,~1997]$

§ 520.812 Enrofloxacin.

- (a) Specifications. Each tablet contains:
- (1) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin: or
- (2) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

- (b) *Sponsors*. See sponsor numbers in §510.600(c) of this chapter for use as in paragraph (c) of this section.
- (1) Nos. 000859 and 026637 for use of product described in paragraph (a)(1) of this section.
- (2) No. 058198 for use of product described in paragraph (a)(2) of this section.
- (c) Conditions of use in dogs and cats—(1) Amount. Administer orally as a single, daily dose or divided into two equal doses at 12-hour intervals.
- (i) Dogs. 5 to 20 mg per kilogram (/kg) (2.27 to 9.07 mg per pound (/lb)) of body weight.
- (ii) Cats. 5 mg/kg (2.27 mg/lb) of body weight.
- (2) *Indications for use*. For the management of diseases associated with bacteria susceptible to enrofloxacin.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[78 FR 30197, May 22, 2013, as amended at 78 FR 52853, Aug. 27, 2013]

§ 520.816 Epsiprantel tablets.

- (a) *Specifications*. Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.
- (b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 2.5 milligrams per pound of body weight.
- (ii) Indications for use. Removal of canine cestodes Dipylidium caninum and Taenia pisiformis.
- (2) Cats—(i) Amount. 1.25 milligrams per pound of body weight.
- (ii) Indications for use. Removal of feline cestodes D. caninum and T. taeniaeformis.
- (3) Limitations. For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]