

§ 520.804

21 CFR Ch. I (4–1–03 Edition)

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams 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 2-week 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.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(2) [Reserved]

[59 FR 17694, Apr. 14, 1994, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.812 Enrofloxacin tablets.

(a) *Specifications.* Each tablet contains either 22.7, 68.0, or 136.0 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Amount.* 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use.* Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations.* Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 3444, Jan. 24, 1989, as amended at 55 FR 43327, Oct. 29, 1990; 62 FR 38906, July 21, 1997; 64 FR 48295, Sept. 3, 1999]

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications.* Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.228 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys—(i) Amount.* 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications.* Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations.* Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have