

§ 520.816

21 CFR Ch. I (4–1–12 Edition)

§ 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]

§ 520.823 Erythromycin phosphate.

(a) *Specifications.* Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

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

(1) *Broiler and replacement chickens*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3

days should not be used; withdraw 1 day before slaughter.

(2) *Replacement chickens and chicken breeders*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of infectious coryza due to *Hemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) *Growing turkeys*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003]

§ 520.852 Estriol.

(a) *Specifications.* Each tablet contains 1 milligram (mg) estriol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer at an initial dose of 2 mg per dog per day. The dosage may be titrated to as low as 0.5 mg per dog every second day, depending on response.

(2) *Indications for use.* For the control of estrogen-responsive urinary incontinence in ovariectomized female dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 78150, Dec. 16, 2011]