

§ 520.1510

pound of body weight per day in divided doses for a maximum of 14 days.

(2) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats.

(3) *Limitations.* Administer undiluted or in drinking water. Prepare a fresh solution daily. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Discontinue treatment prior to slaughter as follows: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

[58 FR 38972, July 21, 1993, as amended at 60 FR 3079, Jan. 13, 1995; 61 FR 31398, June 20, 1996; 62 FR 60657, Nov. 12, 1997; 63 FR 45944, Aug. 28, 1998; 65 FR 45877, July 26, 2000; 65 FR 53581, Sept. 5, 2000]

§ 520.1510 Nitentpyram.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams of nitentpyram.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs and cats—*(1) *Amount.* One tablet given orally, as needed.

(2) *Indications for use.* For the treatment of flea infestations on dogs, puppies, cats, and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

[65 FR 70662, Nov. 27, 2000]

§ 520.1615 Omeprazole.

(a) *Specifications.* Each gram of oral paste contains 0.37 gram of omeprazole.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—*(1) *Amount.* For treatment of gastric ulcers, 1.8 milligrams of omeprazole per pound of body weight (4 milligrams per kilogram) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 milligram of omeprazole per pound of body weight (2 milligrams per kilogram) once daily for at least an additional 4 weeks.

21 CFR Ch. I (4–1–03 Edition)

(2) *Indications for use.* For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 18573, Apr. 15, 1999]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

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

(c) [Reserved]

(d) *Conditions of use—*(1) *Dogs and cats—*(i) *Amount.* 2.5 to 7.5 milligrams per kilogram body weight.

(ii) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) *Limitations.* Administer orally once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs and cats during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 29012, May 29, 1997, as amended at 62 FR 61627, Nov. 19, 1997]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications—*(1) *Powder for suspension.* Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets.* Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 10 milligrams per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of the following gastrointestinal worms: Large