

**§ 520.1484**

**21 CFR Ch. I (4–1–14 Edition)**

initial intravenous dosage is 5 milligrams per kilogram of body weight.

(ii) For oral dosage only, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as a top dressing in the animal's feed for up to 14 consecutive days.

(3) Not for use in horses intended for food.

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

[41 FR 14188, Apr. 2, 1976, as amended at 51 FR 24525, July 7, 1986; 61 FR 5506, Feb. 13, 1996]

**§ 520.1484 Neomycin.**

(a) *Specifications*—(1) Each ounce of powder contains 20.3 grams (g) neomycin sulfate (equivalent to 14.2 g neomycin base).

(2) Each milliliter of solution contains 200 milligrams (mg) neomycin sulfate (equivalent to 140 mg neomycin base).

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 000069 and 054925 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 000009, 046573, 058005, and 061623 for use of product described in paragraph (a)(1) as in paragraphs (e)(1) and (e)(2) of this section.

(3) Nos. 000009, 000859, 054925, and 058005 for use of product described in paragraph (a)(2) as in paragraph (e)(1) of this section.

(c) *Related tolerances*. See § 556.430 of this chapter.

(d) *Special labeling considerations*. Labeling shall bear the following warning statements: "A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues."

(e) *Conditions of use*—(1) *Cattle, swine, sheep, and goats*—(i) *Amount*. 10 mg per pound (lb) of body weight per day (22 mg per kilogram (/kg)) in divided doses for a maximum of 14 days.

(ii) *Indications for use*. For the treatment and control of colibacillosis (bac-

terial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

(iii) *Limitations*. Add powder to drinking water or milk; not for use in liquid supplements. Administer solution undiluted or in drinking water. Prepare a fresh solution in drinking water 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: Cattle, 1 day; sheep, 2 days; swine and goats, 3 days.

(2) *Turkeys*—(i) *Amount*. 10 mg/lb of body weight per day (22 mg/kg) for 5 days.

(ii) *Indications for use*. For the control of mortality associated with *E. coli* susceptible to neomycin sulfate in growing turkeys.

(iii) *Limitations*. Add to drinking water; not for use in liquid supplements. 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 5 consecutive days.

[71 FR 56866, Sept. 28, 2006, as amended at 71 FR 68738, Nov. 28, 2006; 78 FR 17596, Mar. 22, 2013]

**§ 520.1510 Nitenpyram tablets.**

(a) *Specifications*. Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

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

(c) *Special considerations*. The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003]

#### § 520.1604 Oclacitinib.

(a) *Specifications*. Each tablet contains 3.6, 5.4, or 16 milligrams (mg) of oclacitinib as oclacitinib maleate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer orally 0.18 to 0.27 mg/per pound of body weight (0.4 to 0.6 mg/kg body weight) twice daily for up to 14 days; then administered once daily for maintenance therapy.

(2) *Indications for use*. For control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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

[78 FR 42007, July 15, 2013]

#### § 520.1615 Omeprazole.

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

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

(c) *Special considerations*. When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

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

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

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

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations*. Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004, as amended at 71 FR 59374, Oct. 10, 2006]

#### § 520.1616 Orbifloxacin tablets.

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

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*. 2.5 to 7.5 mg per kilogram body weight once daily.

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

(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.

[71 FR 14643, Mar. 23, 2006, as amended at 75 FR 26646, May 12, 2010]

#### § 520.1618 Orbifloxacin suspension.

(a) *Specifications*. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

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