

§ 520.1454

21 CFR Ch. I (4–1–10 Edition)

§ 520.1454 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

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

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this section.

(e) *Conditions of use in sheep—(1) Amount.* Administer 1 mL per 11 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) *Indications for use.* For the treatment and control of the adult and L4 larval stages of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*.

(3) *Limitations.* Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use in female sheep providing milk for human consumption.

[70 FR 76163, Dec. 23, 2005]

§ 520.1468 Naproxen granules.

(a) *Specifications.* Naproxen granules contain 50 percent naproxen.

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

(c) *Conditions of use—(1) Horses.* The drug is used for the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

(2)(i) For oral maintenance therapy following initial intravenous dosage, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as top dressing in the animal's feed for up to 14 consecutive days. The 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, 054925, 058005, and 059130 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 (bacterial 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