

§ 520.1450c

same grazing season/calendar year by untreated cattle. Do not administer to cattle within 106 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 47831, Dec. 7, 1984, as amended at 51 FR 23415, June 27, 1986; 51 FR 41081, Nov. 13, 1986]

§ 520.1450c Morantel tartrate sustained-release trilaminar cylinder/sheet.

(a) *Specifications.* The drug product consists of a trilaminar, perforated, plastic sheet formed into a cylinder having plastic plugs in its ends. The core lamina contains 19.8 grams of morantel tartrate equivalent to 11.8 grams of morantel base.

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use—(1) Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum*.

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 102 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[56 FR 13396, Apr. 2, 1991]

21 CFR Ch. I (4-1-03 Edition)

§ 520.1451 Moxidectin.

(a) *Specifications.* Each tablet contains 30, 68, or 136 micrograms of moxidectin.

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

(c) [Reserved]

(d) *Conditions of use—(1) Amount.* 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.—

(2) *Indications for use.* To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

(3) *Limitations.* Use once-a-month in dogs at 8 weeks of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 37713, July 15, 1997]

§ 520.1452 Moxidectin gel.

(a) *Specifications.* The gel contains 2 percent moxidectin (20 milligrams per milliliter).

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

(c) [Reserved]

(d) *Conditions of use—(1) Amount.* 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated luminal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)); hairworms (*Trichostrongylus axei* (adults)); large-mouth stomach worms (*Habronema muscae* (adults)); and horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations*. Not for use in horses and ponies intended for food.

[62 FR 42902, Aug. 11, 1997, as amended at 64 FR 66105, Nov. 24, 1999]

§ 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 sulfate soluble powder.

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

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

(1) Nos. 000069 and 051259 for use as in paragraph (d)(1) of this section.

(2) Nos. 000009, 046573, and 061623 for use as in paragraphs (d)(1) and (d)(2) of this section.

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

(d) *Conditions of use*—(1) *Cattle (excluding veal calves), swine, sheep, and goats*.

(i) *Amount*. 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) 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 in cattle (excluding veal calves), swine, sheep, and goats.

(iii) *Limitations*. Add to drinking water or milk; 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 14 consecutive days. Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

(2) *Turkeys*—(i) *Amount*. 10 milligrams of neomycin sulfate per pound of body weight per day (22 milligrams per kilogram) for 5 days.

(ii) *Indications for use*. For the control of mortality associated with *E. coli* organisms 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.

[64 FR 31497, June 11, 1999, as amended at 66 FR 14073, Mar. 9, 2001; 67 FR 72366, Dec. 5, 2002; 67 FR 78971, Dec. 27, 2002; 68 FR 4914, Jan. 31, 2003]

§ 520.1485 Neomycin sulfate oral solution.

(a) *Specifications*. Each milliliter contains 200 milligrams of neomycin sulfate (equivalent to 140 milligrams of neomycin base).

(b) *Sponsors*. See Nos. 000009, 051259, and 059130 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Amount*. 10 milligrams of neomycin sulfate per