

(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.

(2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount*—(i) 200 micrograms (mcg) per kilogram (/kg) ivermectin (91 mcg per pound (/lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.

(ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.

(2) *Indications for use.* For treatment and control of:

(i) Tapeworms—*Anoplocephala perfoliata*; Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(ii) Tapeworms—*Anoplocephala perfoliata*; Large Strongyles (adults)—

Strongylus vulgaris (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp.; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

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

[68 FR 55309, Sept. 25, 2003, as amended at 69 FR 49808, Aug. 12, 2004; 70 FR 65835, Nov. 1, 2005]

§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet contains:

(1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;

(2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;

(3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or

(4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.

(b) *Sponsors.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer monthly according to body weight as follows:

(i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.

(ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.

§ 520.1200

(iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(3) of this section.

(iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(4) of this section.

(v) Greater than 100 lb: use the appropriate combination of tablets.

(2) *Indications for use.* Prevents canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis*, *Toxascaris leonina*), hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*) and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections.

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

[71 FR 65052, Nov. 7, 2006]

§ 520.1200 Ivermectin, fenbendazole, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet contains either:

(1) 68 micrograms (µg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or

(2) 27 µg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer tablets to provide 6 µg per kilogram (kg) ivermectin, 100 mg/kg fenbendazole, and 5 mg/kg praziquantel.

(2) *Indications for use.* For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.

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

[73 FR 33692, June 13, 2008, as amended by 74 FR 61516, Nov. 25, 2009]

§ 520.1204 Kanamycin, bismuth subcarbonate, activated attapulgite.

(a) *Specifications*—(1) Each 5 milliliters (mL) of suspension contains 100 milligrams (mg) kanamycin (as the

21 CFR Ch. I (4–1–12 Edition)

sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite (aluminum magnesium silicate).

(2) Each tablet contains 100 mg kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mL of suspension or 1 tablet per 20 pounds body weight every 8 hours. Maximum dose: 5 mL of suspension or 3 tablets every 8 hours. Dogs under 10 pounds: 2.5 mL of suspension or 1/2 tablet every 8 hours. A recommended initial loading dose should be twice the amount of a single dose.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of the associated diarrhea.

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

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999; 71 FR 43968, Aug. 3, 2006]

§ 520.1242 Levamisole hydrochloride oral dosage forms.

§ 520.1242a Levamisole powder for oral solution.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, 362.7, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 053501 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 057561 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i),