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age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000; 67 FR 71820, Dec. 3, 2002]

§ 520.1193 Ivermectin tablets and chewables.

(a) *Specifications.* (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

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

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

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

(d) *Conditions of use—(1) Dogs.* For use in dogs 6 weeks of age and older as follows:

(i) *Amount.* 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound (lb)), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(2) *Cats.* For use in cats 6 weeks of age and older as follows:

(i) *Amount.* Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use.* To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and

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control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

[67 FR 11230, Mar. 13, 2002, as amended at 67 FR 21996, May 2, 2002]

§ 520.1195 Ivermectin liquid.

(a) *Specifications—(1)* Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 050604, 051259, 058829, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section.

(2) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

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

(e) *Conditions of use—(1) Horses—(i) Amount.* 200 micrograms (mcg) per kilogram (/kg) of body weight as a single dose by stomach tube or as an oral drench.

(ii) *Indications for use.* For the treatment and control of large strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. edentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); small strongyles, including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); hairworms (*Trichostongylus axei* (adult)); large-mouth stomach worms (*Habronema muscae* (adult)); stomach bots (*Gastrophilus* spp. (oral and gastric stages)); lungworms (*Dictyocaulus arnfieldi* (adult and fourth-stage larvae)); intestinal threadworms (*Strongyloides westeri* (adult)); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

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

(2) *Sheep*—(i) *Amount.* 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) *Indications for use.* For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (*Haemonchus contortus*, *H. placei* (adults only), *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora* (adults only), *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults only), *Nematodirus battus*, *N. spathiger*, *S. papillosus* (adults only), *Chabertia ovina* (adult only), *Trichuris ovis* (adults only)); lungworms (*D. filaria*); and all larval stages of the nasal bot *Oestrus ovis*.

(iii) *Limitations.* For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

[67 FR 50597, Aug. 5, 2002]

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablets.

(a) *Specifications.* Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg and 114 mg, or 272 µg and 227 mg, respectively.

(b) *Sponsors.* See Nos. 050604 and 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* A minimum of 6 µg of ivermectin and 5 mg of pyrantel (as pamoate salt) per kilogram (2.72 µg and 2.27 mg per pound) of body weight.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for up to a month (30 days) after infection and treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina*, and adult hookworms *Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*.

(iii) *Limitations.* Use monthly. Recommended for dogs 6 weeks of age and older. Federal law restricts this drug to

use by or on the order of a licensed veterinarian.

(2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997; 66 FR 35756, July 9, 2001; 67 FR 21996, May 2, 2002]

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

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

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms *Haemonchus placei*, *Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*; lungworms *Dictyocaulus viviparus*; grubs *Hypoderma* spp.; sucking lice *Linognathus vituli*, *Solenopotes capillatus*; mange mites *Psoroptes ovis*, *Sarcoptes scabiei*, and ticks *Amblyomma americanum*.

(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000]