Food and Drug Administration, HHS

§ 520.1192 Ivermectin paste.

(a) Specifications. Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

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

(c) Conditions of use. Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

§ 520.1182 Iron dextran suspension.

(a) Specifications. Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

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

(c) Conditions of use. Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

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

(c) Conditions of use. Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

§ 520.1192 Ivermectin paste.

(a) Specifications. Each millimeter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

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

(c) Conditions of use. Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.
§ 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 (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 059130 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 a 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 6.6 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 canine heartworm disease by eliminating the tissue stage of heartworm larvae (Dirofilaria immitis) for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms Ancylostoma tubaeforme and A. braziliense.

§ 520.1194 Ivermectin meal.

(a) Specifications. Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) Sponsor. See No. 017135 in §510.600(c) of this chapter.

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

(d) Conditions of use in horses—(1) Amount. Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) Indications for use. For treatment and control of Large Strongyles (adults); Strongyulus 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): Coronoclycus spp. including C. coronatus, C. labiatus, and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylcoclycus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicapsulatus, Cylcodontophorus spp., Cylcostephanus spp. including C. calicatus, C. goldi, C. longibursatus, and C. minutus, and Petrocynema pocalatum; 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): Trichosirongyulus 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...