

Food and Drug Administration, HHS

§ 522.1192

inject 200 milligrams of elemental iron at the first sign of anemia.

[49 FR 38938, Oct. 2, 1984, as amended 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 61 FR 18672, Apr. 29, 1996; 62 FR 35076, June 30, 1997; 63 FR 53578, Oct. 6, 1998]

§ 522.1183 Iron hydrogenated dextran injection.

(a) *Specifications.* Each milliliter contains 100 milligrams of elemental iron stabilized with a low molecular weight hydrogenated dextran and 0.5 percent phenol as a preservative.

(b) [Reserved]

(c)(1) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 100 milligrams of elemental iron to each animal when indicated between 5 and 28 days of age.

(d)(1) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

(e)(1) *Sponsors.* See Nos. 000010, 017287, and 059130 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly 100 milligrams at 2 to 4 days of age.

(ii) For the treatment of iron deficiency anemia, administer

intramuscularly 100 milligrams. Treatment may be repeated in 10 days.

[42 FR 53955, Oct. 4, 1977, as amended at 46 FR 39128, July 31, 1981; 50 FR 23298, June 3, 1985; 52 FR 18691, May 19, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 40728 and 40729, Oct. 18, 1988; 55 FR 8462, Mar. 8, 1990; 55 FR 33670, Aug. 17, 1990; 62 FR 35076, June 30, 1997; 63 FR 44384, Aug. 19, 1998; 65 FR 45877, July 26, 2000]

§ 522.1192 Ivermectin injection.

(a) *Specifications*—(1) *Horses.* Each milliliter of sterile aqueous solution contains 20 milligrams of ivermectin (2 percent).

(2) *Cattle, reindeer, swine, and American bison.* Each milliliter of sterile aqueous solution contains 10 milligrams of ivermectin (1 percent).

(3) *Piglets 70 pounds or less and ranch-raised foxes.* Each milliliter of sterile aqueous solution contains 2.7 milligrams of ivermectin (0.27 percent).

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See No. 059130 in § 510.600(c) of this chapter for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section.

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

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 20 milligrams per 100 kilograms (220 pounds) of body weight.

(ii) *Indications for use.* It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *Strongylus edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (*microfilariae*) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *Limitations.* For intramuscular use only. Do not use intravenously. Not for use in horses intended for food. Effects of this drug on pregnant mares have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.