no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(B) Protamine zinc recombinant human insulin. Administer an initial dose of 0.1 to 0.3 IU/pound of body weight (0.2 to 0.7 IU/kilogram) every 12 hours. The dose should be given concurrently with or right after a meal. Re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained.

(ii) Indications for use. For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

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

§ 522.1182 Iron injection.

(a) Specifications. See §510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:
   (i) Ferric hydroxide;
   (ii) Ferric oxide; or
   (iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) Sponsors and conditions of use. It is used in baby pigs by sponsors in §510.600(c) of this chapter as follows:

(1) Nos. 000659 and 042552 for use of product described in paragraph (a)(1)(i) of this section as follows:
   (i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age. Dosage may be repeated at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.
   (ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(2) Nos. 000061 and 059120 for use of product described in paragraph (a)(1)(i) of this section as follows:
   (i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.
   (ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(3) Nos. 051311 and 054771 for use of product described in paragraph (a)(1)(ii) of this section as follows:
   (i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated in 2 weeks of age.
   (ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

(4) Nos. 054771 for use of product described in paragraph (a)(1)(iii) of this section as follows:
   (i) For prevention of iron deficiency anemia, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.
   (ii) For treatment of iron deficiency anemia, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(5) No. 054771 for use of product described in paragraph (a)(1)(iii) of this section as follows:
   (i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.
   (ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(6) Nos. 000859 and 058005 for use of product described in paragraph (a)(1)(iii) of this section as follows:
   (i) For prevention of anemia due to iron deficiency, administer 1 mL by intramuscular injection at 2 to 5 days of age.
   (ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(7) Nos. 000859 and 042552 for use of product described in paragraph (a)(2) of this section as follows:
   (i) For prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 mg
Food and Drug Administration, HHS

§ 522.1192 Ivermectin.

(a) Specifications—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

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

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 000859, 055529, 058005, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

(d) Special considerations—(1) See § 500.25 of this chapter.

(2) Labeling shall bear the following precaution: “This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.”

(e) Conditions of use—(1) Horses—(i) Amount. 200 micrograms per kilogram (μg/kg) of body weight by intramuscular injection.

(2) Indications for use. For the treatment and control of large strongyles (adult) (Strongyulus vulgaris, S. 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)