§522.1182

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) Conditions of use—(1) Dogs—(i) Amount. Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(ii) Indications for use. For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs 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.

The amount of porcine insulin zinc. Administer an initial dose of 1 to 2 IU by subcutaneous injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, 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.

(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.

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.

(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)(i), (e)(2)(ii)(A), (e)(2)(iii), (e)(2)(iii), (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. 055529 and 059130 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(C), (e)(2)(iii), (e)(3), (e)(4) and (e)(5) of this section.

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

(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.

(ii) Indications for use. For the treatment and control of large strongyles (adult) (Strongylus vulgaris, S. edentatus, Triodontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cylicocyclus spp., Cylcostephanus 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.).