§ 522.1155 Imidocarb powder for injection.

(a) Specifications. The product is a sterile powder containing imidocarb dipropionate. Each milliliter of constituted solution contains 100 milligrams (mg) of imidocarb base.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Special considerations. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to licensed or full-time State, Federal, or military veterinarians.

(d) Conditions of use in horses and zebras—(1) Amount. For Babesia caballi infections, administer 2 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage once after 24 hours. For Babesia equi infections, administer 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage four times at 72-hour intervals.

(2) Indications for use. For the treatment of babesiosis (piroplasmosis) caused by Babesia caballi and Babesia equi.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1156 Imidocarb solution.

(a) Specifications. Each milliliter of solution contains 120 milligrams (mg) of imidocarb dipropionate.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular injection. Repeat the dose after 2 weeks for a total of two treatments.

(2) Amount. For Babesia caballi and Babesia equi infections, administer 2 and 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage once after 24 hours. For Babesia equi infections, administer 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage four times at 72-hour intervals.

(2) Indications for use. For the treatment of clinical signs of babesiosis and/or demonstrated Babesia organisms in the blood.

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

§ 522.1160 Insulin.

(a) Specifications—(1) Each milliliter (mL) of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

(2) Each mL of protamine zinc recombinant human insulin suspension contains 40 IU of insulin.

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

(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.

(2) Cats—(1) Amount—(A) 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,