(mL)) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg (2 mL) should be administered at least 4 weeks after the first dose.

(2) *Indications for use.* For the temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

(3) *Limitations.* Not approved for use in female pigs and barrows. Do not use in intact male pigs intended for breeding because of the disruption of reproductive function. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Pigs should be slaughtered no earlier than 3 weeks and no later than 10 weeks after the second dose.

[76 FR 27889, May 13, 2011, as amended at 77 FR 4227, Jan. 27, 2012]

§ 522.1085 Guaifenesin sterile powder.

(a) *Specifications.* It is a sterile powder containing guaifenesin.

(b) *Sponsor.* See Nos. 000856 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for intravenous use as a muscle relaxant in horses.

(2) A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution. It is administered by rapid intravenous infusion at a fixed dosage of 1 milliliter of prepared solution per pound of body weight.

(3) Not to be used in horses intended for food.

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

[49 FR 48039, Dec. 10, 1984, as amended at 60 FR 27223, May 23, 1995; 67 FR 67521, Nov. 6, 2002; 76 FR 53051, Aug. 25, 2011]

§ 522.1086 Guaifenesin injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of guaifenesin and 50 milligrams of dextrose.

(b) *Sponsor.* See Nos. 037990 and 000859 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) The drug is used intravenously in horses as a skeletal muscle relaxant.

(2) Administer rapidly at a dosage of 1 milliliter per pound of body weight.

(3) No to be used in horses intended for food.

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

[60 FR 27223, May 23, 1995, as amended at 63 FR 29352, May 29, 1998; 78 FR 17597, Mar. 22, 2013]

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations.* For intravenous use only. Overdosage or an excessive rate of administration (greater than 10 milliliters per kilogram per hour) may result in circulatory overload. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000]

§ 522.1145 Hyaluronate sodium.

(a)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000009 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams; larger joint (hock)—40 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. 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.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 053501 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—10 milligrams; larger joint (hock)—20 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment may be repeated at weekly intervals for a total of four treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams.

(ii) *Indications for use.* Treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use.* For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(iii) *Limitations.* For intraarticular injection in horses only. Not for use in horses intended for food. Not intended for use in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

(2) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use in horses*—(i) *Amount.* 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use.* For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *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.

(f)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 060865 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—22 milligrams; larger joint (hock)—44 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. 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.

[49 FR 45124, Nov. 15, 1984, as amended at 51 FR 11438, Apr. 3, 1986; 51 FR 25032, July 10, 1986; 53 FR 19773, May 31, 1988; 53 FR 22297, June 15, 1988; 56 FR 50814, Oct. 9, 1991; 57 FR 2837, Jan. 24, 1992; 59 FR 33198, June 28, 1994; 61 FR 59003, Nov. 20, 1996; 63 FR 59216, Nov. 3, 1998; 71 FR 1689, Jan. 11, 2006; 71 FR 39204, July 12, 2006; 75 FR 1274, Jan. 11, 2010; 75 FR 10167, Mar. 5, 2010]

§ 522.1150 Hydrochlorothiazide injection.

(a) *Specifications.* Each milliliter contains 25 milligrams of hydrochlorothiazide.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 to 10 milliliters (125 to 250 milligrams) intravenously or intramuscularly once or twice a day. After onset of diuresis, treatment may be continued with an orally administered maintenance dose.

(2) *Indications for use.* For use in cattle as an aid in the treatment of postparturient udder edema.[1]

(3) *Limitations.* Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. Milk taken from dairy animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[43 FR 59058, Dec. 19, 1978, as amended at 62 FR 63271, Nov. 28, 1997]

§ 522.1155 Imidocarb dipropionate sterile powder.

(a) *Specifications.* Imidocarb dipropionate powder is reconstituted with sterile water. Each milliliter of solution contains 100 milligrams of imidocarb base.

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

(c) *Conditions of use.* The drug is used in horses and zebras as follows:

(1) *Amount.* For *Babesia caballi* infections, use intramuscularly 2 milligrams of imidocarb base per kilogram of body weight, repeating dosage once after 24 hours. For *Babesia equi* infections, use 4 milligrams of imidocarb base per kilogram of body weight, 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.* Administer intramuscularly in the neck region. Do not inject intravenously. Do not use for other equidae or for animals of other species. Do not use in horses less than 1 year old. Do not use for animals in near-term pregnancies. Imidocarb dipropionate is a cholinesterase inhibitor. Do not use this product simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, APHIS, USDA, to licensed or full-time State, Federal, or military veterinarians.

[43 FR 40455, Sept. 12, 1978, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications.* Each milliliter of injectable solution contains 120 milligrams of imidocarb.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use.* Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations.* Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.