(2) *Indications for use.* For the treatment of cystic ovaries (ovarian follicular cysts) in cattle to reduce the time to first estrus.

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

[54 FR 50235, Dec. 5, 1989]

§ 522.1078 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (μg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 000061, 050604, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle.* It is used as follows:

(1) *Amount.* 100 μg per cow as a single intramuscular or intravenous injection.

(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

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

[67 FR 68759, Nov. 13, 2002, as amended at 74 FR 61516, Nov. 25, 2009]

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

(a) *Specifications.* Each dose consists of 400 international units (I.U.) serum gonadotropin and 200 I.U. chorionic gonadotropin as a freeze-dried powder to be reconstituted with 5 milliliters of sterile aqueous diluent.

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

(c) *Conditions of use in swine*—(1) *Amount.* 400 I.U. serum gonadotropin with 200 I.U. chorionic gonadotropin per 5 milliliters dose per animal.

(2) *Indications for use.* (i) *Gilts.* For induction of fertile estrus (heat) in healthy prepuberal (noncycling) gilts.

(ii) *Sows.* For induction of estrus in healthy weaned sows experiencing delayed return to estrus.

(3) *Limitations.* For subcutaneous use only.

(i) *Gilts.* For use only in gilts over 5 1/2 months of age and weighing at least 85 kilograms (187 pounds).

(ii) *Sows.* Delayed return to estrus is most prevalent after the first litter. The effectiveness has not been established after later litters. Delayed return to estrus often occurs during periods of adverse environmental conditions, and sows mated under such conditions may farrow smaller than normal litters.

[55 FR 1405, Jan. 16, 1990, as amended at 58 FR 52222, Oct. 7, 1993; 74 FR 61516, Nov. 25, 2009]

§ 522.1081 Chorionic gonadotropin.

(a) *Specifications.* Each vial contains 5,000, 10,000 or 20,000 USP units of lyophilized powder for constitution with accompanying diluent to a 10-milliliter solution.

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

(1) Nos. 000402 and 053501 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B) and (d)(1)(i)(C) of this section.

(2) Nos. 058639 and 063323 for use as in paragraphs (d)(1)(i)(A) and (d)(1)(i)(B) of this section.

(3) No. 000061 for use as in paragraphs (d)(1)(i)(A) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.304 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* As a single dose. Dosage may be repeated in 14 days if the animal's behavior or examination of the ovaries *per rectum* indicates retreatment.

(A) 10,000 USP units by intramuscular injection.

(B) 500 to 2,500 USP units by intrafollicular injection.

(C) 2,500 to 5,000 USP units by intravenous injection.

(ii) *Indications for use.* For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

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

(2) *Finfish*—(i) *Amount.* 50 to 510 IU per pound of body weight for males, 67 to 1,816 IU per pound of body weight for females, by intramuscular injection. Up to three doses may be administered.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* In fish intended for human consumption, the total dose administered per fish (all injections combined) should not exceed 25,000 IU

chorionic gonadotropin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 61516, Nov. 25, 2009]

§ 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]

§ 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 059130 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]

§ 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.