

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) No. 058639 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 com-

bined) 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, as amended at 76 FR 17778, Mar. 31, 2011]

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligrams (mg) gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 0.4 mg (2 milliliter (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.