

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If no improvement is seen after 3 days, treatment should be discontinued and the diagnosis reevaluated. Treatment not to exceed 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 1942, Jan. 13, 1978, as amended at 48 FR 791, Jan. 7, 1983; 51 FR 15606, Apr. 25, 1986; 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 60 FR 29985, June 7, 1995; 61 FR 24441, May 15, 1996; 62 FR 45157, Aug. 26, 1997]

§ 522.1055 Gleptoferron injection.

(a) *Specifications.* Each milliliter contains the equivalent of 200 milligrams of elemental iron as gleptoferron (complex of ferric hydroxide and dextran glucoheptonic acid), and 0.5 percent phenol as a preservative.

(b) *Sponsor.* See 062408 in § 510.600(c) of this chapter.

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

(1) For prevention of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly on or before 3 days of age.

(2) For treatment of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly.

[45 FR 61288, Sept. 16, 1980, as amended at 61 FR 18672, Apr. 29, 1996]

§ 522.1066 Glycopyrrolate injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 0.2 milligram of glycopyrrolate.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated as a preanesthetic agent in dogs and cats.

(2) It is administered intravenously, intramuscularly, or subcutaneously in dogs and intramuscularly in cats at a dosage level of 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight).

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

[48 FR 21567, May 13, 1983]

§ 522.1077 Gonadorelin injectable.

(a) *Specifications.* Each milliliter sterile aqueous solution contains 50

micrograms of gonadorelin (as hydrochloride).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle—*(1) *Amount.* 100 micrograms per cow intramuscularly.

(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 injection

(a) *Specifications.* The drug contains 50 micrograms of gonadorelin diacetate tetrahydrate in each milliliter of sterile solution.

(b) *Sponsor.* See Nos. 050604 and 057926 in § 510.600(c) of this chapter.

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

(1) *Amount.* 100 micrograms per cow.

(2) *Indications for use.* The drug is used for the treatment of ovarian cysts.

(3) *Limitations.* Administer as a single intramuscular or intravenous injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 9804, Mar. 10, 1978, as amended at 45 FR 56798, Aug. 26, 1980; 61 FR 37682, July 19, 1996]

§ 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. 057926 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]

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.

(a)(1) *Specifications*. Chorionic gonadotropin for injection is supplied in vials containing 5,000, 10,000 or 20,000 U.S.P. units of lyophilized powder for reconstitution with the accompanying sterile diluent to a 10 milliliter solution.

(2) *Sponsor*. See sponsor numbers in § 510.600(c) of this chapter, as follows:

(i) Nos. 000402 and 053501 for use of 10,000 U.S.P. units intramuscularly, 2,500 to 5,000 U.S.P. units intravenously, and 500 to 2,500 U.S.P. units intrafollicularly.

(ii) Nos. 000469 and 058639 for use of 10,000 U.S.P. units intramuscularly and 500 to 2,500 U.S.P. units intrafollicularly.

(iii) No. 057926 for use of 10,000 U.S.P. units intramuscularly.

(3) *Conditions of use*—(i) *Amount*. (a) 10,000 U.S.P. units as a single, deep intramuscular injection.¹

(b) 500 to 2,500 U.S.P. units for intrafollicular injection.¹

(c) 2,500 to 5,000 U.S.P. units intravenously.

(ii) *Indications for use*. For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified as § 514.111 of this chapter.

(iii) *Limitations*. Dosage may be repeated in 14 days if the animal's behavior or rectal examination of the ovaries indicates the necessity for retreatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(b)(1) *Specifications*. Chorionic gonadotropin suspension, veterinary contains in each milliliter, 750 I.U. of chorionic gonadotropin suspended in white wax and sesame oil.

(2) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 2 milliliters (1,500 I.U.) subcutaneously, at the time of insemination, in the neck or shoulder region.

(ii) *Indications for use*. The drug is used as an aid in increasing pregnancy rate of estrus-synchronized and normalcycling heifers.

(iii) *Limitations*. The drug is not to be used to induce multiple ovulations. Doses higher than recommended may reduce pregnancy rate. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 58167, Nov. 8, 1977, as amended at 45 FR 81038, Dec. 9, 1980; 50 FR 41489, Oct. 11, 1985; 50 FR 45603, Nov. 1, 1985; 52 FR 25212, July 6, 1987; 56 FR 67175, Dec. 30, 1991; 56 FR 14642, Apr. 11, 1991]

§ 522.1085 Guaifenesin sterile powder.

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

(b) *Sponsor*. See No. 000031 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]