

**§ 522.1077**

**21 CFR Ch. I (4–1–03 Edition)**

**§ 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.**

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

(b) *Sponsors.* See Nos. 050604, 057926, 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]

**§ 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 in cattle.

(ii) Nos. 058639 and 063323 for use of 10,000 U.S.P. units intramuscularly and 500 to 2,500 U.S.P. units intrafollicularly in cattle.

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

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

(4) *Conditions of use in cattle*—(i) *Amount.* 10,000 USP units as a single, deep intramuscular injection; 500 to 2,500 USP units for intrafollicular injection; 2,500 to 5,000 USP units intravenously.

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

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