

prepartum usage, full relaxation of the cervix should be accomplished either naturally or by administration of estrogen prior to oxytocin therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980, as amended at 52 FR 18691, May 19, 1987; 52 FR 25212, July 6, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 14642, Apr. 11, 1991; 56 FR 16002, Apr. 19, 1991; 59 FR 31139, June 17, 1994; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997]

**§ 522.1696 Penicillin G procaine implantation and injectable dosage forms.**

**§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.**

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

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

(1) See Nos. 000008, 049185, 000856, 000864, and 010515 for use as in paragraph (d)(1) of this section.

(2) See Nos. 049185 and 000856 for use as in paragraph (d)(2) of this section.

(3) See Nos. 000069, 000864, and 010515 for use as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use—(1) Horses, dogs, and beef cattle.* Treatment of bacterial infections susceptible to penicillin G. Repeat dosage in 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(i) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Do not use in horses intended for food purposes.

(ii) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously.

(iii) *Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Treatment should be limited to two doses. Not to be used

in beef cattle within 30 days of slaughter.

(iv) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use were NAS/NRC reviewed and found 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.

(2) *Beef cattle.* Treatment of bacterial pneumonia (*Streptococcus* spp., *Corynebacterium pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*C. pyogenes*); blackleg (*Clostridium chauvoei*); and prophylaxis of bovine shipping fever in 300 to 500 pound beef calves.

(i) *Amount.* 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours. Limit treatment to two doses. Not for use within 30 days of slaughter.

(ii) *NAS/NRC status.* The conditions of use were NAS/NRC reviewed and found 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.

(3) *Beef cattle.* Treatment of bacterial pneumonia (shipping fever) (*Streptococcus* spp., *C. pyogenes*, *S. aureus*); upper respiratory infections such as rhinitis or pharyngitis (*C. pyogenes*); and blackleg (*C. chauvoei*).

(i) 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours. Limit treatment to two doses. Not for use within 30 days of slaughter.

(ii) [Reserved]

[57 FR 37332, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 65285, Dec. 14, 1993; 59 FR 38119, July 27, 1994]

**§ 522.1696b Penicillin G procaine aqueous suspension.**

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Related tolerances.* See § 556.510 of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use were NAS/

NRC reviewed and found 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.

(d) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use as in paragraph (d) of this section, see No. 000864 for use as in paragraph (d)(3) of this section.

(1) *Dogs*—(i) *Amount*. 10,000 units per pound of body weight daily at 24-hour intervals.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. For intramuscular use only. Continue treatment at least 48 hours after symptoms disappear. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 10,000 units per pound of body weight daily at 24-hour intervals.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. For intramuscular use only. Continue treatment at least 48 hours after symptoms disappear. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound of body weight (1 milliliter per 100 pounds body weight) daily.

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Administer by deep intramuscular injection. Continue treatment at least 48 hours after symptoms disappear but do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle

(calves)—7; all other cattle—4; sheep—8; and swine—6. Not for use in horses intended for food.

(e) *Sponsor*. See No. 055529 in § 510.600(c) of this chapter.

(1) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound of body weight (1 milliliter per 100 pounds body weight) daily.

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. For intramuscular use only. Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days). Treatment should not exceed 4 consecutive days. Do not exceed 10 milliliters per injection site. Milk that has been taken during treatment and for 72 hours (six milkings) after the latest treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7. Not for use in horses intended for food.

(2) [Reserved]

(f) *Sponsor*. See Nos. 000069 and 010515 in § 510.600(c) of this chapter. See paragraph (d) of this section for conditions of use, except that milk taken during treatment and for 48 hours (four milkings) after the latest treatment shall not be used for food.

[57 FR 37332, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 11964, Mar. 2, 1993]

#### § 522.1696c Penicillin G procaine in oil.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use were NAS/NRC reviewed and found 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.