

§ 522.1696b

21 CFR Ch. I (4–1–10 Edition)

(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) Nos. 000856, 010515, 049185, 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 010515, 059130, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

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

(d) *Conditions of use—(1) Horses, dogs, and beef cattle—(i) Amount—(A) Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations.* In beef cattle, treatment should be limited to two doses. Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle—(i) Amount.* 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Actinomyces pyogenes pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*A. pyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations.* Limit treatment to two doses. Not for use within 30 days of slaughter. For Nos. 010515, 049185, 059130, and 061623: A withdrawal period has not been established for this prod-

uct in preruminating calves. Do not use in calves to be processed for veal.

[66 FR 711, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 70 FR 21947, Apr. 28, 2005; 70 FR 50182, Aug. 26, 2005; 73 FR 16754, Mar. 31, 2008]

§ 522.1696b Penicillin G procaine aqueous suspension.

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

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 055529 and 061623 for use as in paragraph (d)(2) of this section.

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

(d) *Conditions of use—(1) Dogs and cats—(i) Amount.* 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

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

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

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

(A) For Nos. 010515, 053501, 059130, and 061623: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

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

(iii) *Limitations.* Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 053501 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle.

Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 010515, 055529, and 059130: Treatment should not exceed 4 consecutive days. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 68 FR 42589, July 18, 2003; 69 FR 17586, Apr. 5, 2004; 70 FR 16935, Apr. 4, 2005; 73 FR 14177, Mar. 17, 2008]

#### § 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.

(d) *Conditions of use—(1) Amount.* Dogs and cats—10,000 units per pound of body weight once daily. Horses—3,000 units per pound of body weight once daily.

(2) *Indications for use.* Treatment of infections of dogs, cats, and horses caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(3) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

#### § 522.1698 Pentazocine lactate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains pentazocine lactate equivalent to 30 milligrams of pentazocine base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Horses—(i) Amount.* 0.15 milligram of pentazocine base per pound of body weight per day.

(ii) *Indications for use.* For symptomatic relief of pain due to colic.

(iii) *Limitations.* Administer intravenously or intramuscularly. Intravenous injections are given slowly in the jugular vein. In cases of severe pain, a second dose is recommended intramuscularly 10 to 15 minutes after the initial dose at the same level. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs—(i) Amount.* 0.75 to 1.50 milligrams of pentazocine base per pound of body weight.

(ii) *Indications for use.* For amelioration of pain accompanying post-operative recovery, fracture, trauma, and spinal disorders.

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

[42 FR 31450, June 21, 1977, as amended at 42 FR 36995, July 19, 1977; 47 FR 5409, Feb. 5, 1982; 55 FR 23076, June 6, 1990]

#### § 522.1704 Sodium pentobarbital injection.

(a)(1) *Specifications.* Sodium pentobarbital injection is sterile and contains in each milliliter 64.8 milligrams of sodium pentobarbital.

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

(3) *Conditions of use.* (i) The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(ii) The drug is administered intravenously “to effect”. For general surgical anesthesia, the usual dose is 11 to 13 milligrams per pound of body weight. For sedation, the usual dose is approximately 2 milligrams per pound of body weight. For relieving convulsive seizures in dogs, when caused by strychnine, the injection should be administered intravenously “to effect”. The drug may be given