

**§ 522.1680**

**21 CFR Ch. I (4–1–14 Edition)**

intramuscular or subcutaneous injection of 1 mL per 22 pounds (lb) body weight (BW) (13.6 mg oxytetracycline and 0.9 mg flunixin per lb BW) where retreatment of calves and yearlings for bacterial pneumonia is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.

(2) *Indications for use.* For the treatment of bacterial pneumonia associated with *Pasteurella* spp. and for the control of associated pyrexia in beef and nonlactating dairy cattle.

(3) *Limitations.* Discontinue treatment at least 21 days prior to slaughter of cattle. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 3489, Jan. 20, 2011, as amended at 79 FR 16192, Mar. 25, 2014]

**§ 522.1680 Oxytocin.**

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

(b) *Sponsors.* See Nos. , 000859, 054628, 054771 and 061623 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cats .....	0.25 to 0.5 .....	5 to 10.
Dogs .....	0.25 to 1.5 .....	5 to 30.
Ewes, Sows .....	1.5 to 2.5 .....	30 to 50.
Cows, Horses .....	5.0 .....	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cows .....	0.5 to 1.0 .....	10 to 20.
Sows .....	0.25 to 1.0 .....	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* 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; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001; 68 FR 36913, June 20, 2003; 77 FR 55414, Sept. 10, 2012; 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 16192, Mar. 25, 2014]

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

**§ 522.1696a Penicillin G benzathine and penicillin G procaine 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) Nos. 054771, 055529, and 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 000859, 055529, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) No. 054771 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