

before slaughter. Not for use in lactating dairy animals.

(i)(1) *Specifications*. Each milliliter of sterile solution contains 50 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 059130 in §510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly per pound of body weight per day.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations*. In severe forms of the indicated diseases, administer the equivalent of 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site. Discontinue treatment at least 18 days before slaughter. Not for use in lactating dairy cattle.

(j) [Reserved]

(k)(1) *Specifications*. Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 000864 in §510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*. (i) *Amount*. 3 to 5 milligrams per pound of body weight daily, 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases.

(ii) *Indications for use*. Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; acute metritis and wound infections caused by staphylococcal and streptococcal organisms; if labeled for use by or on the order of a licensed veterinarian, it may be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations*. Administer by intravenous injection. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not to exceed a total of 4 consecutive days. If no improvement occurs within 24 to 48 hours, reevaluate diagnosis and therapy. Discontinue use at least 19 days prior to slaughter. Not for use in lactating dairy cattle.

[40 FR 13853, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.1662a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications*. The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus*, *Streptococcus* spp., Bacterial pulmonary infections caused by *Brucella bronchiseptica*, *Streptococcus pyogenes*, *Staphylococcus aureus*, secondary bacterial infections caused by *Micrococcus pyogenes* var.

albus, Brucella bronchiseptica, Streptococcus spp.

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

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

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983]

§ 522.1680 Oxytocin injection.

(a) *Specifications.* Each milliliter of oxytocin injection contains 20 U.S.P. units of oxytocin.

(b) *Sponsors.* See Nos. 000010, 000856, 000864, 059130, 058639, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*¹—(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

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bio-equivalency and safety information.

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.* Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished. For parturition 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; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001]

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

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

(3) Nos. 000864, 010515, and 059130 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.