

§ 522.1663

21 CFR Ch. I (4–1–25 Edition)

Administer 3 to 5 mg/lb body weight daily by intravenous injection. Administer 5 mg/lb for anaplasmosis, severe foot rot, and severe forms of other diseases. Treatment should be continued 24 to 48 hours following remission of clinical signs of disease, but not to exceed 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* 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*, anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*; and acute metritis and wound infections caused by staphylococcal and streptococcal organisms.

(iii) *Limitations.* Not for use in lactating dairy cattle. Discontinue use at least 19 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 88 FR 14898, Mar. 10, 2023]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1662, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

§ 522.1663 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. 054771 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; 79 FR 16192, Mar. 25, 2014. Redesignated at 88 FR 14898, Mar. 10, 2023]

§ 522.1664 Oxytetracycline and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

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

(c) *Related tolerances.* See §§ 556.286 and 556.500 of this chapter.

(d) *Conditions of use cattle—(1) Amount.* Administer once as an 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. 054771 and 061133 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]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1680, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

**§ 522.1684 Pegbovigrastim.**

(a) *Specifications.* Each pre-filled, single-dose syringe contains 15 milligrams of pegbovigrastim.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* Administer the first dose (syringe) by subcutaneous injection 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) by subcutaneous injection within 24 hours after calving.

(2) *Indications for use.* For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

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

[81 FR 36789, June 8, 2016, as amended at 81 FR 48702, July 26, 2016]

**§ 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 and 061133 for use as in paragraph (d)(1) of this section.

(2) Nos. 016592 and 061133 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