

withdrawal time. Discontinue treatment at least 28 days prior to slaughter. For sponsor 061623: Not for use in lactating dairy cattle. For sponsors 000010, 000069, 011722, 053389, 055529, and 059130: Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food; use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

(2) *Swine*—(i) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(ii) *Indications for use*. Treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(iii) *Limitations*. Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980, as amended at 46 FR 20160, Apr. 3, 1981; 46 FR 27913, May 22, 1981; 52 FR 19502, May 26, 1987; 60 FR 14218, Mar. 16, 1995; 60 FR 29755, June 6, 1995; 61 FR 31028, June 19, 1996; 61 FR 36291, July 10, 1996; 62 FR 13825, Mar. 24, 1997; 62 FR 27692, May 21, 1997; 63 FR 52158, Sept. 30, 1998; 64 FR 23187, Apr. 30, 1999; 64 FR 26670, May 17, 1999; 64 FR 42831, Aug. 6, 1999; 66 FR 13235, Mar. 5, 2001; 67 FR 12471, Mar. 19, 2002; 67 FR 47451, July 19, 2002; 67 FR 72366, 72367, Dec. 5, 2002; 67 FR 78357, Dec. 24, 2002; 68 FR 8153, Feb. 20, 2003]

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications*. The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.*; *Hemophilis spp.*; *Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

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

(2) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a) *Amount*. Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body