

(2) *Indications for use.* As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by *Mycoplasma gallisepticum* and secondary bacterial organisms associated with chronic respiratory disease such as *E. coli*.

(3) *Limitations.* Administer for not more than 5 days; not for use in chickens producing eggs for human consumption; withdraw 24 hours before slaughter.

§ 520.1660b Oxytetracycline hydrochloride capsules.

(a) *Specifications.* The drug is in capsule form with each capsule containing 125 or 250 milligrams of oxytetracycline hydrochloride. Oxytetracycline is the antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

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

(c) *Conditions of use.* (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by *Brucella bronchiseptica*, tonsillitis caused by *Streptococcus hemolyticus*, bacterial enteritis caused by *Escherichia coli*, urinary tract infections caused by *Escherichia coli*, and wound infections caused by *Staphylococcus aureus*.¹

(2) The drug is administered orally to dogs and cats at a dosage level of 25–50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the severity and degree of involvement and the susceptibility of the infectious agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsid-

ered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications.* Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors.* For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See 000069 for use of 250 and 500 milligram tablets.

(c) *Tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1)(i) *Amount.* 250 milligrams per 100 pounds of body weight every 12 hours (5 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use.* For control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(2)(i) *Amount.* 500 milligrams per 100 pound of body weight every 12 hours (10 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use.* For treatment of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(3) *Limitations.* Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily). For sponsor 000069: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do

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 bioequivalency and safety information.

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not use in calves to be processed for veal.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998; 70 FR 16394, Apr. 4, 2005]

§ 520.1660d Oxytetracycline powder.

(a) *Specifications.* The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 oz.; pail: 5 lb). Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz).

(7) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 and 9.6 oz.; pails: 2 and 5 lb); each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb).

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and, 19.75 oz, and 3.91 lb; pails: 3.09 and 5 lb).

(10) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.74 oz; pails: 5 lb).

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

(1) No. 000069 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 046573 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

(3) No. 000010 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 057561 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, sheep, and honeybees.

(6) No. 048164 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

(7) No. 061623 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(8) No. 059320 for use of OTC concentration in paragraph (a)(10) of this section in chickens, turkeys, and swine as in paragraph (d) of this section.

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

(d) *Conditions of use.* (1) It is used in drinking water as follows:

(i) *Chickens—(A)(1) Amount per gallon.* 200 to 400 milligrams.

(2) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(B)(1) *Amount per gallon.* 400 to 800 milligrams.

(2) *Indications for use.* Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.