

§ 520.2345e

21 CFR Ch. I (4-1-01 Edition)

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

(4) *Turkeys*—(i) *Amount.* For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

[59 FR 17693, Apr. 14, 1994, as amended at 59 FR 19133, Apr. 22, 1994; 62 FR 5319, Feb. 5, 1997; 62 FR 35076, June 30, 1997; 62 FR 46668, Sept. 4, 1997; 62 FR 55160, Oct. 23, 1997; 64 FR 37673, July 13, 1999]

§ 520.2345e Tetracycline oral liquid.

(a) *Specifications.* Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

(b) *Sponsor.* See No. 000069, in § 510.600(c) of this chapter for use of 25 or 100 milligrams per milliliter liquid in dogs as in paragraph (c)(1) of this section; see No. 000009 in § 510.600(c) of this chapter for use of 100 milligrams per milliliter liquid in dogs and cats as in paragraph (c)(2).

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *Escherichia coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations.* Administer orally; continue treatment until symptoms have subsided and the temperature is

normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *National Academy of Sciences/National Research Council (NAS/NRC) status.* These conditions were NAS/NRC reviewed and found 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.

(2) *Dogs and cats*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations.* Administer orally; continue treatment until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.

(a) *Specifications.* Each capsule contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin.

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* *Dogs*—(1) *Amount.* 10 milligrams of each antibiotic per pound of body weight (1 capsule for each 6 pounds) every 12 hours.

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations.* Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment

should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin, or 180 milligrams of tetracycline hydrochloride and 180 milligrams of novobiocin.

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Amount.* 10 milligrams of each antibiotic per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds).

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations.* Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride, 60 milligrams of novobiocin, and 1.5 milligrams of prednisolone or 180 milligrams of tetracycline hydrochloride, 180 milligrams of novobiocin, and 4.5 milligrams of prednisolone.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Amount.* 10 milligrams of each antibiotic and 0.25 milligram of prednisolone per pound of body weight (one single-strength tablet for each 6 pounds

or one triple-strength tablet for each 18 pounds) every 12 hours for 48 hours. Treatment is to be continued with novobiocin and tetracycline alone at the same dose schedule for an additional 3 days or longer as needed.

(2) *Indications for use.* Treatment of acute and chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*, when it is necessary to initially reduce the severity of associated clinical signs.

(3) *Limitations.* As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Administer for 48 hours only. Continue treatment if needed with tetracycline/novobiocin alone. The product is contraindicated in animals with tuberculosis, hyperadrenocorticalism, or peptic ulcers. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2362 Thienium closylate tablets.

(a) *Chemical name.* (N,N-Dimethyl-N-2-phenoxyethyl-N-2'-thenylammonium)-p-chlorobenzene-sulfonate.

(b) *Specifications.* Thienium closylate tablets contain thienium closylate equivalent to 500 milligrams thienium as base in each tablet.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs as a single day treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms). Dogs weighing 10 pounds and over are administered 1 tablet as a single dose. Dogs