

§ 520.2345g

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

21 CFR Ch. I (4–1–03 Edition)

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

weighing 5 to 10 pounds are administered one-half tablet twice during a single day. All dosages are given for 1 day only. The treatment should be repeated after 2 or 3 weeks.

(2) Suckling puppies or recently weaned puppies weighing less than 5 pounds should not be treated with the drug. Animals that are severely infected, exhibiting evidence of intestinal hemorrhage, debilitation, and anemia, should be given supportive treatment.

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 53477, Dec. 7, 1976; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2380 Thiabendazole oral dosage forms.

§ 520.2380a Thiabendazole top dressing and mineral protein feed block.

(a) *Chemical name.* 2-(4-Thiazolyl)-benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* (1) See No. 017800 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (e)(1)(ii) of this section.

(2) See No. 050604 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e)(1)(ii) of this section.

(3) See No. 021930 in § 510.600(c) of this chapter for the sponsor of the usage provided for by paragraph (e)(2) of this section.

(d) *Related tolerances.* See § 556.730 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Route of administration.* In feed, as a top dressing.

(a) *Amount.* 2 grams per 100 pounds of body weight.

(b) *Indications for use.* For control of large strongyles, small strongyles, pinworms, and threadworms (including members of the genera *Strongylus*, *Cyathostomum*, *Cylicobrachytus*, and related genera, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*, *Oxyuris*, and *Strongyloides*).

(c) *Limitations.* Add to the usual feed of horses mixed into that amount of

the feed normally consumed at one feeding. Warning: Not for use in horses intended for food.

(ii) *Route of administration.* In feed.

(a) *Amount.* 2 grams per 100 pounds of body weight.

(1) *Indications for use.* For control of large and small strongyles, *Strongyloides*, and pinworms of the genera *Strongylus*, *Cyathostomum*, *Cylicobrachytus* and related genera, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*, *Oxyuris*, and *Strongyloides*.

(2) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(b) *Amount.* 4 grams per 100 pounds of body weight.

(1) *Indications for use.* For control of ascarids of the genus *Parascaris*.

(2) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(2) *Cattle*—(i) *Route of administration.* In feed block.

(ii) *Amount.* 3.3 percent block consumed at the recommended level of 0.11 pound per 100 pounds of body weight per day.

(iii) *Indications for use.* For control of infections of gastrointestinal roundworms (*Trichostrongylus*, *Haemonchus*, *Ostertagia* and *Cooperia*).

(iv) *Limitations.* Administer to cattle on pasture or range accustomed to mineral protein block feeding for 3 days. Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or diagnostic laboratory prior to worming. Animals maintained under conditions of constant worm exposure may require re-treatment within 2 to 3 weeks. Animals that are severely parasitized, sick, or off feed should be isolated and a veterinarian consulted for advice concerning treatment.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 9149, Mar. 3, 1976; 62 FR 63271, Nov. 28, 1997]