by § 514.111 of this chapter, but may require bioequivalency and safety information.

(5) *Conditions of use*—(i) *Swine*—(*a*) *Amount.* 1 tablet (400 milligrams) per gallon of drinking water for no more than 6 days, or 1 tablet (400 milligrams) per 2 fluid ounces of warm water per 50 pounds of body weight as a drench once daily for 1 to 2 days.

(*b*) *Indications for use.* As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).

(*c*) *Limitations.* Treatment may be repeated after 5 days off medication. If no improvement is observed, consult a veterinarian. Treated animals must consume enough medicated water to provide a therapeutic dose. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) [Reserved]

(c)(1) *Specifications.* Each tablet contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.60 of this chapter.

(4) *Conditions of use in growing chickens and growing turkeys*—(i) *Amount.* 1 tablet in each gallon of drinking water (0.002 percent roxarsone).

(ii) *Indications for use.* For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) *Limitations.* Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[46 FR 41040, Aug. 14, 1981, as amended at 46 FR 42448, Aug. 21, 1981; 47 FR 15238, Apr. 9, 1982; 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992; 58 FR 65664, Dec. 16, 1993; 65 FR 10705, Feb. 29, 2000]

§ 520.2089 Roxarsone liquid.

(a) *Specifications.* Each teaspoon (5 milliliters) of solution contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.60 of this chapter.

(d) *Conditions of use in growing chickens and growing turkeys*—(1) *Amount.* 1 teaspoon (5 milliliters) to each gallon of drinking water (0.002 percent roxarsone).

(2) *Indications for use.* For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) *Limitations.* Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[58 FR 65665, Dec. 16, 1993, as amended at 65 FR 10705, Feb. 29, 2000]

§ 520.2098 Selegiline hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 2, 5, 10, 15, or 30 milligrams of selegiline hydrochloride.

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

(c) [Reserved]

(d) *Conditions of use—Dogs*—(1) *Dosage.* 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(i) *Indications for use.* For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) *Limitations.* Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dosage.* 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use.* For the control of clinical signs associated with canine cognitive dysfunction syndrome.

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

[62 FR 34632, June 27, 1997; 62 FR 55159, Oct. 23, 1997, as amended at 63 FR 29551, June 1, 1998; 64 FR 2122, Jan. 13, 1999]

§ 520.2100 Selenium, vitamin E capsules.

(a) *Specifications.* The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium)

and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate.)

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

(c) *Conditions of use.* (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(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 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

§ 520.2123 Spectinomycin oral dosage forms.

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride pentahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

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

[73 FR 6607, Feb. 5, 2008]

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts*—(i) For increased rate of weight gain and improved feed efficiency in broiler chickens, administer 0.5 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(ii) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(iii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[73 FR 6607, Feb. 5, 2008]

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.