

(ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug.

(iv) Warning: Do not use in horses or colts intended for food.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 28769, June 3, 1994; 69 FR 41427, July 9, 2004]

#### § 520.2087 Roxarsone soluble powder.

(a) *Specifications*. Each ounce (avoirdupois) of soluble powder contains 21.7 grams of roxarsone (monosodium 3-nitro-4-hydroxyphenylarsonate).

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

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

(d) *NAS/NRC status*. These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(e) *Conditions of use*—(1) *Growing chickens and growing turkeys*—(i) *Amount*. 0.002 percent roxarsone in drinking water (one packet per each 250 gallons of drinking water).

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

(iii) *Limitations*. Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(2) *Swine*—(i) *Amount*. 0.01 percent roxarsone in drinking water (one packet per each 50 gallons of drinking water); or 30 milliliters of a 1.55 percent roxarsone solution (one packet per 3 pints of water) per 50 pounds of body weight as a drench.

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

(iii) *Limitations*. Administer drinking water continuously for not more than 6 days. Administer drench once daily for 1 or 2 days. If no improvement is observed, consult a veterinarian. Treatment may be repeated after 5 days.

Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

[46 FR 41039, Aug. 14, 1981, as amended at 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992; 69 FR 41427, July 9, 2004]

#### § 520.2088 Roxarsone tablets.

(a)(1) *Specifications*. Each tablet contains 36 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) *NAS/NRC status*. The weight gain, feed efficiency, and pigmentation claims are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(5) *Conditions of use*—(i) *Growing chickens and growing turkeys*—(a) *Amount*. Dissolve 2 tablets in each gallon of drinking water (0.002 percent roxarsone).

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

(c) *Limitations*. Administer continuously throughout growing period. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(ii) *Growing chickens*—(a) *Amount*. Dissolve 8 tablets in each gallon of drinking water (0.008 percent roxarsone).

(b) *Indications for use*. As an aid in the prevention of coccidiosis due to *Eimeria tenella*.

(c) *Limitations*. Administer for not more than 10 consecutive days. Treatment may be repeated after 5 days off medication. Withdraw 5 days before slaughter. Use as sole source of organic arsenic.

(b)(1) *Specifications*. Each tablet contains 400 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) *NAS/NRC status*. These conditions are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified

## § 520.2089

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.

## 21 CFR Ch. I (4–1–10 Edition)

(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)