(3) *Limitations.* Administer for 2 days at 747 milligrams of sulfanitran per gallon and 954 milligrams of aklomide per gallon, followed by 5 days at 374 milligrams of sulfanitran per gallon and 477 milligrams of aklomide per gallon; do not treat birds over 6 weeks of age; do not administer within 5 days of slaughter; not for laying chickens.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 9396, Mar. 5, 1982; 54 FR 18280, Apr. 28, 1989; 55 FR 8460, Mar. 8, 1990; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

§ 520.2325 Sulfaquinoxaline oral dosage forms.

§ 520.2325a Sulfaquinoxaline drinking water.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) To No. 059130 for use of a 25-percent sulfaquinoxaline soluble powder and a 20-percent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To No. 061623 for use of 3.44- and 12.85-percent sulfaquinoxaline sodium solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) To No. 046573 for use of a 31.92-percent sulfaquinoxaline solution (sodium and potassium salts) as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(4) No. 053501 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(b) *Related tolerances.* See § 556.685 of this chapter.

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

(1) *Chickens.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti.*

(ii) Administer at the 0.04 percent level for 2 or 3 days, skip 3 days then administer at the 0.025 percent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 percent level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(2) *Turkeys.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides.*

(ii) Administer at the 0.025 percent level for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(3) *Chickens and turkeys.* (i) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(ii) Administer at the 0.04 percent level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. If cholera has become established as the respiratory or chronic form, use feed medicated with sulfaquinoxaline. Poultry which have survived typhoid outbreaks should not be kept for laying house replacements or breeders unless tests show they are not carriers.

(4) *Cattle and calves.* (i) For the control and treatment of outbreaks of coccidiosis caused by *Eimeria bovis* or *E. zurnii.*

(ii) Administer at the 0.015-percent level for 3 to 5 days in drinking water medicated with sulfaquinoxaline solution.

(iii) In lieu of treatment as provided in paragraph (e)(4)(ii) of this section, administer 1 teaspoon of 25-percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations.* Consult a veterinarian or poultry pathologist for diagnosis. May cause toxic reactions unless the drug is evenly mixed in water at dosages indicated and used according to directions. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, cattle, and calves must actually consume enough medicated water which provides a recommended dosage of approximately 10 to 45 milligrams per pound per day in chickens, 3.5 to 55 milligrams per pound per day in turkeys, and approximately 6 milligrams per pound per day in cattle and calves depending on the age, class of animal, ambient temperature, and other factors. A withdrawal period has not been

established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Make fresh drinking water daily.

[48 FR 3964, Jan. 28, 1983, as amended at 48 FR 26762, June 10, 1983; 55 FR 29843, July 23, 1990; 59 FR 28769, June 3, 1994; 59 FR 33197, June 28, 1994; 61 FR 24443, May 15, 1996; 61 FR 63711, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 65 FR 10705, Feb. 29, 2000; 69 FR 41427, July 9, 2004; 69 FR 60547, Oct. 12, 2004; 74 FR 36112, July 22, 2009]

§ 520.2325b Sulfaquinoxaline drench.

(a)–(b) [Reserved]

(c) *Sponsor*. See No. 050749 in § 510.600(c) of this chapter.

(d) *NAS/NRC status*. The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Conditions of uses*. As a 25-percent sulfaquinoxaline soluble powder.

(1) For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zurnii*.

(2) Give one teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(f) *Limitations*. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[48 FR 3964, Jan. 28, 1983, as amended at 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications*. Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer one tablet orally per 4 pounds of body weight.[1]

(2) *Indications for use*. Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.[1]

(3) *Limitations*. Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.[1]

[43 FR 60895, Dec. 29, 1978]

§ 520.2340 Tepoxalin.

(a) *Specifications*. Each tablet contains 30, 50, 100, or 200 milligrams (mg) tepoxalin.

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

(c) *Conditions of use in dogs*—(1) *Amount*. 10 mg per kilogram (/kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

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

[68 FR 34795, June 11, 2003]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications*. Each capsule contains 50, 100, 125, 250, or 500 milligrams (mg) tetracycline hydrochloride.

(b) *Sponsor*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

[1] These 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.