Food and Drug Administration, HHS

§ 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-per cent sulfaquinoxaline soluble powder and a 20-per cent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To No. 061623 for use of 3.44- and 12.85-per cent 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-per cent 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-per cent sulfaquinoxaline sodium solution as provided for 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 0.025 per cent level for 2 or 3 days, skip 3 days, then administer at the 0.025 per cent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 per cent 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 per cent 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 per cent 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 per cent 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-per cent 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 doses 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 for cattle and calves.
§ 520.2325b Sulfadimethoxine (Stovax) injection.

(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 use. As a 25-percent sulfadimethoxine soluble powder.

(1) For the control and treatment of contagious bovine pleuropneumonia caused by Mycoplasma bovis.

(2) Give one teaspoon of 25 percent sulfadimethoxine 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.