

**§ 520.2261b**

**21 CFR Ch. I (4–1–03 Edition)**

turkeys must actually consume enough medicated water which provides the recommended dosages.

(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 and safety information.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982; 67 FR 78355, Dec. 24, 2002]

**§ 520.2261b Sulfamethazine sodium soluble powder.**

(a) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter for use of a soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Related tolerances in edible products.* See §556.670 of this chapter.

(c) *Conditions of use—(1) Amount.* Administer in drinking water to provide: Chickens 58 to 85 milligrams of sulfamethazine sodium per pound of body weight per day; turkeys 50 to 124 milligrams of sulfamethazine sodium per pound of body weight per day; depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors. Administer to cattle and swine in drinking water, or as a drench, to provide 108 milligrams of sulfamethazine sodium per pound of body weight on the first day and 54 milligrams of sulfamethazine sodium per pound of body weight per day on the second, third, and fourth days of administration.

(2) *Indications for use.* For treatment and control of disease caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine.* Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease in chickens, medicate for 6 consecutive days; coccidiosis in chickens and turkeys, medicate as in paragraph (c) of this section for 2 days, then reduce drug concentration to one-half for 4 additional days.

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days prior to slaughter for food. Not for use in lactating dairy animals. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages.

(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 and safety information.

[47 FR 25322, June 11, 1982, as amended at 67 FR 78355, Dec. 24, 2002]

**§ 520.2280 Sulfamethizole and methenamine mandelate tablets.**

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

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

(c) *Conditions of use.* (1) The drug is indicated for the treatment of urinary tract infections in dogs and cats such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. It is also used as an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

(2) It is administered at a dosage level of one tablet for each 20 pounds of body weight given three times per day. The drug should be given until all signs are alleviated. To reduce the possibility of a relapse, it is suggested that therapy be continued for a further period of a week to 10 days.

(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 50 FR 13561, Apr. 5, 1985]

**§ 520.2320 Sulfanitrans and aklomide in combination.**

(a) *Chemical names.* (1) Sulfanitrans: Acetyl-(*p*-nitrophenyl)-sulfanilamide.

(2) Aklomide: 2-Chloro-4-nitrobenzamide.

(b) *Specifications.* (1) Sulfanitrans conforms to the following specifications:

(i) Melting point range: 260 °C. to 261 °C.

(ii) Assay (by sodium nitrite titration): 97 to 100.5 percent.

(iii) Moisture (Method No. 6.123, "Toluene Distillation Method—Official Final Action" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, p. 83. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001): Not more than 2.0 percent.

(iv) Molecular weight: 335.34.

(v) Soluble in 0.1N sodium hydroxide, reprecipitating unchanged on acidification.

(2) Aklomide conforms to the following specifications:

(i) Minimum melting point: 170 °C.

(ii) Moisture content: Not to exceed 1.0 percent.

(iii) Purity: Not less than 98 percent on an anhydrous basis.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See §§ 556.30 and 556.680 of this chapter.

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

(1) *Amount.* 374-747 milligrams of sulfanitrans with 477-954 milligrams of aklomide.

(2) *Indications for use.* As an aid in the treatment of coccidiosis caused by *E. tenella*, *E. necatrix*, and *E. acervulina*.

(3) *Limitations.* Administer for 2 days at 747 milligrams of sulfanitrans per gallon and 954 milligrams of aklomide per gallon, followed by 5 days at 374 milligrams of sulfanitrans 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]

**§ 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. 050749 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. 060594 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.