

§ 520.90e

21 CFR Ch. I (4–1–04 Edition)

to *Staphylococcus* spp., *Streptococcus* spp., *Bacillus* spp., and *Pasteurella* spp.

(iii) *Limitations.* Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90e Ampicillin trihydrate soluble powder.

(a) *Specifications.* Each gram contains ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use. Swine*—(1) *Amount.* 5 milligrams of ampicillin per pound of body weight twice daily, orally by gavage or in drinking water for up to 5 days.

(2) *Indications for use.* Oral treatment of porcine colibacillosis (*Escherichia coli*) and salmonellosis (*Salmonella* spp.) infections in swine up to 75 pounds of body weight, and bacterial pneumonia caused by *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

(3) *Limitations.* For use in swine only. Not for use in other animals which are raised for food production. Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90f Ampicillin trihydrate boluses.

(a) *Specifications.* Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter for use as in

paragraph (d)(1), 000069 for use as in paragraph (d)(2).

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use. Nonruminating calves*—(1) *Amount.* 5 milligrams per pound of body weight twice daily for up to 5 days.

(i) *Indications for use.* Oral treatment of colibacillosis caused by *Escherichia coli*, bacterial enteritis caused by *Salmonella* spp., and bacterial pneumonia caused by *Pasteurella* spp.

(ii) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount.* 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(i) *Indications for use.* Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli*.

(ii) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995]

§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

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

(1) *Chickens and turkeys*—(i) *Amount.* 20 percent soluble powder.

(ii) *Indications for use.* Treatment of coccidiosis.

(iii) *Limitations.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024

percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves*—(i) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations*. Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations*. Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.100b Amprolium drench.

(a) *Chemical name*. 1-(4-Amino-2-*n*-propyl - 5 - pyrimidinylmethyl) - 2 - picolinium chloride hydrochloride.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is used for calves as follows:

(1) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.100c Amprolium crumbles.

(a) *Specifications*. Amprolium crumbles contain 1.25 percent amprolium.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) *Amount*. 1.6 ounces of crumbles per 250 pounds of body weight per day (5