Food and Drug Administration, HHS

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*.