

## § 520.90f

## 21 CFR Ch. I (4–1–11 Edition)

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.

(a) *Specifications—(1)* Each milliliter of solution contains 96 milligrams (mg) amprolium (9.6 percent solution).

(2) Each gram of powder contains 200 mg amprolium (20 percent).

(3) Each ounce (28.4 grams) of crumbles contains 355 mg amprolium (1.25 percent).

(b) *Sponsors.* See sponsors in 510.600(c) of this chapter.

(1) No. 016592 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) No. 66104 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

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

(d) *Conditions of use—(1) Chickens and turkeys.* It is used in drinking water as follows:

(i) *Amount.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for 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.

(ii) *Indications for use.* For the treatment of coccidiosis.

(iii) *Limitations.* Use as the sole source of amprolium.

(2) *Calves.* Administer crumbles top-dressed on or thoroughly mixed in the daily feed ration; administer concentrate solution or soluble powder as a drench or in drinking water as follows:

(i) *Indications for use and amounts—(A)* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

(ii) *Limitations.* Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in

**Food and Drug Administration, HHS**

**§ 520.154a**

calves to be processed for veal. Use as the sole source of amprolium.

[71 FR 56346, Sept. 27, 2006, as amended at 72 FR 60551, Oct. 25, 2007; 73 FR 45611, Aug. 6, 2008; 73 FR 70276, Nov. 20, 2008; 74 FR 10484, Mar. 11, 2009]

**§ 520.110 Apramycin sulfate soluble powder.**

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use.* (1) In swine for control of porcine colibacillosis (weanling pig scours) caused by strains of *E. coli* sensitive to apramycin.

(2) It is administered for 7 days in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day. Swine will normally consume 1 gallon per day of medicated water containing 375 milligrams of apramycin for each 66 pounds of body weight. Water consumption should be monitored to determine that the required amount of apramycin is being consumed. The drug concentration should be adjusted according to water consumption which varies depending on ambient temperature, humidity, and other factors.

(3) Prepare fresh medicated water daily.

(4) Do not slaughter treated swine for 28 days following treatment

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988]

**§ 520.154 Bacitracin oral dosage forms.**

**§ 520.154a Soluble bacitracin methylene disalicylate.**

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Growing turkeys*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler and replacement chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Treponema hyodysenteriae*. Administer continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations.* Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

(4) *Growing quail*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 63 FR 38474, July 17, 1998; 64 FR 13068, Mar. 17, 1999]