

milligrams per kilogram of body weight).

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

(ii) *Limitations.* Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) *Amount.* 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

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

(ii) *Limitations.* Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination 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. Use as sole source of amprolium.

[42 FR 41855, Aug. 19, 1977, as amended at 62 FR 63270, Nov. 28, 1997]

#### § 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

## § 520.154b

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]

## § 520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.

(a) *Specifications.* Each gram contains 200 units of soluble bacitracin methylene disalicylate, streptomycin sulfate equivalent to 20 milligrams of streptomycin, and 850 milligrams of carob flour.

(b) *Sponsor.* See No. 062925 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use.* Treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

(3) *Limitations.* If no improvement is noted in 2 to 3 days, diagnosis should be reevaluated. 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 61 FR 66581, Dec. 18, 1996]

## § 520.154c Bacitracin zinc soluble powder.

(a) *Specifications.* Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

## 21 CFR Ch. I (4–1–01 Edition)

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

(d) *Conditions of use.* (1) *Broiler chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

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

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

(A) *Indications for use.* Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

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

(2) *Growing quail*—(i) *Amount.* 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use.* Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

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

[57 FR 37322, Aug. 18, 1992]

## § 520.182 Bicyclohexylammonium fumagillin.

(a) *Specifications.* The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) *Sponsor.* See No. 059620 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prevention of nosema in honey bees.<sup>1</sup>

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar sirup.<sup>1</sup>

(3) Colonies used for package production should be fed medicated sirup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.<sup>1</sup>

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed 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.