

§ 520.1204

21 CFR Ch. I (4-1-03 Edition)

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.

(a) *Specifications.* Each five milliliters of suspension of the drug contains: 100 milligrams of kanamycin as the sulfate, 0.033 milligram of aminopentamide hydrogen sulfate, 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

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

(c) *Conditions of use.* (1) It is administered orally to dogs for the symptomatic relief of acute bacterial diarrhea caused by kanamycin-susceptible organisms.

(2) The drug is recommended for use at the rate of one teaspoonful (5 milliliters) of suspension per 20 pounds of body weight every 8 hours. Animals weighing under 10 pounds should be given one-half the above amount every 8 hours. The initial dose should be twice the amount of a single dose. Maximum dosage should not exceed three times the recommended dose.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999]

§ 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgite tablets.

(a) *Specifications.* Each tablet contains 100 milligrams of kanamycin (as the sulfate), 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

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

(c) *Conditions of use*—(1) *Amount.* One tablet per 44 kilograms (20 pounds) of body weight every 8 hours. Maximum dose 3 tablets every 8 hours. For animals under 22 kilograms (10 pounds) ½ tablet every 8 hours. The initial loading dose should be twice the amount of a single dose.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of associated diarrhea in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 8710, Mar. 1, 1991]

§ 520.1242 Levamisole hydrochloride oral dosage forms.

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) *Specifications.* Each package contains either 9.075, 11.7, 18.15, 46.8, or 544.5 grams of levamisole hydrochloride.

(b) *Sponsors.* Approval for sponsors in 21 CFR 510.600(c) for use as in paragraph (d) of this section as follows:

(1) See No. 053501 for use of 46.8 gram package as in paragraph (d)(1) of this section, for 11.7 and 46.8 gram packages as in paragraph (d)(2) of this section, and for 9.075 and 18.15 gram packages as in paragraph (d)(3) of this section.

(2) See 000061 for use of 46.8 and 544.5 gram packages as in paragraph (d)(1) of this section, for 11.7, 46.8, and 544.5 gram packages as in paragraph (d)(2) of this section, and for 18.15 gram package as in paragraph (d)(3) of this section.

(3) See 057561 for use of 46.8 and 544.5 gram packages as in paragraphs (d)(1) and (d)(2) of this section.

(4) See No. 059130 for use of 18.15-gram packages as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used as an anthelmintic at 0.365 gram per 100 pounds of body weight as follows:

(1) *Cattle*—(i) *Amount.* As a single oral dose drench using 46.8 or 544.5 gram packet.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagotomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment.