

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 043781 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.

(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. Not for use in dairy animals of breeding age. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(a) Dissolve contents of 46.8 gram package in water to provide 1 quart (32 fluid ounces) of drench solution and administer as a drench at 1/4 ounce per 100 pounds of body weight as a single oral dose.

(b) Dissolve contents of 46.8 gram package in water to provide 8.75 fluid ounces of concentrate solution and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose by syringe.

(c) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(2) *Sheep*—(i) *Amount*. As a single oral dose drench using 11.7, 46.8, or 544.5 gram packet.

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

(b) *Limitations*. Dissolve in 1 gallon (128 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 72 hours

§ 520.1242b

21 CFR Ch. I (4–1–02 Edition)

of treatment; consult veterinarian before using in severely debilitated animals.

(ii) *Amount.* 11.7 grams per packet.

(a) *Indications for use.* See paragraph (f)(2)(i)(a) of this section.

(b) *Limitations.* Dissolve in 1 quart (32 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight or dissolve 1 packet in 10.9 fluid ounces of water and administer as a single drench at 1 cubic centimeter (0.036 gram) per 10 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 72 hours of treatment; consult veterinarian before using in severely debilitated animals.

(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 72 hours of treatment. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(a) Dissolve contents of 11.7 gram package in 1 quart (32 ounces) of water and administer as a drench at 1 ounce per 100 pounds of body weight, or dissolve in 10.9 fluid ounces of water and administer as a drench at 1 milliliter per 10 pounds of body weight as a single oral dose.

(b) Dissolve contents of 46.8 gram package in 128 fluid ounces (1 gallon) of water and administer as a drench at 1 ounce per 100 pounds of body weight as a single oral dose.

(c) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(3) *Swine*—(i) *Amount.* 9.075 or 18.15 grams per bottle.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(iii) *Limitations.* Dissolve in water to provide 9.075 grams per 250 milliliters or 18.15 grams per 500 milliliters. Add 10 milliliters (2 teaspoons) of this concentrate solution to each gallon of drinking water. Allow 1 gallon of medicated drinking water for each 100 pounds of body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 44 FR 59508, Oct. 16, 1979; 44 FR 72586, Dec. 14, 1979; 46 FR 25085, May 5, 1981; 52 FR 20598, June 2, 1987; 54 FR 18280, Apr. 28, 1989; 62 FR 61625, Nov. 19, 1997; 63 FR 59713, Nov. 5, 1998]

§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

(a) *Chemical name.* (-)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-*b*] thiazole monohydrochloride.

(b) *Specifications.* Assay of not less than 98 percent by nonaqueous titration with 0.1 N potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Sponsor.* See Nos. 000061 and 043781 in § 510.600(c) of this chapter.

(d) *Required labeling.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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

(f) *Conditions of use.* (1) It is used in an oblet for cattle as follows:

(i) *Amount.* 2.19 grams per oblet.

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