

§ 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*).

(iii) *Limitations*. Administer as a single dose as follows: 250 to 450 pounds, ½ oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, 1½ oblets; conditions of constant helminth exposure may require re-treatment 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 veterinarian before using in severely debilitated animals.

(2) It is used in a tablet for sheep as follows:

(i) *Amount*. 0.184 gram per tablet.

(ii) *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*).

(iii) *Limitations*. Administer one tablet for each 50 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 a veterinarian before using in severely debilitated animals.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 59507, Oct. 16, 1979; 62 FR 61625, Nov. 19, 1997]

#### § 520.1242c Levamisole hydrochloride and piperazine dihydrochloride.

(a) *Specifications*. (1) The drug is an aqueous solution which contains in each fluid ounce 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) The drug is a soluble powder which when reconstituted with water contains in each fluid ounce 0.45 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 5.0 grams of piperazine base.

(b) *Sponsor*. See No. 043781 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*. It is used as a drench for horses as follows:

(1) *Indications for use*. An anthelmintic effective against infections of large strongyles (*Strongylus vulgaris*, *S.*

*edentatus*), small strongyles (*Cylicocercus* spp., *Cylicocylclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp., *Cylicotetrapedon* spp.), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equii*).

(2) *Limitations*. Aqueous solution: administer by stomach tube or drench 1 fluid ounce per 100 pounds of body weight. Reconstituted soluble powder: administer by stomach tube 1 fluid ounce per 125 pounds of body weight. If reinfection occurs, re-treat animals at 6- to 8-week intervals. Do not treat animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 32831, Aug. 5, 1975, as amended at 41 FR 48731, Nov. 5, 1976; 43 FR 11176 Mar. 17, 1978]

#### § 520.1242d Levamisole resinate.

(a) *Specifications*. The drug is levamisole adsorbed on a resin, in a concentration equivalent to 10 percent levamisole hydrochloride. Each 2.05-ounce (58.1 gram) packet contains levamisole equivalent to 5.806 grams of levamisole hydrochloride.

(b) *Sponsor*. See No. 043781 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*. In swine it is used as follows:

(1) *Amount*. The equivalent of 8 milligrams per kilogram of body weight, as a single dose, mixed in the animal's ration.

(2) *Indications for use*. For the removal of and control of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and swine kidney worms (*Stephanurus dentatum*).

(3) *Limitations*. For pigs from weaning to market weight, mix one 58.1-gram packet of levamisole resinate containing the equivalent of 10-percent levamisole hydrochloride in 40 pounds of feed and administer 1 pound of medicated feed per 40 pounds of body weight as sole ration. For breeding swine, mix 1 packet of the 10-percent resinate in 16 pounds of feed and administer 1 pound of medicated feed per 100 pounds of