Food and Drug Administration, HHS

(iii) Limitations. Administer as a single dose as follows: 250 to 450 pounds, $\frac{1}{2}$ oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, $\frac{1}{2}$ 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, Chabertia), Oesophagostomum, 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 piper-azine 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 equi).

(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 2.05ounce (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 lungworms spp.), (Metastrongylus intestinal spp.). 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 body weight as sole ration. Administer as single doses. Withhold regular feed overnight and administer medicated feed the following morning. Do not withhold water during fasting. Do not treat within 72 hours of slaughter. Salivation or muzzle foam may be observed. The reaction will disappear a short time after feeding. If pigs are infected with mature lungworms. coughing and vomiting may be observed. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 18171, Apr. 28, 1978, as amended at 45 FR 3574, Jan. 18, 1980]

§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) *Specifications*. Each tablet contains 907 milligrams 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*. It is used for swine as follows:

(1) Amount. The equivalent of 8 milligrams of levamisole hydrochloride per kilogram of body weight, as a single dose.

(2) Indications for use. See \$520.1242a(f)(3)(ii).

(3) Limitations. Withholding water from pigs before treatment is not necessary. Add one tablet for each 2½ gallons of water; mix thoroughly. Allow 1 gallon of medicated water for each 100 pounds 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 worm exposure may require re-treatment within 4 to 5 weeks. 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.

[45 FR 6087, Jan. 25, 1980]

21 CFR Ch. I (4–1–02 Edition)

§520.1242f Levamisole hydrochloride gel.

(a) *Specifications*. The drug is a gel containing 11.5 percent 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—(1) Cattle—(i) Amount. Eight milligrams of levamisole hydrochloride per kilogram of body weight, as a single oral dose.

(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. Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not administer to cattle within 6 days of slaughter for food; do not administer to dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) Breeding swine—(i) Amount. Eight milligrams per kilogram of body weight (3.6 milligrams per pound) as a single oral dose.

(ii) Conditions of use. For treating breeding swine infected with the following nematodes: Large roundworms (Ascaris suum). nodular worms (Oesophagostomum spp.), lungworms intestinal (Metastrongylus spp.), threadworms (Strongyloides ransomi), (Stephanurus and kidney worms dentatus).

(iii) *Limitations*. May require retreatment in 4 to 5 weeks. Do not use within 11 days of slaughter for food. Consult your veterinarian for assistance before using in severely debilitated animals and in the diagnosis, treatment, and control of parasitism.

[47 FR 22517, May 25, 1982; 47 FR 30242, July
13, 1982, as amended at 48 FR 11429, Mar. 18, 1983; 51 FR 29215, Aug. 15, 1986]