Food and Drug Administration, HHS

§520.1242g Levamisole resinate and famphur paste.

(a) Chemical name of famphur. O, O-Dimethyl O-[p-(dimethylsulfamoyl) phenyl] phosphorothioate.

(b) *Specifications*. The drug is a paste containing 11.6 percent levamisole resinate (50 percent potency) and 23.6 percent famphur.

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

(d) *Special considerations*. Do not use any cholinesterase-inhibiting drugs, pesticides, insecticides, or chemicals on cattle simultaneously or within a few days before or after treatment with this product.

(e) *Related tolerances.* See §556.350 of this chapter for levamisole and §556.273 of this chapter for famphur.

(f) Conditions of use in cattle—(1) Amount. 8 milligrams of levamisole hydrochloride (equivalent) and 30 milligrams of famphur activity per kilogram of body weight.

(2) Indications for	<i>use</i> . For treatment
of cattle infected	with the following
parasites: St	omach worms
(Haemonchus,	Trichostrongylus,
Ostertagia), in	testinal worms
(Trichostrongylus,	Cooperia,
Nematodirus,	Bunostomum,
Oesophagostomum),	lungworms
(Dictyocaulus),	cattle grubs
(Hypoderma), biting lice (Bovicola), and	
sucking lice (Linognathus, Solenoptes).	

(3) Limitations. Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54
FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992;
62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997]

§ 520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.

§520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.

(a) *Specifications*. The sirup contains lincomycin hydrochloride equivalent to either 25 milligrams or 50 milligrams of lincomycin.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated in infections caused by grampositive organisms which are sensitive to its action, particularly streptococci and staphylococci.

(2) It is administered orally to dogs and cats at a dosage level of 10 mgs per pound of body weight every 12 hours, or 7 mgs per pound of body weight every 8 hours. Treatment may be continued for periods as long as 12 days if clinical judgment indicates.

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

[40 FR 13838, Mar. 27, 1975, as amended at 44
 FR 7130, Feb. 6, 1979; 64 FR 403, Jan. 5, 1999]

§520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.

(a) Specifications. The spectinomycin sulfate tetrahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of Streptomyces spectabilis or the same antibiotic substance produced by any other means. The quantity of total antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drugs. Lincomycin hydrochloride monohvdrate and spectinomycin sulfate tetrahydrate are present in the drug in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base.

(b) Sponsor. See No. 000009 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.600 and 556.360 of this chapter.

(d) Conditions of use. (1) It is administered in the drinking water of chickens

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up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma* gallisepticum susceptible to lincomycinspectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M.* gallisepticum susceptible to lincomycinspectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 1891, Jan. 13, 1976; 64 FR 403, Jan. 5, 1999]

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) Specifications. Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin. The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) Sponsors. Approval for use of 40and 80-gram packet to Nos. 000009 and 046573 in \$510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in \$510.600(c) of this chapter. Approval for use of 40-gram packet to No. 046573 \$510.600(c) of this chapter.

(c) *Tolerances*. See §556.360 of this chapter.

(d) *Conditions of use*—(1) It is used in drinking water for swine as follows:

(i) Amount. 250 milligrams per gallon.(A) Dosage. 3.8 milligrams per pound of body weight per day.

(B) *Indications for use*. Treatment of swine dysentery (bloody scours).

(C) Limitations. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. Not for use in swine weighing more than 250 pounds.

(ii) [Reserved]

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(2) It is used in drinking water for broiler chickens as follows:

(i) Amount. 64 milligrams per gallon.(A) Indications for use. For the con-

(A) Indications for use. For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

(B) Limitations. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

(ii) [Reserved]

[48 FR 3966, Jan. 28, 1983, as amended at 55
FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16,
1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341,
Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR
66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000]

§ 520.1284 Sodium liothyronine tablets.

(a) Specifications. Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

(b) Sponsor. See No. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8µg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

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

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron.

(2) Cats. Each tablet contains either 90, 135, 204.9 or 270 mg of lufenuron.