Food and Drug Administration, HHS

§522.1185 Isoflupredone.

(a) Specifications. Each milliliter of suspension contains 2 milligrams (mg) of isoflupredone acetate.

(b) Sponsor. See No. 054771 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Cattle—(i) Amount. Administer 10 to 20 mg by intramuscular injection.

(ii) Indications for use. For use in the treatment of bovine ketosis. For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) Limitations. Animals intended for human consumption should not be slaughtered within 7 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§522.1192 Ivermectin.

(a) Specifications—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

(b) Sponsors. See sponsors in §510.600(e) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 000859, 055529, 058005, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

(d) Special considerations—(1) See §500.25 of this chapter.

(2) Labeling shall bear the following precaution: “This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.”

(e) Conditions of use—(1) Horses—(i) Amount. 200 micrograms per kilogram (μg/kg) of body weight by intramuscular injection.

(ii) Indications for use. For the treatment and control of large strongyles (adult) (Strongylus vulgaris, S. edentatus, Triodontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp.), pinworms (adult and fourth-stage larvae) (Oxyuris equi), large roundworms (adult) (Parascaris equorum), hairworms (adult)
(Trichostrongylus axei), large mouth stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca spp.), and stomach bots (Gastrophilus spp.).

(iii) Limitations. Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cattle—(i) Amount. 200 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. spathiger (adults only), Bunostomum phlebotomum); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); grubs (parasitic stages) (Hypoderma bovis, H. lineatum); sucking lice (Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus); mites (scabies) (Psoroptes ovis (syn. P. communis var. bovis), Sarcoptes scabiei var. bovis). For control of infections and to protect from reinfection with D. viviparus and O. radiatum for 28 days after treatment; O. ostertagi, T. axei, and C. punctata for 21 days after treatment; H. placei and C. oncophora for 14 days after treatment.

(iii) Limitations. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) Swine—(i) Amount. 300 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (large roundworm, Ascaris suum; red stomach worm, Hyostrongylus rubidus; nodular worm, Oesophagostomum spp.; threadworm, Strongyloides ransomi (adults only); somatic roundworm larvae (threadworm, S. ransomi (somatic larvae)); lungworms (Metastrongylus spp. (adults only)); lice (H. suis); and mites (S. scabiei var. suis). (iii) Limitations. Do not treat swine within 18 days of slaughter.

(4) American bison—(1) Amount. 200 μg/kg of body weight by subcutaneous injection.

(i) Indications for use. For the treatment and control of grubs (H. bovis).

(ii) Limitations. Do not slaughter within 56 days of last treatment.

(5) Reindeer—(1) Amount. 200 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of warbles (Oedemagena tarandi).

(iii) Limitations. Do not treat reindeer within 56 days of slaughter.

(6) Ranch-raised foxes—(i) Amount. 200 μg/kg of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) Indications for use. For treatment and control of ear mites (Otodectes cynotis).

§ 522.1193 Ivermectin and clorsulon.

(a) Specifications. Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) Sponsors. See Nos. 050604, 055529, and 058005 in §510.600(c) of this chapter.

(c) Related tolerances. See §§556.163 and 556.344 of this chapter.

(d) Special considerations. See §500.25 of this chapter.

(e) Conditions of use in cattle—(1) Amount. Administer 1 mL (10 mg ivermectin and 100 mg clorsulon) per 50 kilograms (110 pounds) by subcutaneous injection.

(2) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. spathiger (adults only), Bunostomum phlebotomum); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); liver flukes (adults only) (Fasciola hepatica); grubs

21 CFR Ch. I (4–1–14 Edition)