

milligrams (mg) imidacloprid and 800 micrograms (µg) ivermectin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of Use in Dogs*—(1) *Amount*. The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 µg/lb (80 µg/kg) of ivermectin, topically once a month.

(2) *Indications for Use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*).

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

[67 FR 78685, Dec. 26, 2002]

#### § 524.1146 Imidacloprid and moxidectin.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) imidacloprid and 25 mg moxidectin for use as in paragraph (d)(1) of this section.

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraphs (d)(2) and (d)(3) of this section.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use*—(A) For the prevention of heartworm disease caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(B) For treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*.

(2) *Cats*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg)

imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(3) *Ferrets*—(i) *Amount*. Topically apply 9.0 mg/lb body weight (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

[72 FR 10597, Mar. 9, 2007, as amended at 78 FR 73698, Dec. 9, 2013]

#### § 524.1193 Ivermectin topical solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 5 milligrams of ivermectin.

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

(1) Nos. 050604, 055529, 058829, 061623 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 000859, 054925, and 086001 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

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

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

(e) *Conditions of use in cattle*—(1) *Amount*. One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma*