

hydrogenated dextran and 0.5 percent phenol as a preservative.

(b) *NAS/NRC status.* Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(c)(1) *Sponsor.* See No. 000986 in §510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 100 milligrams of elemental iron to each animal when indicated between 5 and 28 days of age.

(d)(1) *Sponsor.* See No. 000003 in §510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

(e)(1) *Sponsors.* See Nos. 000010, 017287, and 050604 in §510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly 100 milligrams at 2 to 4 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly 100 milligrams. Treatment may be repeated in 10 days.

[42 FR 53955, Oct. 4, 1977, as amended at 46 FR 39128, July 31, 1981; 50 FR 23298, June 3, 1985; 52 FR 18691, May 19, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 40728 and 40729, Oct. 18, 1988; 55 FR 8462, Mar. 8, 1990; 55 FR 33670, Aug. 17, 1990; 62 FR 35076, June 30, 1997]

§ 522.1192 Ivermectin injection.

(a) *Specifications—(1) Horses.* Each milliliter of sterile aqueous solution contains 20 milligrams of ivermectin (2 percent).

(2) *Cattle, reindeer, swine, and American bison.* Each milliliter of sterile aqueous solution contains 10 milligrams of ivermectin (1 percent).

(3) *Piglets 70 pounds or less and ranch-raised foxes.* Each milliliter of sterile aqueous solution contains 2.7 milligrams of ivermectin (0.27 percent).

(b) *Sponsor.* See No. 050604 in §510.600(c) of this chapter.

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

(d) *Conditions of use—(1) Horses—(i) Amount.* 20 milligrams per 100 kilograms (220 pounds) of body weight.

(ii) *Indications for use.* It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *Strongylus 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.* For intramuscular use only. Do not use intravenously. Not for use in horses intended for food. Effects of this drug on pregnant mares have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle—(i) Amount.* 10 milligrams per 50 kilograms (110 pounds) body weight (200 micrograms per kilogram).

(ii) *Indications for use.* It is used in cattle 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 (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment.

(iii) *Limitations*. For subcutaneous use only. Not for intramuscular use. 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. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Reindeer*—(i) *Amount*. 10 milligrams per 50 kilograms (110 pounds) body weight.

(ii) *Indications for use*. It is used in reindeer for treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations*. For subcutaneous use only. Not for intramuscular use. Do not treat reindeer within 56 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount*. 300 micrograms per kilogram (2.2 pounds).

(ii) *Indications for use*. It is used in swine for treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostrogylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *Strongyloides ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

(iii) *Limitations*. For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assist-

ance in the diagnosis, treatment, and control of parasitism.

(5) *Ranch-raised foxes*—(i) *Amount*. 200 micrograms per kilogram body weight. Repeat in 3 weeks.

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

(iii) *Limitations*. For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) *American bison*—(i) *Amount*. 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use*. It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations*. For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 5344, Feb. 13, 1984, as amended at 50 FR 30268, July 25, 1985; 51 FR 25686, July 16, 1986; 51 FR 27021, July 29, 1986; 51 FR 29463, Aug. 18, 1986; 53 FR 11064, Apr. 5, 1988; 56 FR 14020, Apr. 5, 1991; 60 FR 45041, Aug. 30, 1995; 62 FR 14634, Mar. 27, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 7702, Feb. 17, 1998]

§ 522.1193 Ivermectin and clorsulon injection.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams (1 percent) of ivermectin and 100 milligrams (10 percent) of clorsulon.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Amount*. 1 milliliter (10 milligrams of ivermectin and 100 milligrams of clorsulon) per 50 kilograms (110 pounds).

(2) *Indications for use*. It is used in cattle 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)