Food and Drug Administration, HHS

(b) Sponsors. See No. 055246 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer 2 mg/kg of body weight twice daily.

(2) *Indications for use*. For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

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

[77 FR 15961, Mar. 19, 2012]

§520.1780 Pimobendan.

(a) *Specifications*. Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) Indications for use. For the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a caseby-case basis.

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

 $[72\ {\rm FR}\ 27733,\ {\rm May}\ 17,\ 2007,\ {\rm as}\ {\rm amended}\ {\rm at}\ 79\ {\rm FR}\ 18158,\ {\rm Apr.}\ 1,\ 2014]$

§ 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

§ 520.1802a Piperazine-carbon disulfide complex suspension.

(a) Specifications. Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

(b) Sponsor. See 000009 in §510.600(c) of this chapter.

(c) Conditions of use. Horses and ponies—(1) Amount. One fluid ounce per 100 pounds of body weight.¹

(2) Indications for use. For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongyles* spp.), and pinworms (*Oxyuris equi*).¹

(3) Limitations. Administer by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours. Provide water as usual. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics and other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

[45 FR 52781, Aug. 8, 1980]

§ 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications*. Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) Sponsor. See 000009 in 510.600(c) of this chapter.

(c) Conditions of use: Horses and ponies—(1) Amount. For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.¹

(2) Indications for use. For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).¹

(3) *Limitations*. Withhold feed overnight or for 8 to 10 hours. Give water

¹These conditions are 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.