

(c) *Conditions of use*—(1) *Amount*. 30 micrograms for animals weighing 1 to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, German Shepherds, or German Shepherd mix.

(2) *Indications for use*. For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations*. Administer daily, orally or in a small amount of food, at least 30 days before expected initiation of heat, and continue daily as long as desired, but not for more than 24 months. Mibolerone should not be used in bitches before the first estrous period. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 15625, Apr. 14, 1978]

#### § 520.1445 Milbemycin oxime tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats*. Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(b) *Sponsor*. See 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and puppies*—(i) *Amount*. For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).

(ii) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.

(iii) *Limitations*. Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer

once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats and kittens*—(i) *Amount*. 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(ii) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations*. Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 25301, June 21, 1990, as amended at 55 FR 49888, Dec. 3, 1990; 58 FR 5608, Jan. 22, 1993; 60 FR 50097, Sept. 28, 1995; 61 FR 43654, Aug. 26, 1996; 63 FR 29352, May 29, 1998; 63 FR 41189, Aug. 3, 1998]

#### § 520.1446 Milbemycin oxime and lufenuron tablets.

(a) *Specifications*—(1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use*—(A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult

§520.1448

21 CFR Ch. I (4-1-05 Edition)

*Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in §520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

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

(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998; 68 FR 51905, Aug. 29, 2003]

§520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the  $R_f$  value must be comparable to a reference standard (the  $R_f$  value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

[55 FR 3586, Feb. 2, 1990]

§520.1448a Monensin blocks.

(a)(1) *Specifications.* Each pound of protein-mineral block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor.* See 067949 in §510.600(c) of this chapter.

(3) *Related tolerances.* See §556.420 of this chapter.

(4) *Conditions of use—(i) Amount.* 80 to 200 milligrams of monensin (0.2 to 0.5 pound of block) per head per day.

(ii) *Indications for use.* Increased rate of weight gain.

(iii) *Limitations.* Block to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or min-

erals containing salt. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

(b) [Reserved]

(c)(1) *Specifications.* Each pound of protein block contains 175 milligrams of monensin (0.038 percent) as monensin sodium.

(2) *Sponsor.* See 021676 in §510.600(c) of this chapter.

(3) *Related tolerances.* See §556.420 of this chapter.

(4) *Conditions of use—(i) Amount.* 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day.

(ii) *Indications for use.* Increased rate of weight gain.

(iii) *Limitations.* Blocks to be fed free choice to pasture cattle (slaughter, stocker, and feeder). Provide at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established.

(d)(1) *Specifications.* Each pound of block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor.* See 051267 in §510.600(c) of this chapter.

(3) *Related tolerances.* See §556.420 of this chapter.

(4) *Conditions of use—(i) Amount.* 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day.

(ii) *Indications for use.* Pasture cattle: Increased rate of weight gain.

(iii) *Limitations.* Blocks to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least one block per five head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not