placed on or mixed with feed. Do not use in dogs that may harbor adult heartworms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 28768, July 16, 1985, as amended at 53 FR 45759, Nov. 14, 1988; 54 FR 3776, Jan. 26, 1989; 54 FR 6804, Feb. 14, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

### § 520.645 Difloxacin.

(a) *Specifications.* Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

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

(c) [Reserved]

(d) *Conditions of use*—(i) *Amount.* Administer 5 to 10 mg per kilogram (2.3 to 4.6 mg per pound) of body weight orally once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

(ii) *Indications for use.* For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations.* Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, Mar. 5, 2010]

### § 520.666 Dirlotapide.

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

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

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

[72 FR 263, Jan. 4, 2007]

### § 520.763 Dithiazanine iodide oral dosage forms.

### § 520.763a Dithiazanine iodide tablets.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene) - 1,3 - pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

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

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

| | Milligrams per pound of body weight | Length of treatment—days |
|---|---|---|
| Large roundworms (*Toxocara canis, Toxascaris leonina*) | 10 | 3–5 |
| Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*) | 10 | 7 |
| Whipworms (*Trichuris vulpis*) | 10 | |
| Strongyloides (*Strongyloides canis, Strongyloides stercoralis*) | 10 | 10–12 |
| Heartworm microfilariae (*Dirofilaria immitus*) | 3–5 | 7–10 |

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111