Food and Drug Administration, HHS

§ 520.763b

| 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 immitis) | 3–5 | 7–10 |

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

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

(b) 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 of this chapter, but may require bioequivalency and safety information.

(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.

§ 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.

§ 520.763a Dithiazanine iodide tablets.

(a) [Reserved]

(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. 054628 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:

| Large roundworms (Toxocara canis, Toxascaris leonina) | 10 | 3–5 |

§ 520.763b Dithiazanine iodide powder.

(a) [Reserved]

(b) Specifications. Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) Sponsor. See No. 054628 in § 510.600(c) of this chapter.

(d) Conditions of use. (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog’s food, using the following dosage schedule for various parasite infestations: