Food and Drug Administration, HHS

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]

§ 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 Breaded and Coated Foods.

§ 520.763a Dithiazanine iodide oral dosage forms.

§ 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:

<table>
<thead>
<tr>
<th>Parasite Infestation</th>
<th>Milligrams per pound of body weight</th>
<th>Length of treatment—days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large roundworms</td>
<td>10</td>
<td>3–5</td>
</tr>
<tr>
<td>Hookworms</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Whipworms</td>
<td>10</td>
<td>10–12</td>
</tr>
<tr>
<td>Heartworms</td>
<td>3–5</td>
<td>7–10</td>
</tr>
</tbody>
</table>

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


§ 520.763c Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763d Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763e Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763f Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763g Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763h Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763i Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763j Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763k Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763l Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763m Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763n Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763o Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763p Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763q Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763r Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763s Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763t Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763u Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763v Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763w Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763x Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763y Dithiazanine iodide and related substances.

(c) [Reserved]

§ 520.763z Dithiazanine iodide and related substances.

(c) [Reserved]