Food and Drug Administration, HHS

§ 520.522

(d) Conditions of use.—(1) Horses—(i) Amount. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is non-responsive to clenbuterol and treatment should be discontinued.

(ii) Indications for use. Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) Limitations. Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with doses higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

§ 520.462 Clorsulon drench.

(a) Specifications. The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Conditions of use. Cattle—(1) Amount. One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) Indications for use. For the treatment of immature and adult liver fluke (Fasciola hepatica) infestations in cattle.

(3) Limitations. Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 520.522 Cyclosporine.

(a) Specifications. Each capsule contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

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

(c) [Reserved]

(d) Conditions of use in dogs—(1) Amount. 5 mg per kilogram of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(2) Indications for use. For the control of atopic dermatitis in dogs weighing at least 4 pounds body weight.

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

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