Food and Drug Administration, HHS

§ 520.300c Cambendazole paste.

(a) *Specifications*. The drug is a paste containing 45 percent cambendazole.

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

(c) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascaris); pinworms (Oxyuris); and threadworms (Strongyloides).

(2) Administer 20 milligrams cambendazole per kilogram body weight (5 grams per 550 pounds (250 kilograms)) by depositing the paste on the back of the tongue using a dosing gun.

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

 $\left(4\right)$ Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

 $[41\ {\rm FR}\ 1276,\ {\rm Jan.}\ 7,\ 1976,\ {\rm as}\ {\rm amended}\ {\rm at}\ 42\ {\rm FR}\ 3838,\ {\rm Jan.}\ 21,\ 1977;\ 62\ {\rm FR}\ 63270,\ {\rm Nov.}\ 28,\ 1997]$

§520.309 Carprofen.

(a) *Specifications*. Each caplet or chewable tablet contains 25, 75, or 100 milligrams (mg) carprofen.

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

(c) [Reserved]

(d) Conditions of use in dogs—(1) Amount. 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily.

(2) *Indications for use*. For the relief of pain and inflammation associated with osteoarthritis in dogs.

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

[61 FR 66581, Dec. 18, 1996, as amended at 64
 FR 32181, June 16, 1999; 66 FR 63165, Dec. 5, 2001; 67 FR 6866, Feb. 14, 2002]

§520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of 5stcaramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.¹

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1)Amount. One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.¹

(2) Indications for use. For relief of $cough.^1$

[43 FR 55385, Nov. 28, 1978]

§ 520.312 Carnidazole tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of carnidazole.

(b) Sponsor. See 053923 in 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use*. For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations*. Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989]

§ 520.314 Cefadroxil tablets.

(a) *Specifications*. 50-, 100-, and 200milligram tablets for dogs and cats; 1 gram tablet for dogs.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) For use in dogs as follows:

(i) Indications for use. For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of Staphylococcus aureus. For the treatment of

¹These conditions are 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.

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genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*.

(ii) *Amount*. Ten milligrams per pound of body weight twice daily.

(iii) Limitations. The drug is administered orally. For skin and soft tissue infections, treatment should be continued for a minimum of 3 days. For genitourinary tract infections, treatment should be continued for a minimum of 7 days. Continue treatment at least 48 hours after the dog has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 30 days. Safety for use in pregnant bitches and stud dogs has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) For use in cats as follows:

(i) Indications for use. For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of Pasteurella multocida, Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus spp.

(ii) *Amount*. Ten milligrams per pound of body weight once daily.

(iii) Limitations. The drug is administered orally. Continue treatment at least 48 hours after the cat has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 21 days. Safety for use in pregnant cats and breeding male cats has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 41105, Sept. 17, 1982, as amended at 49
FR 43052, Oct. 26, 1984; 51 FR 4165, Feb. 3, 1986;
52 FR 11989, Apr. 14, 1987; 53 FR 27851, July 25, 1988]

§520.315 Cefadroxil powder for oral suspension.

(a) *Specifications*. Cefadroxil powder is reconstituted to form a 50 milligramper-milliliter aqueous suspension.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) *Conditions of use*. (1) For use in dogs as follows:

(i) Indications for use. For treating genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*; and skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses caused by susceptible strains of *Staphylococcus aureus*.

(ii) Amount. 10 milligrams per pound of body weight, twice daily.

(2) For use in cats as follows:

(i) Indications for use. For treating skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of Pasteurella multocida, Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus spp.

(ii) *Amount*. 10 milligrams per pound of body weight, once daily.

(3) Limitations. Discard unused portion of reconstituted product after 14 days. Treatment should continue for 48 hours after animal is afebrile or asymptomatic. If no response after 3 days, discontinue treatment and reevaluate therapy. Not for use in animals raised for food production. Safe use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 FR 27344, July 20, 1988]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) *Specifications*. Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) Sponsor. In §510.600(c) of this chapter: No. 000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-. and 500-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) Conditions of use. Dogs—(i) Amount. 25 milligrams per pound of body weight every 6 hours.