# Food and Drug Administration, HHS

(Trichostrongylus axei—adult), brown stomach worms (Ostertagia ostertagi adult, L4, inhibited L4); intestinal worms; nodular worms (Oesophagostomum radiatum—adult), hookworms (Bunostomum phlebotomum—adult), small intestinal worms (Cooperia punctata, C. oncophora, and C. mcmasteri—adult, L4), and tapeworms (Moniezia benedeni—adult).

(iii) *Limitations*. For use in cattle only. Administer 9.06 percent suspension orally only with a dose syringe, and 22.5 percent suspension either orallv with a dose svringe or intraruminally with a rumen injector. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle. For use of 9.06 percent suspension orally: Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism. For use of 22.5 percent suspension orally or intraruminally: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 46943, Nov. 8, 1990, as amended at 56 FR 8710, Mar. 1, 1991; 61 FR 5506, Feb. 13, 1996]

# § 520.1631 Oxfendazole and trichlorfon paste.

(a) *Specifications*. Each gram of paste contains 28.5 milligrams oxfendazole and 454.5 milligrams trichlorfon.

(b) Sponsor. See 000856 in \$510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 2.5 milligrams of oxfendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) Indications for use. The drug is used in horses for removal of bots (Gasterophilus intestinalis, 2nd and 3rd instars; G. nasalis, 3rd instar) and the following gastrointestinal worms: Large roundworms (Parascaris equorum), pinworms (Oxyuris equi), adult and 4th stage larvae; large strongyles (Strongylus edentatus, S. vulgaris, and S. equinus); and small strongyles.

(3) *Limitations.* Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water before use is unnecessary. Administer with caution to sick or debilitated horses. Not for use in horses intended

for food. Do not administer to mares during the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not use this product in animals simultaneously with, or within a few days before or after treatment with or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

 $[50\ {\rm FR}\ 50291,\ {\rm Dec.}\ 10,\ 1985,\ {\rm as}\ {\rm amended}\ {\rm at}\ 61\ {\rm FR}\ 5506,\ {\rm Feb}.\ 13,\ 1996]$ 

### § 520.1638 Oxibendazole paste.

(a) *Specifications*. The paste contains 22.7 percent oxibendazole.

(b) Sponsor. See 000069 in 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. For uses other than for threadworms (Strongyloides westeri), 10 milligrams of oxibendazole per kilogram of body weight; for threadworms (Strongyloides westeri), 15 milligrams per kilogram.

(2) Indications for use. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (genera Cylicostephanus, Cylicocyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyalocephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

(3) *Limitations*. Administer orally by syringe. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 50948, Oct. 16, 1981, as amended at 47 FR 36418, Aug. 20, 1982; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

#### § 520.1640 Oxibendazole suspension.

(a) *Specifications*. The suspension contains 10 percent oxibendazole.

(b) Sponsor. See 000069 in §510.600(c) of this chapter.

(c) Conditions of use in horses-(1) Amount. For use other than threadworms (Strongyloides westeri), 10 milligrams of oxibendazole per kilogram of body weight; for threadworms, 15 milligrams per kilogram of body weight.

(2) Indications for use. For removal and control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris); small strongyles (species of the genera Cylicostephanus Cylicocyclus, Cyathostomum, Triodontophorus, Cylicodontophorus, and Gyalocephalus); large roundworms (Parascaris equorum); pinworms (Oxyuris equi) including various larval stages; and threadworms (Strongyloides westeri).

(3) Limitations. Administer by stomach tube in 3 to 4 pints of warm water, or by top dressing or mixing into a portion of the normal grain ration. Prepare individual doses to ensure that each animal receives the correct amount. Horses maintained on premises where reinfection is likely to occur should be re-treated in 6 to 8 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 78119, Nov. 28, 1980, as amended at 47 FR 39812, Sept. 10, 1982; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

### § 520.1660 Oxytetracycline.

# § 520.1660a Oxytetracycline and carbomycin in combination.

(a) Specifications. (1) Oxytetracycline: The antibiotic substance produced by growth of Streptomyces rimosus or the same antibiotic substance produced by any other means.

(2) Carbomycin: The antibiotic substance produced by growth of *Streptomyces halstedii* or the same antibiotic substance produced by any other means.

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

(c) Special considerations. The quantities of oxytetracycline in paragraph (e) of this section refer to the activity of oxytetracycline hydrochloride and the quantities of carbomycin listed refer to the activity of an appropriate standard.

(d) *Related tolerances*. See §§556.110 and 556.500 of this chapter.

(e) Conditions of use. It is used as oxytetracycline hydrochloride plus 21 CFR Ch. I (4–1–02 Edition)

carbomycin base in drinking water of chickens as follows:

(1) Amount. 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon.

(2) Indications for use. As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by Mycoplasma gallisepticum and secondary bacterial organisms associated with chronic respiratory disease such as E. coli.

(3) *Limitations*. Administer for not more than 5 days; not for use in chickens producing eggs for human consumption; withdraw 24 hours before slaughter.

## § 520.1660b Oxytetracycline hydrochloride capsules.

(a) Specifications. The drug is in capsule form with each capsule containing 125 or 250 milligrams of oxytetracycline hydrochloride. Oxytetracycline is the antibiotic substance produced by growth of Streptomyces rimosus or the same antibiotic substance produced by any other means.

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

(c) Conditions of use. (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by Brucella bronchiseptica, tonsilitis caused by Streptococcus hemolyticus, bacterial enteritis caused by Escherichia coli, urinary tract infections caused by Escherichia coli, and wound infections caused by Staphylococcus aureus.<sup>1</sup>

(2) The drug is administered orally to dogs and cats at a dosage level of 25–50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the susceptibility of the infectious

<sup>&</sup>lt;sup>1</sup>These 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.