

licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[64 FR 39919, July 23, 1999, as amended at 66 FR 46369, Sept. 5, 2001]

§ 520.1320 Mebendazole oral.

(a) *Chemical name.* Methyl 5-benzoyl-benzimidazole-2-carbamate.

(b) *Specifications.* As oral powder: Each gram contains either 40 or 166.7 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. As oral suspension: Each milliliter contains 33.3 milligrams of mebendazole.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use.* It is used in horses for treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small strongyles; and mature and immature (4th larval stage pinworms (*Oxyuris equi*)).

(iii) *Limitations*—(a) *Oral powder.* The drug is given by sprinkling directly on the grain portion of the ration or dissolving in 2 to 4 pints of water and administering by stomach tube. The drug is compatible with carbon disulfide, which can be used concurrently for both control (*Gastrophilus spp.*). Routine cautions regarding the use of carbon disulfide must be observed. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) *Oral paste.* The drug is given by dosing gun (syringe), inserting the tip of the gun at the interdental space in the horse's mouth and depositing the paste on the animal's tongue. The hand is placed under the animal's jaw, and the head is raised to assure that the paste is deposited on the roof of the mouth. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(c) *Oral suspension.* The drug is administered by stomach tube. Not for horses intended for food use. Federal

law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* One hundred milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder.

(ii) *Indications for use.* The drug is used for treatment of infections of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Administer as an oral powder by mixing with a small quantity of food, preferably before the regular meal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 61255, Dec. 2, 1977, as amended at 43 FR 35686, Aug. 11, 1978; 45 FR 3574, Jan. 18, 1980; 46 FR 47218, Sept. 25, 1981; 46 FR 53658, Oct. 30, 1981; 62 FR 61625, Nov. 19, 1997]

§ 520.1326 Mebendazole and trichlorfon oral dosage forms.

§ 520.1326a Mebendazole and trichlorfon powder.

(a) *Specifications.* Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorofon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* *Horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorofon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for the treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Administer orally as an individual dose by stomach tube or thoroughly mixed in the ground grain portion of the ration to be consumed in one feeding. Discard treated feed not consumed. Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorofon is a cholinesterase inhibitor. Do not administer simultaneously or within a few

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days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 10759, Feb. 19, 1980, as amended at 46 FR 52330, Oct. 27, 1981. Redesignated at 51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997]

§ 520.1326b Mebendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams of mebendazole and 454 milligrams of trichlorfon.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not administer simultaneously or within a few days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997]

§ 520.1330 Meclofenamic acid granules.

(a) *Chemical name.* N-(2,6-Dichloromethyl) anthranilic acid.

(b) *Specifications.* The drug is in granular form containing 5 percent meclofenamic acid.

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

(d) *Conditions of use.* (1) The drug is used in horses for the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(2) It is administered orally at a dosage of 1 milligram per pound of body weight (1 gram per 1,000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(3) Treatment beyond the initial 5- to 7-day period may be indicated. A maintenance dosage level should be individualized for each animal.

(4) This drug should not be administered to horses with active gastrointestinal, hepatic, or renal disease.

(5) Not for use in horses intended for food.

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

[41 FR 5632, Feb. 9, 1976, as amended at 53 FR 23390, June 22, 1988]

§ 520.1331 Meclofenamic acid tablets.

(a) *Specifications.* Each tablet contains either 10 or 20 milligrams of meclofenamic acid.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 1.1 milligrams per kilogram (0.5 milligram per pound) daily for 5 to 7 days.

(2) *Indications for use.* For the relief of signs and symptoms of chronic inflammatory disease involving the musculoskeletal system.

(3) *Limitations.* For oral use only. Should not be administered to animals with congestive heart failure or active gastrointestinal, hepatic, or renal disease. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 43385, Oct. 25, 1985, as amended at 53 FR 23390, June 22, 1988]

§ 520.1341 Megestrol acetate tablets.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams of megestrol acetate.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.