

§ 520.1616

21 CFR Ch. I (4–1–10 Edition)

§ 520.1616 Orbifloxacin.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

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

(c) *Conditions of use in dogs and cats—*(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

[71 FR 14643, Mar. 23, 2006]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications—*(1) *Powder for suspension.* Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets.* Each gram of pellets contains 6.49 percent oxfendazole.

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

(c) *Conditions of use—*(1) *Amount.* 10 milligrams per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations—*(i) *Powder for suspension.* For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets.* The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior to administration is not necessary. Administer drug with caution to sick or debilitated horses. Not for use in

horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[44 FR 35211, June 19, 1979, as amended at 46 FR 26301, May 12, 1981; 46 FR 60570, Dec. 11, 1981; 49 FR 28549, July 13, 1984; 61 FR 5506, Feb. 13, 1996]

§ 520.1629 Oxfendazole paste.

(a)(1) *Specifications.* Each gram of paste contains 0.375 gram oxfendazole (37.5 percent).

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

(3) *Conditions of use—*(i) *Amount.* 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use.* The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations.* Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications.* Each gram of paste contains 185 milligrams of oxfendazole (18.5 percent).

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

(3) *Related tolerances.* See § 556.495 of this chapter.

(4) *Conditions of use—*(i) *Amount.* 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use.* The drug is used in cattle for the removal and control of the following worms: lungworms (*Dictyocaulus viviparus—adult, L4*); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei—adult*), small stomach worms (*Trichostrongylus axei—adult*), brown stomach worms (*Ostertagia ostertagi—adult, L4, inhibited L4*); intestinal worms; nodular worms (*Oesophagostomum radiatum—adult*), hookworms (*Bunostomum*