Food and Drug Administration, HHS

(i) Indications for use—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in §520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in §520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) Cats—(i) Amount—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) Indications for use—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in §520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

§ 520.1604 Oclacitinib.

(a) Specifications. Each tablet contains 3.6, 5.4, or 16 milligrams (mg) of oclacitinib as oclacitinib maleate.

(b) Sponsor. See No. 054771 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer orally 0.18 to 0.27 mg per pound of body weight (0.4 to 0.6 mg/kg body weight) twice daily for up to 14 days; then administer once daily for maintenance therapy.

(2) Indications for use. For control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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

§ 520.1615 Omeprazole.

(a) Specifications. Each gram of paste contains 0.37 gram omeprazole.

(b) Sponsor. See No. 054776 in §510.600(c) of this chapter.

§ 520.1618 Orbifloxacin tablets.

(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.

§ 520.1618 Orbifloxacin suspension.

(a) Specifications. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

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