Food and Drug Administration, HHS

§524.1450 Moxidectin.

(a) Specifications. Each milliliter contains 5 milligrams (mg) moxidectin (0.5 percent solution).

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.426 of this chapter.

(d) Special considerations. See §500.25 of this chapter.

§524.1455 Miconazole, polymixin B, and prednisolone suspension.

(a) Specifications. Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

(b) Sponsor. See No. 000986 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Instill five drops in the ear canal twice daily for 7 consecutive days.

(d) Special considerations. See Nos. 000069, 000070, 025463, and 051672 in §510.600(c) of this chapter.

§524.1456 Milbemycin oxime solution.

(a) Specifications. Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

(b) Sponsor. See No. 058198 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. One tube administered topically into each external ear canal.

(d) Special considerations. See §500.25 of this chapter.

§524.1465 Mupirocin.

(a) Specifications. Each gram of ointment contains 20 milligrams mupirocin.

(b) Sponsors. See Nos. 000069, 025463, and 051672 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Apply twice daily. Treatment should not exceed 30 days.
(2) **Indications for use.** For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *S. intermedius*.

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

§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment.

(a) **Specifications.** The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) **Sponsor.** See No. 000009 in §510.600(c) of this chapter.

(c) **Conditions of use.** (1) It is used in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

(2) In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(3) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the drug. If such signs are noted, therapy with the drug should be stopped. Treatment should be limited to the period when local anesthesia is essential to control self-inflicted trauma.

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

§ 524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear ointment.

(a) **Specifications.** The product contains 5 milligrams of neomycin sulfate,