Food and Drug Administration, HHS

§ 524.1195 Ivermectin otic suspension.

(a) Specifications. Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

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

(c) Conditions of use—(1) Amount. Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) Indications for use. For the treatment of adult ear mite (Otodectes cynotis) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.

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

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) Specifications. The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

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

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal. For use only by or on the order of a licensed veterinarian.

§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) Specifications. (1) Calcium amphomycin is the calcium salt of amphomycin. It conforms to the following specifications:

(i) Its potency is not less than 863 micrograms of amphomycin per milligram;

(ii) Its moisture content is not more than 10 percent; and

(iii) Its pH in a 2-percent aqueous suspension is 6.0 to 7.5.