Food and Drug Administration, HHS

§ 524.981e Fluocinolone acetonide, dimethyl sulfoxide otic solution.

(a) Specifications. Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide with propylene glycol and citric acid.

(b) Sponsor. See No. 000033 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs for the relief of pruritus and inflammation associated with acute and chronic otitis. It is administered at 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters. The ear canal should be cleansed by some appropriate method prior to instillation of the solution and the ear should be massaged gently following instillation.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996]