

NDA 20-010

Combination Anti-Fungal/Corticosteroid Topical Drug Products

NDA 20-010

Lotrisone (betamethasone dipropionate and clotrimazole) Lotion

**Dermatologic and Ophthalmic Drugs Advisory Committee
June 29, 2000**

Contents of Briefing Packet:

- 1) Combination Anti-Fungal/Corticosteroid Topical Drug Products – Overview
- 2) Questions for Advisory Committee
- 3) Executive Summary NDA 20-010 Lotrisone Lotion
- 4) Questions for Advisory Committee
- 5) Package Insert for Lotrisone Cream
- 6) Executive Summary: Lotrisone Adverse Events from the Office of Postmarketing Drug Risk Assessment
- 7) Executive Summary: Lotrisone Labeling Options from the Office of Postmarketing Drug Risk Assessment
- 8) Selected Literature References
 - a) Rosen, T.R. and Elewski, B.E. Failure of clotrimazole-betamethasone dipropionate cream in treatment of *Microsporum canis* infections. *J. Am. Acad. Dermatol.* 1995; 32:1050-1051.
 - b) Elgart, M.L. Tinea Incognito: An Update on Majocchi Granuloma. *Dermatologic Clinics.* 1996; 14(1):51-55.
 - c) Fleischer, A.B. and Feldman, S.R. Prescription of High-Potency Corticosteroid Agents and Clotrimazole-Betamethasone Dipropionate by Pediatricians. *Clin. Therapeutics.* 1999; 21(10):1725-1731.