

**FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Dermatologic and Ophthalmic Drugs Advisory Committee
Meeting # 54**

**AGENDA
November 16, 2000**

**CDER Advisory Committee, Conference Room 1066
Rockville, Maryland**

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NDA 50-777, (tacrolimus) ointment, Fujisawa Healthcare, for short and long term treatment of the signs and symptoms of atopic dermatitis in adults and pediatric patients 2 years of age or older

10:00	Call to Order and Welcome Conflict of Interest Statement Overview of Issues	Robert Stern, M.D., Acting Chair Jaime Henriquez, Executive Secretary Jonathan Wilkin, M.D.
10:10	Sponsor Presentation: <ul style="list-style-type: none">• Introduction• Pharmacology of Tacrolimus Ointment• Efficacy and Safety of Tacrolimus Ointment	Jerry D. Johnson, Ph.D. William Fitzsimmons, Pharm.D. Ira D. Lawrence, M.D., F.A.C.P.
11:10	FDA Presentation: <ul style="list-style-type: none">• Nonclinical Pharmacology/ Toxicology Data for Protopic• Systemic Exposure of Topical Tacrolimus• Clinical Review of Protopic Ointment Safety, Potential Risk and Efficacy	Barbara Hill, Ph.D. Veneeta Tandon, Ph.D. Martin Okun, M.D., Ph.D.
12:25	Lunch	
2:00	Open Public Hearing – The meeting will proceed when last open public hearing participant has spoken.	
3:00	Questions to the Committee	Jonathan Wilkin, M.D.
3:10	Committee Discussion	
3:30	Break	
3:45	Committee Discussion Continue	
5:00	Adjournment	