

Pediatric Advisory Committee
Food and Drug Administration
ACS Conference Room, Room 1066
5630 Fishers Lane, Rockville, Maryland 20857

Agenda

Potential Cancer Risk in Children from Use of Topical Immunosuppressants
February 15, 2005
8:00 AM to 5:30 PM

8:00 AM	Welcome and Introductions	Jan Johannessen, PhD
	Opening Remarks and Introduction to the Day	Dianne Murphy, MD
8:40 AM	Assessing Cancer Risk and Assuring Safe Use of Topical Immunosuppressants: Recent History	Susan Cummins, MD, MPH
9:00 AM	Epstein-Barr Virus Infection and Cancer	Jeffrey I. Cohen, MD
9:30 AM	Questions and Answers for Speaker	
9:45 AM	FDA Perspective- Topical Immunosuppressants	Bindi Nikhar, MD
10:05 AM	Systemic Human Exposure of Pimecrolimus and Tacrolimus Following Topical Application	Tapash Ghosh, PhD
10:20 AM	Topical Immunosuppressants (Calcineurin Inhibitors) - Animal Toxicology	Barbara Hill, PhD
10:40 AM	Break	
10:55 AM	Post-Marketing Cases of Tumors Reported With the Topical Immunosuppressants (Calcineurin Inhibitors)	Marilyn Pitts, PharmD
11:10 AM	Questions and Answers for Speakers	
11:20 AM	Presentation by Novartis Pharmaceuticals Corporation	TBD
11:40 AM	Presentation by Fujisawa Healthcare, Incorporated	TBD
12:00 Noon	Open Public Hearing	
12:30 PM	Lunch	
1:30 PM	Risk Minimization Action Plans	Anne Trontell, MD, MPH
2:00 PM	Product Labeling and Drug Promotion	Melissa Moncavage, MPH
2:10 PM	Questions and Answers	
2:15 PM	Break	
2:30 PM	Summary of the Issues and the Evidence	Jonathan Wilkin, MD
	Discussion of Questions to the Committee	Joan Chesney, MD
5:30 PM	Adjourn	