

**Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Hilton, The Ballrooms, 620 Perry Parkway, Gaithersburg, MD.

***Tracking Cancer Risk among Children with Atopic Dermatitis  
who are Treated with Topical Calcineurin Inhibitors***

Draft Agenda for October 30, 2003

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| 8:00  | <b>Call to Order, Introductions:</b>   | Joan P. Chesney, M.D., Chair   |
|       | <b>Meeting Statement:</b>  | Thomas H. Perez, R.Ph., M.P.H.<br>Executive Secretary  |
|       | <b>Opening Comments:</b>   | Dianne Murphy, M.D.<br>Director, Office of Counter-<br>terrorism and Pediatric Drug<br>Development<br>and<br>Jonathan Wilkin, M.D.<br>Director, Division of Dermatologic<br>and Dental Drug Products |
| 8:30  | <b>Review of Topical Calcineurin Inhibitors</b>  | Bindi Nikhar, M.D.<br>Division of Dermatologic and<br>Dental Drug Products   |
| 8:50  | <b>Topical Immunosuppressants (Calcineurin Inhibitors) - Animal Toxicology</b>                       | Barbara Hill, Ph.D.<br>Division of Dermatologic and<br>Dental Drug Products  |
| 9:20  | <b>Post Marketing Adverse Event Reports</b>  | ODS Staff  |
| 9:30  | <b>Q&amp;A for Presenters</b>  |  |
| 9:45  | <b>Break</b>   |  |
| 10:00 | <b>Studying the Risk of Cancer with Topical Calcineurin Inhibitor Use in Children: Design Issues</b> | Lois La Grenade, M.D.<br>Office of Drug Safety   |
| 10:50 | <b>Practical and Methodological Issues in Long Term Follow-up Studies</b>                            | Elizabeth Andrews, Ph.D.<br>RTI Health Solutions   |
| 11:20 | <b>The Role of Cancer Registries in Long Term Follow-up Studies</b>                                  | Phyllis Wingo, Ph.D.<br>Centers for Disease Control<br>Cancer Registry Program   |
| 11:50 | <b>Q&amp;A for Presenters</b>  |  |
| 12:00 | <b>Lunch</b>   |  |
| 1:00  | <b>Open Public Hearing</b>   |  |
| 2:00  | <b>Discussion of Questions 1 &amp; 2</b>   |  |
| 3:30  | <b>Wrap up and adjourn</b>   |  |