

Draft Agenda
Pediatric Advisory Committee

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

Agenda

Adverse Event Reporting as per Section 17, BPCA

February 14, 2005

2:00 PM – 6:00 pm

2:00 PM	Welcome and Introductory Remarks	Joan Chesney, MD, Chair Jan Johannessen, PhD Dianne Murphy, MD
2:10 PM	Adverse Event Reporting for Benazepril	Lawrence Grylack, MD
2:20 PM	Adverse Event Reporting for Esmolol	Lawrence Grylack, MD
2:30 PM	Questions and Answers	
2:40 PM	Adverse Event Reporting for Orlistat	Hari Cheryl Sachs, MD
2:50 PM	Adverse Event Reporting for Glyburide/Metformin	Hari Cheryl Sachs, MD
3:00 PM	Questions and Answers	
3:10 PM	Adverse Event Reporting for Atovaquone/Proguanil	Alan M. Shapiro, MD, PhD
3:20 PM	Adverse Event Reporting for Nelfinavir	Alan M. Shapiro, MD, PhD
3:30 PM	Questions and Answers	
3:40 PM	Break	
4:00 PM	Open Public Hearing	
4:30 PM	BPCA-mandated Review and Reporting of Adverse Events for Drugs Granted Exclusivity: Committee Feedback and Options for Improvement	Solomon Iyasu, MD, MPH
4:40 PM	Committee Discussion	
6:00 PM	Adjourn	