

Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
ACS Conference Room, Room 1066, 5630 Fishers Lane, Rockville, MD

Draft Agenda for June 9, 2004

8:00	Call to Order, Introductions:	Joan P. Chesney, M.D., Chair
	Meeting Statement:	Thomas H. Perez, M.P.H. Executive Secretary
	Welcome:	Office of Pediatric Therapeutics
8:20	Adverse Event Reports per Section 17 of BPCA	Solomon Iyasu, M.D. Lead Medical Officer Division of Pediatric Drug Development
	Fexofenodine	Jane Filie, M.D. Medical Officer Division of Pediatric Drug Development
	Topotecan Temozolomide	Susan McCune, M.D. Medical Officer Division of Pediatric Drug Development
	Moxifloxacin Ciprofloxacin	Harry Gunkel, M.D. Medical Officer Division of Pediatric Drug Development
	Fosinopril	Larry Grylack, M.D. Medical Officer Division of Pediatric Drug Development
	Fentanyl	ShaAvhree Buckman, M.D. Medical Officer Division of Pediatric Drug Development
10:00	Break	
10:15	Adverse Event Reports per Section 17 of BPCA (cont.)	
	Venlafaxine	Hari Sachs, M.D. Medical Officer Division of Pediatric Drug Development

11:15	Open Public Hearing	
11:45	Pediatric Update	Dianne Murphy, M.D. Director, Office of Counter- terrorism and Pediatric Drug Development
Noon	Lunch	
1:00	Update on Neonatal Withdrawal Syndrome	
2:45	Update on Congenital Eye Malformations in Infants	
3:00	Break	
3:15	Open Public Hearing	
3:45	Pediatric Research Equity Act (PREA) Update	Shirley Murphy, M.D. Director, Division of Pediatric Drug Development
4:00	Overview of IOM Report, <i>Ethical Conduct of Clinical Research Involving Children</i>	Robert Nelson, M.D., Ph.D. The Children's Hospital of Philadelphia
4:45	Final Comments and Adjourn	