

**Pediatric Advisory Committee Meeting  
November 28, 2006**

Hilton Washington DC North/Gaithersburg, Grand Ballroom,  
620 Perry Parkway, Gaithersburg, Maryland

8:00AM	Welcome and Introductory Remarks	Marsha Rappley, MD Chair Dean, College of Human Medicine Michigan State University  Carlos Peña, PhD, MS Executive Secretary Office of Science and Health Coordination OC, FDA
8:10	<b>Azopt (brinzolamide)</b> Brief Review of Adverse Events <b>Bextaxon (levobetaxolol)</b>	Felicia Collins, MD, MPH, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
8:20	<b>Emtriva (emtricitabine)</b> - Review of Adverse Events	Hari Cheryl Sachs, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
8:35	<b>Gleevec (imatinib mesylate)</b> - Review of Adverse Events	Hari Cheryl Sachs, MD, Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
8:50	<i>Clarification Questions</i>	
9:00	<b>Serevent (salmeterol)</b> – Background overview and labeling changes, One-Year Post Exclusivity Adverse Event Review Salmeterol	Hari Cheryl Sachs, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
9:30	<b>Serevent (salmeterol)</b> – Safety Considerations Safety Considerations in Pediatric Salmeterol Use	Andrew Mosholder, MD, MPH Office of Surveillance and Epidemiology, CDER, FDA
10:00	<i>Clarification Questions</i>	
10:15	<b>Serevent (salmeterol)</b> – Sponsor Presentation	GlaxoSmithKline Presentation
10:45	Break	
11:00	<i>Open Public Hearing</i>	

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11:30	<i>Committee Deliberation and Recommendations</i>	
12:00PM	Lunch	
1:00	<b>Provigil (modafinil)</b> – ADHD Review	Glenn Mannheim, MD, Medical Officer Division of Psychiatry Products, Office of New Drugs, CDER, FDA
1:30	<b>Provigil (modafinil)</b> – Narcolepsy Review	Ronald Farkas, MD, Medical Officer Division of Neurology Products, Office of New Drugs, CDER, FDA
1:45	<i>Clarification Questions</i>	
1:55	<b>Provigil (modafinil)</b> – Safety Review of Skin Reactions	Lourdes Villalba, MD, Senior Medical Officer Division of Neurology Products/Division of Psychiatry Products Safety Team Office of New Drugs, CDER, FDA
2:15	<b>Provigil (modafinil)</b> – Safety Overview	Charlene M. Flowers, RPh, Safety Evaluator Office of Surveillance and Epidemiology, CDER, FDA
2:35	<i>Clarification Questions</i>	
2:45	Break	
3:00	<i>Open Public Hearing</i>	
3:30	Committee Deliberation and Recommendations	
4:00	Global Pediatric Drug Development: EMEA & USA Cooperative Work	Dianne Murphy, MD Director, Office of Pediatric Therapeutics
4:30	Questions	
5:00	Adjourn	

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