

Pediatric Advisory Committee Meeting

March 22, 2006 , Gaithersburg Hilton

DRAFT Agenda

7:30 am	Call to Order, Introductions Conflict of Interest Statements	Robert Nelson, M.D., Ph.D. (Chair) Jan Johannessen, Ph.D.
7:40 am	Committee Role in BPCA Safety Reviews	Solomon Iyasu, M.D., M.P.H.
7:50 am	Clofarabine (Clolar [®]) Irbesartan (Avapro [®]) Sibutramine (Meridia [®]): <ul style="list-style-type: none">o Background and Citizen Petitionso BPCA Review	Larry Grylack, M.D. Alan Shapiro, M.D. Eric Colman, M. D. Hari Sachs, M.D.
8:20 am	Opportunity for Sponsor Comments and Response to Committee Questions	Sponsors
8:25 am	Q&As	
8:30 am	Overview of ADHD Portion of the Meeting Introduction of Questions for the Committee	Dianne Murphy, M.D.
8:40 am	New Physician Labeling: Where is the Safety Information?	Rosemary Roberts, M.D.
9:00 am	Summary of June 2005 PAC Interim Actions and Landmark Events	Paul Andreason, M.D.
9:20 am	General Overview of Recent DSaRM meeting	Marsha Rappley, M.D.
9:35 am	Break	
9:50 am	Efficacy of Pharmacological Treatment of ADHD	Benedetto Vitiello, M.D.
10:10 am	Adderall XR [®] —BPCA Review	Susan McCune, M.D.
10:35 am	Use of Drugs for ADHD in the U.S.	Andrew Mosholder, M.D., M.P.H.
10:50 am	Cardiovascular Risk with Drug Treatments of ADHD: Overview of Available Safety Data in Children	Kate Gelperin, M.D., M.P.H.
11:10 am	ADHD Drugs and Cardiovascular Outcomes: Preliminary Feasibility Results and Potential Observational Studies	David Graham, M.D., M.P.H.
11:25 am	Psychiatric Adverse Events in ADHD Clinical Trials	Andrew Mosholder, M.D., M.P.H.
11:50 am	Psychiatric Adverse Events with Drug Treatments of ADHD: Review of Postmarketing Safety Data in the Pediatric Population	Kate Gelperin, M.D., M.P.H.
12:15 pm	Clarification Questions	
12:25 pm	LUNCH	
1:00 pm	Open Public Hearing	
3:15 pm	Sponsor presentations	
4:00 pm	Break	
4:15 pm	Review of Committee Questions Committee Questions and Discussion	Robert Nelson, M.D., Ph.D. (Chair)
	Adjourn	