

DRAFT Agenda  
**Pediatric Advisory Committee**  
*June 29-30, 2005*  
*5630 Fishers Lane, Rm 1066*

***Wednesday, June 29, 2005***

12:30 p.m.	Call to Order Introductions, Meeting Statement	Joan Chesney, M.D. (Chair) Director of Academic Programs St. Jude Children's Research Hosp.
12:35 p.m.	Meeting Overview	Dianne Murphy, M.D., Director Office of Pediatric Therapeutics, FDA
	Role of Committee In Subpart D Referrals	Sara Goldkind, M.D., M.A. Bioethicist, Office of Pediatric Therapeutics, FDA
12:45	Summary of Deliberations from the Pediatric Ethics Subcommittee meeting of June 28 <sup>th</sup> .	Robert Nelson, M.D., Ph.D., Chair Pediatric Ethics Subcommittee
1:00 p.m.	Discussion and Pediatric Advisory Committee Recommendations	
2:00 p.m.	BREAK	
2:15 p.m.	Introductory Remarks - Safety Reporting	Dianne Murphy, M.D., Director Office of Pediatric Therapeutics, FDA
2:20 p.m.	Overview of Agenda Committees Role in BPCA Safety Reviews	Solomon Iyasu, M.D., M.P.H. Division of Pediatric Drug Development OCTAP, CDER, FDA
2:30 p.m.	Ethinyl estradiol; norgestimate (ORTHO TRI-CYCLEN <sup>®</sup> )	Jean Temeck, M.D. Division of Pediatric Drug Development OCTAP, CDER, FDA
	Tolterodine (DETROL <sup>®</sup> and DETROL LA <sup>®</sup> )	Larry Grylack, M.D. Division of Pediatric Drug Development OCTAP, CDER, FDA
3:20 p.m.	Open Public Hearing	
3:50 p.m.	Ciprofloxacin (CIPRO <sup>®</sup> ) Paricalcitol (ZEMPLAR <sup>®</sup> ) Zolmitriptan (ZOMIG <sup>®</sup> ) Dorzolamide (TRUSOPT <sup>®</sup> ) Leflunomide (ARAVA <sup>®</sup> )	Alan Shapiro, M.D. Solomon Iyasu, M.D., M.P.H. Division of Pediatric Drug Development OCTAP, CDER, FDA
	Committee Discussion	
4:30 p.m.	Concluding Remarks	Dianne Murphy, M.D.

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***Thursday, June 30, 2005***

8:00 a.m.	Call to Order Introductions Meeting Statement	Robert Nelson, M.D., Ph.D. (Acting Chair) Dept. of Anesthesia and Critical Care Med. Children's Hospital of Philadelphia
8:05 a.m.	Charge to Committee and Agenda Overview	Solomon Iyasu, M.D., M.P.H. Division of Pediatric Drug Development OCTAP, CDER, FDA
8:15 a.m.	Clinical Experience with the use of Methylphenidate in the Management of ADHD <i>Questions from the Committee</i>	Marsha Rappley, M.D. Associate Professor, Dept. of Pediatrics and Human Development, Michigan State Univ.
8:55 a.m.	Methylphenidate Cytogenetic Update <i>Questions from the Committee</i>	David Jacobson-Kram, Ph.D. Office of New Drugs, CDER, FDA
9:15 a.m.	Overview and Regulatory History of Methylphenidate <i>Questions from the Committee</i>	Paul Andreason, M.D. Division of Neuropharmacologic Drug Products ODE I, CDER, FDA
9:35 a.m.	Pharmacokinetics of Methylphenidate <i>Questions from the Committee</i>	Ron Kavanagh, Ph.D. Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
10:25 a.m.	BREAK	
10:45 a.m.	Adverse Event Review for CONCERTA <sup>®</sup> and other Methylphenidates	Susan McCune, M.D. Division of Pediatric Drug Development OCTAP, CDER, FDA
11:30 a.m.	Questions from the Committee (Sponsors will also have the opportunity to respond during this time.)	
12:30 p.m.	LUNCH	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Overview of FDA's Approach to Adverse Events Review for Methylphenidate and other ADHD Products	Dianne Murphy, M.D., Director Office of Pediatric Therapeutics, FDA
2:45 p.m.	Committee Discussion	
3:30 p.m.	Adjourn	