Food and Drug Administration
Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science
Clinical Pharmacology Subcommittee
November 17-18, 2003

CDER Advisors and Consultants Conference Room
5630 Fishers Lane
Rockville, MD 20857

Agenda

Day 1: Monday, November 17, 2003

8:30	**Call to Order and Opening Remarks**	Jürgen Venitz, M.D., Ph.D. Chair, CPSC Associate Professor, Dept. of Pharmaceutics Virginia Commonwealth University School of Pharmacy
	Introduction of Committee	
	Conflict of Interest Statement	Hilda F. Scharen, M.S. Executive Secretary, ACPS
8:40	**Introduction**	Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER, FDA
	Quantitative analysis using exposure-response	
9:10	**Proposal for End-of-Phase-2A (EOP2A) meetings**	Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
9:40	**Issues proposed to be discussed at EOP2A and their impact**	Peter Lee, Ph.D., Associate Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
9:50	**Case Studies**	Ameeta Parekh, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA Hae-Young Ahn, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA Joga Gobburu, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
10:40	*Break*	
11:00	**Committee discussion**	
11:30	*Lunch*	

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Day 1: Monday, November 17, 2003 (Cont'd)

12:30	**Open Public Hearing**	
1:00	**PK-PD (QT) study design: points-to-consider**	Peter Lee, Ph.D., Associate Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
1:10	**Use of clinical trial simulation (CTS) for PK-PD QT studies**	Peter Bonate, Ph.D., Ilex Oncology
1:40	**Case Studies**	Leslie Kenna, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
2:00	**Committee discussion**	
	Pediatric Bridging: Pediatric decision tree	
2:30	**Introduction**	Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
2:40	**Case Studies**	Peter Hinderling, M.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA Albert Chen, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
3:10	**Methods for determining similarity of exposure-response between pediatric and adult populations**	Stella Machado, Ph.D., Director, Quantitative Methods and Research Staff, Office of Biostatistics, CDER, FDA
3:30	*Break*	
3:45	**Research experience in the use of pediatric decision tree**	Gregory Kearns, Pharm D., Ph.D. Children's Mercy Hospital
4:30	**Regulatory experience in using the pediatric decision tree**	Bill Rodriguez, M.D. Office of Counter Terrorism & Pediatric Drug Development, Division of Pediatric Drug Development, CDER, FDA
4:45	**Committee Discussion**	
5:15	**Concluding Remarks**	Jürgen Venitz, M.D., Ph.D. Chair, ACPS
5:30	*Adjourn*	

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Day 2: Tuesday, November 18, 2003

8:30	**Call to Order**	Jürgen Venitz, M.D., Ph.D. Chair, CPSC
	Conflict of Interest Statement	Hilda F. Scharen, M.S. Executive Secretary, ACPS
8:35	**Introduction**	Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
	Drug Interactions	
8:45	**Introduction**	Shiew-Mei Huang, Ph.D. Deputy Office Director for Science, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
9:00	**Evaluation of CYP2B6-based interactions**	David Flockhart, M.D., Ph.D. Professor, Departments of Pharmacology and Medicine, Indiana University School of Medicine
9:15	**Evaluation of CYP2C8-based interactions**	Pertti Neuvonen, M.D. Department of Clinical Pharmacology University of Helsinki and University Central Hospital
9:30	**Committee Discussion**	
	Pharmacogenetics: Integration into new drug development	
10:00	**Introduction**	Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
10:15	**Academic perspectives**	David Flockhart, M.D., Ph.D. Professor, Departments of Pharmacology and Medicine, Indiana University School of Medicine

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Day 2: Tuesday, November 18, 2003 (Cont'd)

Pharmacogenetics: Integration into new drug development **(Cont'd)**

10:30	**Industry perspectives**	Richard Hockett, M.D. Sr. Clinical Research Physician Eli Lilly and Company
10:45	**"Practitioner perspectives"**	Mary V. Relling, Pharm.D. St. Jude Children's Research Hospital
11:00	**Committee Discussion**	
11:15	*Break*	
11:30	**Committee discussion**	
12:30	**Open Public Hearing**	
1:00	**Committee Discussion and Concluding Remarks**	
1:30	*Adjourn*	