Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY (ACPS-CP)
March 18-19, 2008
Advisory & Consultant Staff Conference Room, Rm 1066,
5630 Fishers Lane, Rockville, MD 20857

AGENDA

Day 1: Tuesday, March 18, 2008

8:30	Call to Order	Jürgen Venitz, M.D., Ph.D. Acting Chair, ACPS-CP
	Conflict of Interest Statement	Mimi Phan, Pharm.D., R.Ph. Designated Federal Official, ACPS-CP
8:45	Introduction to the meeting Topics	Lawrence Lesko, Ph.D. Director, Office of Clinical Pharmacology (OCP), CDER, FDA

Topic 1: **New Clinical PGx concept paper**

09:15	Key issues in the concept paper	Felix Frueh, Ph.D. Associate Director, Pharmacogenomics, OCP, CDER, FDA
09:35	An industry survey on collection of PGx samples	Lisa Shipley, Ph.D. Eli Lilly & Co.
09:55	How the PGx in clinical development	Eric Lai, Ph.D. Glaxo-Smith Kline
10:15	Break	
10:30	Open Public Hearing	
11:00	Committee Discussion and Questions	
12:00	Lunch	

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Day 1: Tuesday, March 18, 2008, 2006 (continued)

Topic 2: Quantitative Clinical Pharmacology: Critical Path Opportunities

13:00	Leveraging Prior Knowledge to Guide Drug Development Decisions	Joga Gobburu, Ph.D. Director, Pharmacometrics OCP, CDER, FDA
13:20	An example of disease model: Non Small Cell Lung Cancer (NSCLC)	Yaning Wang, Ph.D. OCP, CDER, FDA
13:40	Application of FDA's NSCLC model	Rene Bruno, Ph.D. Pharsight, France
14:00	Committee Discussions	
14:30	Break	
15:00	FDAAA: Implications on Pediatric Studies	Lisa Mathis, M.D. Associate Director Pediatric & Maternal Health, Office of New Drugs (OND), CDER, FDA
15:10	Pediatric Studies in Cardiovascular area: Experience & Opportunities	Norman Stockbridge, M.D. Division of Cardio-Renal Products OND, CDER, FDA
15:25:	Leveraging Prior Knowledge to Design a Pediatric Study	Pravin Jadhav, Ph.D. Reviewer, Pharmacometrics OCP, CDER, FDA
15:45	Committee Discussion	
16:45	Wrap for Day 1	Lawrence Lesko, Ph.D. Director, OCP, CDER, FDA
17:00	Adjourn	

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AGENDA

Day 2: Wednesday, March 19, 2008

08:30	Call to order	Jürgen Venitz, M.D., Ph.D. Acting Chair, ACPS-CP
	Conflict of Interest Statement	Mimi Phan, Pharm.D. Designated Federal Official, ACPS-CP

Topic 3: Renal Impairment Concept Paper

08:45	When to conduct a study in renal impairment?	Shiew-Mei Huang, Ph.D. Deputy Director, Office of Clinical Pharmacology (OCP), CDER, FDA
09:05	Effect of Renal Impairment on CYP/transporter	Vincent Pichette, M.D., Ph.D. University of Montreal, Québec, Canada
09:25	Methods of Evaluation of Renal Function	Shen Xiao, M.D. Division of Cardio-Renal Drug Products, Office of New Drugs (OND), CDER, FDA
09:45	Effect of Hemodialysis on drug clearance	William Smoyer, M.D. The Research Institute at Nationwide Children's Hospital, Columbus, Ohio
10:00	Break	
10:15	PhRMA Perspectives	John A. Wagner, M.D., Ph.D. Merck & Co., Inc.
10:35	Open Public Hearing	
11:00	Advisory Committee Discussion & Recommendations	Jürgen Venitz, M.D., Ph.D.
12:00	Summary of recommendations	Lawrence Lesko, Ph.D. Director, OCPB, CDER, FDA
12:30	Adjourn	