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Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
Clinical Pharmacology Subcommittee (CPSC)
October 18-19, 2006
CDER Advisory Committee Conference Room, Rm 1066
5630 Fishers Lane
Rockville, MD

AGENDA
9/26/2006 12:18 PM

Day 1: Wednesday, October 18, 2006

8:30	Call to Order	Acting Chair, CPSC
	Conflict of Interest Statement	Mimi Phan, Pharm.D. Designated Federal Officer, ACPS
9:00	Update on previous CPSC meeting recommendations Introduction to the meeting Topics	Lawrence Lesko, Ph.D. Director, Office of Clinical Pharmacology and Biopharmaceutics (OCPB), CDER, FDA

Topic 1: ***Scientific and Clinical Evidence Related to CYP2D6 Polymorphism and Response to Tamoxifen Therapy***

09:15	Importance of pharmacogenetics in Oncology	Richard Pazdur,M.D Director, Office of Oncology Drug Products
09:30	Tamoxifen pharmacogenetics:An FDA Perspective	Atiqur Rahman, Ph.D. Director, Division of Clinical Pharmacology V
10:00	Tamoxifen, Endoxifen and CYP2D6 Polymorphism	Sally Yasuda, Pharm.D. OCP, CDER, FDA
10:30	Break	
10:45	Tamoxifen Pharmacogenetics and Prediction of Breast Cancer Relapse After Administration of Tamoxifen	
11:15	Open Public Hearing	
11:45	Committee Discussion and Questions	
13:15	Lunch	

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Day 1: Wednesday, October 18, 2006 (continued)

Topic 2: Evaluation of transporter-based drug interactions

14:15	Key issues in the evaluation of drug interactions	Shiew-Mei Huang, Ph.D. Deputy Director for Science, OCP
14:40	PhRMA experience in the evaluation of transporter-based drug interactions- current opinion	
15:05	Break	
15:30	Clinical significant transporter-based interactions	
15:55	Clinical significant interactions of OATP1B1 and their transporter-base interactions	
16:20	Committee Discussion and Questions	Acting Chair, CPSC
17:20	Wrap for Day 1	Lawrence Lesko, Ph.D. Director, OCP, CDER, FDA
17:30	Adjourn	

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ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
Clinical Pharmacology Subcommittee
November 14-15, 2005
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA
9/26/2006 12:18 PM

Day 2: Thursday, October 19, 2006

08:30	Call to order	Acting Chair, CPSC
	Conflict of Interest Statement	Mimi Phan, Pharm.D. Designated Federal Officer,ACPS

Topic 3: Using Disease, Placebo, and Drug Prior Knowledge to Improve Decisions

08:45	Decisions in Drug Development and at FDA: How combining prior knowledge with quantitative-based decisions can improve productivity and quality .	Bob Powell, Pharm.D. Director, PM, OCP, FDA
09:15	Impact of Prior Knowledge on Drug Development Decisions: Case studies across companies.	
09:45	Disease Models at FDA: Overview and Case Studies (Diabetes and Obesity)	Joga Gobburu, PH.D. Team Leader, PM, OCP
10:15	Break	
10:30	Disease Models at FDA: Parkinson's Disease	Atul Bhattaram, Ph.D. PM, OCP, FDA Ohid Siddiqui, Ph.D. OB, FDA
11:15	Open Public Hearing	
11:45	Advisory committee discussion & recommendations.	Acting Chair, CPSC
12:45	Summary of recommendations	Lawerence Lesko, Ph.D. Director, OCPB, CDER, FDA
13:00	Adjourn	

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