

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

11/2/2006 6:24 PM

Day 1: Wednesday, October 18, 2006

- |      |   |  |
|------|---|--|
| 8:30 | Call to Order   | Jürgen Venitz, M.D., Ph.D.<br>Acting Chair, CPSC of ACPS   |
|      | Conflict of Interest Statement  | Mimi Phan, Pharm.D., R.Ph.<br>Designated Federal Officer, ACPS   |
| 9:00 | Update on Previous CPSC Meeting Recommendations<br>Introduction to the Meeting Topics | Lawrence Lesko, Ph.D.<br>Director, Office of Clinical Pharmacology and<br>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.<br>Director, Office of Oncology Drug Products                         |
| 09:30 | Tamoxifen Pharmacogenetics: An FDA Perspective   | Atiqur Rahman, Ph.D.<br>Director, Division of Clinical Pharmacology V                      |
| 10:00 | Tamoxifen, Endoxifen and CYP2D6 Polymorphism   | Sally Yasuda, Pharm.D.<br>OCP, CDER, FDA   |
| 10:30 | Break  |  |
| 10:45 | Tamoxifen Pharmacogenetics and Prediction of<br>Breast Cancer Relapse After Administration of<br>Tamoxifen | Matthew Goetz, M.D.<br>Assistant Professor in Oncology<br>College of Medicine, Mayo Clinic |
| 11:15 | Open Public Hearing  |  |
| 11:45 | Committee Discussion and Questions   |  |
| 13:15 | Lunch  |  |

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  
11/2/2006 6:24 PM

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
14:45	Boehringer Ingelheim Experience/Opinion: Transporter-based Drug Interactions	Mitch Taub, Ph.D. Boehringer Ingelheim Pharmaceuticals
15:10	Break	
15:30	Clinical Significant Transporter-based Interactions	David Greenblatt, M.D. Turfs University
15:55	Clinical Significant Interactions of OATP1B1 and Their Transporter-base Interactions	Kathleen Giacomini, Ph.D. University of California, SF
16:20	Committee Discussion and Questions	Jürgen Venitz, M.D., Ph.D. Acting Chair, CPSC of ACPS
17:20	Wrap for Day 1	Lawrence Lesko, Ph.D. Director, OCP, CDER, FDA
17:30	Adjourn	