

Food and Drug Administration
Center for Drug Evaluation and Research

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

AGENDA
11/2/2006 6:28 PM

Day 2: Thursday, October 19, 2006

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|--|---|--|
| 08:30 | Call to order | Jürgen Venitz, M.D., Ph.D.
Acting Chair, CPSC of ACPS |
| | Conflict of Interest Statement | Mimi Phan, Pharm.D., R.Ph.
Designated Federal Officer, ACPS |
| <i>Topic 3: Using Disease, Placebo, and Drug Prior Knowledge to Improve Decisions</i> | | |
| 08:45 | Decisions in Drug Development and at FDA:
How Combining Prior Knowledge with Quantitative-
based Decisions Can Improve Productivity and Quality . | Bob Powell, Ph.D.
Director, PM, OCP, FDA |
| 09:15 | Impact of Prior Knowledge on Drug Development
Decisions: Case Studies Across Companies. | Jacob Mandema, Ph.D.
Quantitative Solutions Inc. |
| 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 Subcommittee Discussion
& Recommendations | Jürgen Venitz, M.D., Ph.D.
Acting Chair, CPSC of ACPS |
| 12:45 | Summary of Recommendations | Shiew-Mei Huang, Ph.D.
Deputy Director for Science, OCP |
| 13:00 | Adjourn | |