

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
Clinical Pharmacology Subcommittee
CDER Advisory Committee Conference Room
April 22 - 23, 2003
5630 Fishers Lane
Rockville, MD

DRAFT AGENDA

Day 1 - April 22, 2003

- 8:30 **Call to Order** Jorgen Venitz, M.D., Ph.D., Chair
Conflict of Interest Kathleen Reedy, Exec.Sec.
- 8:45 **Introduction to Meeting** Lawrence Lesko, Ph.D., Director OCBP
- 9:00 **Topic # 1** Quantitative risk analysis using exposure-response for determining dose adjustment for special populations Peter Lee, Ph.D.
- 9:10 Example 1 Nhi Nguyen, Ph.D.
- 9:30 Example 2 Jenny J. Zheng, Ph.D.
- (9:50 - 10:10 Break)
- 10:10 Committee discussion
- 11:00 Example 3 He Sun., Ph.D.
- 11:20 Committee discussion
- 11:45 **Lunch**
- 12:45 **Open Public Hearing**
- 1:15 **Topic #1 cont.**
- 1:15 Example 4 - Optimizing dosing strategies for defined therapeutic targets Mats Karlsson, Ph.D.
- 1:40 Committee discussion
- 2:10 **Topic # 2 Pediatric population pharmacokinetics study design template and analyses of the FDA pediatric database** Lawrence Lesko, Ph.D.
- 2:20 Pediatric PPK template Peter Lee, Ph.D.
- 2:35 Committee discussion
- (3:05 - 3:30 Break)
- 3:20 Pediatric Database Analysis Gene Williams, Ph.D.

3:35 Committee Discussion

4:00 **Concluding Remarks - First Day Meeting**

Lawrence Lesko, Ph.D.

5:00 **Adjourn**