Clinical Pharmacology Subcommittee of the
ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

CDER Advisory Committee Conference Room
5630 Fishers Lane, Rockville, MD

AGENDA
October 23, 2002

8:00	**Call to Order**	William Jusko, Ph.D., Acting Chair
	Conflict of Interest	Kathleen Reedy, Executive Secretary
8:10	**Welcome**	Helen Winkle, Acting Director OPS
8:15	**Introduction to Meeting**	Lawrence Lesko, Ph.D., Director OCBP

Topic # 1: Consideration of investigational pharmacokinetic studies to identify patient populations at risk: Methods used to adjust dosing given the availability of exposure-response information

8:45 FDA presentation: case studies and a model for the future: Peter Lee, Ph.D.
9:45 Evaluation of methods and clarifying questions: Richard LaLonde, Pharm.D.., Lewis Sheiner, Ph.D.
10:15 **Break**

10:30 Committee discussion
11:30 Using exposure-response relationships to define therapeutic index: a preliminary approach based on utility function: Jurgen Venitz, M.D.

12:00 **Open Public Hearing**

1:00 **Lunch**

Topic # 2: Use of exposure-response relationships in the Pediatric Study Decision Tree: Questions to be asked using the FDA pediatric database

2:00 Introduction — Arzu Selen, Ph.D.
2:10 Medical and clinical pharmacology perspective on the pediatric study decision tree and experience to date: — Rosemary Roberts, Ph.D.
2:30 Committee Discussion

3:00 **Break**

Topic # 3: Scientific and practical considerations in the use of pharmacogenetic tests to determine drug dosage and administration

3:15 Current experience and clinical pharmacology perspective: Questions to the committee — Lawrence Lesko, Ph.D.
3:45 Assessment of TPMT testing and impact on risk management: Richard Weinshilboum, Ph.D., Mary Relling, Pharm.D.
4:00 Committee discussion

4:30 **Concluding Remarks** — Lawrence Lesko, Ph.D.

5:00 **Adjourn** — William Jusko, Ph.D.