ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
Clinical Pharmacology Subcommittee
CDER Advisory Committee Conference Room
October 23, 2002
5630 Fishers Lane
Rockville, MD

DRAFT AGENDA

8:00	**Call to Order**	William Jusko, Ph.D., Acting Chair
	Conflict of Interest	Kathleen Reedy, Exec.Sec.
8:10	**Welcome**	Helen Winkle, Acting Director OPS
8:15	**Introduction to Meeting**	Lawrence Lesko, Ph.D., Director OCBP
8:45	**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, M.D., Ph.D.

(10:15 -10:30 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., Ph.D.
12:00	**Open Public Hearing**	
1:00	**Lunch**	
2:00	**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, M.D.

2:30	Committee Discussion	
3:00	Break	
3:15	**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.
3:30	Assessment of TPMT testing and impact on risk management	Richard Weinshilboum, M.D. Mary Relling, Pharm.D.
4:00	Committee discussion	
4:30	**Concluding Remarks**	Lawrence Lesko, Ph.D.
5:00	**Adjourn**	William Jusko, Ph.D.