ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
Pharmacology Toxicology Subcommittee
June 10, 2003

CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

8:30	Call to Order	Meryl Karol, Ph.D., Chair
	Conflict of Interest	Kimberly Topper, Exec. Sec.
8:40	Introduction to Meeting and Charge to Subcommittee	David Jacobson-Kram, Ph.D.
8:50	**Topic # 1 Overview of Toxicogenomics at the Drug Development and Regulatory Interface**	
	Concept of "No Regulatory Impact" for Nonclinical Pharmacogenomics/Toxicogenomics Data Submissions to CDER	Janet Woodcock, M.D.
	Added Value of Toxicogenomics and Biomarker Signature Development in Pharmaceutical Evaluations	Roger Ulrich, Ph.D.
	PhRMA Perspective on the Utility and Value of Expression Profiling Data at the Drug Development Regulatory Interface and ILSI Experiences with Cross-platform Comparisons	William Pennie, Ph.D.
10:15	Break	
10:30	**Topic # 2 Toxicogenomic Data Quality and Database Issues**	
	Dealing Effectively with Data Quality Issues, Platform Differences, and Developing a Database	Kurt Jarnigan, Ph.D.
	Data Processing, Statistics, and Data Presentation	John Quackenbush. Ph.D.
	Fluorescent Machine Standards and RNA Reference Standards (Summary of Results from the NIST Workshop)	Krishna Ghosh, Ph.D.
12:00	**Open Public Hearing**	
1:00	**Lunch**	
2:00	**Topic # 3 CDER FDA Product Review and Linking Toxicogenomics Data with**	

	Toxicology Outcome	
	CDER IND/NDA Reviews – Guidance, the Common Technical Document and Good Review Practice	John Leighton, Ph.D.
	Electronic Submissions-Guidance, CDISC and HL-7	Randy Levin, M.D.
	MIAME-Tox	William Mattes, Ph.D.
	CDER FDA Initiatives	Lillian Rosario, Ph.D.
3:30	Break	
3:45	**Questions to Subcommittee**	Frank Sistare, Ph.D.
	Committee Discussion	
4:25	**Conclusions and Summary Remarks**	Meryl Karol, Ph.D.
4:30	**Adjourn**	