

**NONCLINICAL STUDIES SUBCOMMITTEE OF  
THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE**

**March 9, 2000**

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

**AGENDA**

---

<b>8:30</b>	Call to Order/Chairman's Remarks/ Conflict of Interest	John Doull, M.D., Ph.D. (Chair)
<b>8:45</b>	FDA Objectives	James MacGregor, Ph.D.
<b>9:00</b>	Biomarkers, Introduction	Frank Sistare, Ph.D.
<b>9:05</b>	NIH Perspective on Biomarkers	Gregory Downing, Ph.D.
<b>9:25</b>	Establishing Biomarkers of Toxicity for Safety Assessment - A Focus on Cardiac and Skeletal Muscle Toxicity	Malcolm York, M.Phil.
<b>9:50</b>	Proteomics and Safety Biomarker Discovery	Gordon Holt, Ph.D.
<b>10:10</b>	Proteomics Technology	Leigh Anderson, Ph.D.
<b>10:30</b>	<b>Break</b>	
<b>10:45</b>	Applications of SELDI to Protein Biomarker Discovery Strategies	E. Chip Petricoin, Ph.D.
<b>11:05</b>	Applications of Gene Expression Analyses in Peripheral Blood Cells to Safety Assessment	Spencer Farr, Ph.D.
<b>11:25</b>	TaqMan Gene Expression Arrays for Accurate Quantification of Toxicity Targets	Frederico Goodsaid, Ph.D.
<b>11:45</b>	Recommendations for Biomarkers Projects	Frank Sistare, Ph.D.
<b>12:00</b>	Subcommittee Discussion	
<b>12:30</b>	<b>Lunch</b>	
<b>1:30</b>	Open Public Hearing	
<b>2:30</b>	Subcommittee Discussion	

---

3:00	Micro-PET: Experiences with Small Animal Imaging	Simon Cherry, Ph.D.
3:20	Break	
3:55	NIH/NCI Initiatives to Stimulate Applications of Imaging Technology	James Tatum, M.D.
3:55	Proposal to Form Expert Working Group on Imaging	Jerry Collins, Ph.D.
4:10	Subcommittee Discussion	
	Adjourn	