Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
October 19-20, 2004
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

TENTATIVE AGENDA

Day 1: Tuesday, October 19, 2004

8:30	**Call to Order**	Arthur Kibbe, Ph.D. Chair, ACPS
	Conflict of Interest Statement	Hilda Scharen, M.S. Executive Secretary, ACPS
	Introduction to Meeting OPS Update Pharmaceutical Quality for the 21st Century	Helen Winkle Director, Office of Pharmaceutical Science (OPS), CDER, FDA
	Subcommittee Reports Manufacturing Subcommittee	Judy Boehlert, Ph.D. Chair, Manufacturing Subcommittee
	Parametric Tolerance Interval Test for Dose Content Uniformity Update on the FDA/IPAC-RS Working Group **Committee Discussions and Recommendations**	
10:15	Break	
	The Critical Path Initiative – Challenges and Opportunities Research Opportunities and Strategic Direction	
12:00	Lunch	
1:00	**Open Public Hearing**	
	Critical Path Initiative (Continued)	
3:15	Break	
	Committee Discussion and Recommendations	
5:00	**Adjourn**	

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Day 2: Wednesday, October 20, 2004

8:30	**Call to Order**	Arthur Kibbe, Ph.D. Chair, ACPS
	Conflict of Interest Statement	Hilda Scharen, M.S. Executive Secretary, ACPS
	The "Desired State" of Science- and Risk-based Regulatory Policies	Ajaz Hussain, Ph.D.
	(1) Science in Regulation -- Visionary Overview (2) Plans and Activities to Move OPS Forward (3) OPS Policy Development (4) GPhA Perspective (5) PhRMA Perspective	Arthur Kibbe, Ph.D.
	Committee Discussion and Recommendations	
12:00	Lunch	
1:00	**Open Public Hearing**	
2:00	**Pharmaceutical Equivalence and Bioequivalence of Generic Drugs**	
	(1) The Concept and Criteria of BioINequivalence (2) Bioequivalence Testing for Locally Acting Gastrointestinal Drugs	
2:45	Break	
	Committee Discussion and Recommendations	
4:30	**Conclusion and Summary Remarks**	Ajaz Hussain Ph.D. Helen Winkle
5:00	**Adjourn**	