ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
April 13-14, 2004
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Tuesday, April 13, 2004

8:30	Call to Order	Art Kibbe, Ph.D., Chair
	Conflict of Interest	Hilda Scharen, Exec. Sec.
8:45	**Introduction to Meeting** OPS Update Pharmaceutical Quality for the 21st Century	Helen Winkle, Director OPS
9:00	**Subcommittee Reports** Clinical Pharmacology .	
9:15	**Parametric Tolerance Interval Test for Dose Content Uniformity**	Ajaz Hussain, Ph.D.
	FDA Perspective IPAC-RS Perspective	
	Committee Discussions and Recommendations	
10:15	Break (15 minutes)	
10:30	**Process Analytical Technologies (PAT) – Next Steps** Finalizing PAT Guidance Rapid Microbial Methods Standards Development Training and Certification	
	Committee Discussions and Recommendations	
12:00	**Lunch**	
1:00	**Open Public Hearing**	
2:00	**PAT Applications for products in Office of Biotechnology Products (OBP)** Overview and Issues	
3:00	Break (15 minutes)	
	Committee Discussion and Recommendations	

5:00 **Adjourn**

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Day 2: Wednesday, April 14, 2004

8:30	Call to Order	Art Kibbe, Ph.D., Chair
	Conflict of Interest	Hilda Scharen, Exec.Sec.
8:45	**Bioequivalence of Highly Variable Drugs** Issues and challenges	
10:00	Break (15 minutes)	
	Committee Discussion and Recommendations	
12:00	**Lunch**	
1:00	**Open Public Hearing**	
2:00	**BioINequivalence – Concept and Definition**	
2:45	Break (15 minutes)	
	Committee Discussion and Recommendations	
3:30	**Update -- Topical Bioequivalence**	
4:15	**Future Topics - Nanotechnology**	
4:45	**Conclusion and Summary Remarks**	Ajaz Hussain Ph.D.
5:00	**Adjourn**	