Food and Drug Administration
Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science
October 21-22, 2003

Best Western Washington Gateway Hotel
1251 West Montgomery Avenue
Rockville, MD 20857

Agenda

Day 1: Tuesday, October 21, 2003

8:30	**Call to Order and Opening Remarks**	Art Kibbe, Ph.D. Chair, ACPS
	Introduction of Committee	
	Conflict of Interest Statement	Hilda F. Scharen, M.S. Executive Secretary, ACPS
8:45	**Introduction**	Helen Winkle Director, Office of Pharmaceutical Science, CDER, FDA
	Subcommittee Reports	
9:00	**Manufacturing**	Judy Boehlert, Ph.D. Chair, Manufacturing Subcommittee
	Clinical Pharmacology	Jürgen Venitz, M.D., Ph.D. Chair, Clinical Pharmacology Subcommittee
	Draft PAT Guidance	
10:00	**Update**	Ajaz Hussain, Ph.D. Deputy Director, Office of Pharmaceutical Science, CDER, FDA
	Questions/Discussion	
10:30	Break	
	Parametric Tolerance Interval Test for Dose Content Uniformity	
10:45	**Overview and Issues**	Ajaz Hussain, Ph.D. Deputy Director, Office of Pharmaceutical Science, CDER, FDA
11:30	**Open Public Hearing**	
12:30	**Lunch**	
1:30	**Approaches for resolving identified issues**	
	IPAC-RS Presentations	
2:30	Break	
2:45	**Committee Discussion and Recommendations**	
4:30	**Adjourn**	

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Day 2: Wednesday, October 22, 2003

8:30	**Call to Order and Opening Remarks**	Art Kibbe, Ph.D. Chair, ACPS
	Introduction of Committee	
	Conflict of Interest Statement	Hilda F. Scharen, M.S. Executive Secretary, ACPS
	Risk-based CMC Review Proposals	
8:45	**Current Thinking**	
	Focus on "process understanding"	Ajaz Hussain, Ph.D. Deputy Director, Office of Pharmaceutical Science, CDER, FDA
	Issues and challenges	
	Committee Discussion	
10:15	**Break**	
	Nomenclature	
10:45	**Proposals for resolving issues and challenges**	
	FDA Perspective	
	Committee Discussion	
12:00	**Lunch**	
1:00	**Open Public Hearing**	

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Day 2: Wednesday, October 22, 2003 (Cont'd)

Research Plan for Generics – Bioequivalence of Topical Products

2:00	**Generic Drug Research Pogram**	
	Dermatopharmacokinetics: Improvement of methodology for assessing bioequivalence of topical products	
	Bioequivalence of topical products: FDA Perspective	
3:00	Break	
3:15	**Committee Discussion**	
4:45	**Conclusion and Summary Remarks**	Ajaz Hussain, Ph.D. Deputy Director, Office of Pharmaceutical Science, CDER, FDA
5:00	**Adjourn**	