ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
Manufacturing Subcommittee
September 17, 2003
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Agenda: September 17, 2003

8:30	Call to Order Conflict of Interest	Judy P. Boehlert, Ph.D., Chair Hilda Scharen, Exec. Sec.
8:45	**Introduction to Meeting**	Ajaz Hussain, Ph.D., Deputy Director OPS
9:00	PQRI/FDA Workshop Report Summary	Tobias Massa, Ph.D.
9:15	Defining Quality	Janet Woodcock, MD, Director CDER
9:30	Considerations for "Quality by Design"	G K Raju, Ph.D.
10:00	Current Regulatory Challenges in Assessing "Quality by Design"	Norman Schmuff, Ph.D.
10:30	Break	
10:45	Proposals for Regulatory Assessment of "Quality by Design"	
	Industry - PhRMA	Gerry Migliaccio
	- GPhA	Gordon Johnston
	Academic	Kenneth Morris, Ph.D.
	Regulatory - GMP	Joe Famulare
	- CMC	Ajaz Hussain, Ph.D.
11:45	Open Public Hearing	
12:45	**Lunch**	
1:45	Committee Discussion and Recommendations	
2:45	Break	
3:00	Quality by Design and Risk Based Regulatory Scrutiny	
	CMC: Specifications and Post-Approval Changes	Colin Gardner, Ph.D.
	GMP:	Greg Guyer, Ph.D.
4:00	Committee Discussion and Recommendations	
4:45	Closing Remarks	Ajaz Hussain, Ph.D.
5:00	**Adjourn**	