Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
Manufacturing Subcommittee
July 20-21, 2004
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

TENTATIVE AGENDA

Day 1: Tuesday, July 20, 2004

8:30 **Call to Order** — Judy Boehlert, Ph.D., Chair, Manufacturing Subcommittee

Conflict of Interest Statement — Hilda Scharen, M.S., Executive Secretary, ACPS

Introduction to Meeting — Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science (OPS), CDER, FDA

Topic Updates - Quality by Design
Updates: (1) ICH Q8 and Q9
(2) Life Cycle Management for Process and System Control: An Industry Proposal
(3) ASTM E55: Pharmaceutical Applications of Process Analytical Technology

10:30 Break

Moving Towards the "Desired State": Manufacturing Science and Quality by Design as a Basis for Risk-based CMC Review
(1) Manufacturing Science and Knowledge
(2) Quality by Design and Specifications

12:00 **Lunch**

Open Public Hearing

Risk-based CMC Review Paradigm Under Quality by Design and Manufacturing Science Framework -- Opportunities, Challenges, Current Activities, and Next Steps:
(1) Office of New Drug Chemistry (ONDC)
(2) Office of Generic Drugs (OGD)
(3) Risk-Based Development and CMC Question-based Review
(4) Topic wrap-up -- goals and next steps

Committee Discussion and Recommendations

3:30 Break

Introduction to Bayesian Approaches

Research and Training Needs: The Industrialization Dimension of the Critical Path Initiative

5:00 **Adjourn**

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TENTATIVE AGENDA

Day 2: Wednesday, July 21, 2004

8:30	**Call to Order**	Judy Boehlert, Ph.D. Chair, Manufacturing Subcommittee
	Conflict of Interest Statement	Hilda Scharen, M.S. Executive Secretary, ACPS
	cGMPs for the Production of Phase I Investigational New Drugs (INDs)	
	Committee Discussion and Recommendations	
10:00	Break	
	Introduction to Pharmaceutical Industry Practices Research Study	
	Update on Pharmaceutical Industry Practices Research Study	
	Committee Discussion and Recommendations	
	Open Public Hearing	
12:00	Lunch	
	Pilot Model for Prioritizing Selection of Manufacturing Sites for GMP Inspection	
	Committee Discussion and Recommendations	
3:15	Break	
	Applying Manufacturing Science and Knowledge: Regulatory Horizons	
	Update : (1) Process Understanding and PAT (2) Comparability Protocol (3) Changes Without Prior Approval	
	Meeting Conclusion and Summary Remarks	Ajaz Hussain, Ph.D.
5:00	**Adjourn**	