Food and Drug Administration
Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science
Manufacturing Subcommittee

Gaithersburg Marriott - Washingtonian Center
9751 Washingtonian Boulevard
Gaithersburg, Maryland 20878

DRAFT Agenda — May 21-22, 2003

8:30	Call to Order and Opening Remarks
	Introduction of Committee
	Conflict of Interest Statement
8:45	**Introduction**

Pharmaceutical cGMPs for the 21st Century: a Risk-Based Approach

9:15	**FDA Perspective**
10:15	Break
10:30	**Academic Perspective**
11:30	**Open Public Hearing**
12:30	Lunch
1:30	**GPhA Pespective**
	PhRMA Perspective
2:30	**Development of subcommittee work plan**
	Purpose and mission of subcommittee
	Questions to Subcommittee
	Subcommittee Discussion
3:00	Break
4:30	**Adjourn**

Thursday, May 22, 2003

8:30 Call to Order and Opening Remarks

Introduction of Committee

Conflict of Interest Statement

Transition from Process Analytical Technologies (PAT) Subcommittee to Manufacturing Subcommittee

8:40 **Role of PAT in GMP Initiative**

Changes without prior approval - FDA perspective

10:00 Break

10:15 **Perspective on risk analysis for the GMP Initiative**

Manufacturing and risk

11:30 **Open Public Hearing**

12:30 **Lunch**

Update - Regulatory approaches regarding aseptic manufacturing

1:30 **Issues and future plans**

PQRI Aspect

2:30 Break

2:45 **Subcommittee next steps**

4:15 **Conclusions and Summary Remarks**

4:30 **Adjourn**