Food and Drug Administration
Center for Drug Evaluation and Research
ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
Manufacturing Subcommittee
CDER Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, MD

Agenda
March 21, 2003

8:30: Call to Order and Introductions: Judy P. Boehlert, Ph.D., Chair air
Meeting Statement: Kathleen Reedy, Executive Secretary

8:15 Introduction to Meeting — Helen Winkle, Acting Director OPS

8:45 Purpose and mission of the subcommittee

9:15 Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach
Introduction — Helen Winkle
David Horowitz

10:30 Break

10:45 Pharmaceutical cGMPs for the 21st Century cont.
GPhA Perspective — Ken Lavin, TEVAUSA
PhRMA Perspective — Gerry Migliaccio, Pfizer
Committee Discussion

11:30 Open Public Hearing

12:30 Lunch

1:30 Update - ACPS Process Analytical Technologies (PAT) Subcommittee — Ajaz Hussain, Ph.D.

2:30 Update - Regulatory approaches regarding aseptic manufacturing
Issues and future plans — Joseph Famulare
Richard Friedman
PQRI Aspect — Glen Wright, Lilly
Conclusions

3:15 Break

3:30 Subcommittee next steps — Helen Winkle

4:00 Conclusions and Summary Remarks — Ajaz Hussain, Ph.D.

4:30 Adjourn