

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

October 21 - 22, 2002
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 2: Tuesday, October 22, 2002

8:30 Call to Order Vincent H. L. Lee, Ph.D., Acting Chair

Conflict of Interest Kathleen Reedy Exec.Sec.

8:45 **Future Subcommittee - GMP/Manufacturing**

8:45 Introduction and Overview Ajaz Hussain, Ph.D. Deputy Director, OPS

9:00 Industry Perspective:
PhRMA Gerry Migliaccio

GPhA Stephen Bende, Ph.D.

9:30 Committee discussion

10:15 Break

10:30 **Manufacturing Issues: Sterile Drug Products Produced by Aseptic Processing**

10:30 Introduction Ajaz Hussain, Ph.D.

10:35 Topic Introduction Joseph Famulare

11:00 Science Background and Issues Richard Friedman

11:40 Microbiology Review Perspective David Hussong, Ph.D.

12:00 **Lunch**

1:00 **Open Public Hearing**

2:00 **Manufacturing Issues cont.**

(Break 3:00 - 3:15)

4:45 **Conclusion and Summary Remarks** Helen Winkle, Acting Director OPS

5:00 **Adjourn**

10/15/02