

**Process Analytical Technologies Subcommittee of the
ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE**

Ramada Inn, Georgetown and Montrose Rooms, 1775 Rockville Pike, Rockville, MD

October 23, 2002

AGENDA

- 8:30 **Call to Order** Thomas Layloff, Ph.D., Acting Chair
Conflict of Interest Kathleen Reedy, Executive Secretary
- 8:40 **Introduction to Meeting** Ajaz Hussain, Ph.D. Deputy Director, OPS
- 9:00 **Computer systems validation - Part 11 issues pertinent to PAT**
Invited speakers: Guy Wingate, Ph.D.
Debbie Thomas
John Murray
- 10:30 **Break**
- 10:45 **Computer systems validation - Part 11 issues pertinent to PAT cont.**
Subcommittee Discussion
- 11:30 **Open Public Hearing**
- 12:30 **Lunch**
- 1:30 **Breakout Sessions**
A. PAT Mock Submission
B. Rapid Microbiology Testing
- 3:00 **Break**
- 3:45 **Breakout Sessions Presentations to Subcommittee**
PAT Mock Submission - 15 minutes
Rapid Microbiology Testing - 15 minutes
- 4:15 **Subcommittee Discussion and Summary**
- 4:50 **Closing Remarks** Ajaz Hussain, Ph.D.
- 5:00 **Adjourn**