

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

November 28 - 29, 2001
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Wednesday, November 28, 2001

- 8:30 Call to Order Vincent H. L. Lee, Ph.D., Acting Chair
- Conflict of Interest Nancy Chamberlin, Pharm.D., Exec.Sec.
- 8:45 Introduction to Meeting Helen Winkle, Acting Director OPS
- 9:00 **Process Analytical Technology Subcommittee**
- Introduction and Overview Ajaz Hussain, Ph.D.,
Update from Science Board Deputy Director OPS
Objectives for subcommittee
- Committee Discussion
Invited Guests:
Tom Layloff, Ph.D., Pharm. Science Consultant
- 10:30 Break
- 10:45 **Stability Testing and Shelf-life**
- Introduction to Issues Ajaz Hussain, Ph.D.
Deputy Director OPS
- Committee Discussion
Invited Guests
Christopher Rhodes, Ph.D., Univ. Rhode Island
Pharmacy Compounding Committee Member
- 12:30 Lunch
- 1:30 Open Public Hearing
- 2:30 **Blend Uniformity and Potential Impact of PQRI Research**
- Introduction to the Issues Ajaz Hussain, Ph.D.
Deputy Director OPS
- Data presentation
- 3:00 Break
- 3:15 **Blend Uniformity - continued**
- Committee Discussion
Invited Guests
Thomas Garcia, Ph.D., Purepac Pharmaceutical Company
Garth Boehm, Ph.D., Pfizer Inc.

4:15 **Update of other Subcommittees and CDER Guidances Committee**
Nonclinical Studies Subcommittee John Doull, Ph.D.
ACPS Committee Member

Drug Safety and Risk Management
Subcommittee Martin Himmel, M.D.
OPDRA ORM

4:30 Adjourn

(Note: 4:30 - 5:30 Training for ACPS Members)

