

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

9:00 **Blend Uniformity and Potential Impact of PQRI Research**

9:00 Introduction to the Issues Ajaz Hussain, Ph.D.  
Data presentation  
Committee Discussion  
Invited Guests  
Thomas Garcia, Ph.D.  
Garth Boehm, Ph.D.

10:30 Break

10:45 **Stability Testing and Shelf-life**

Introduction to Issues Ajaz Hussain, Ph.D.  
Presentation Chi-Wan Chen, Ph.D.  
Committee Discussion  
Invited Guests  
Christopher Rhodes, Ph.D.

12:30 Lunch

1:30 Open Public Hearing

2:30 **Process Analytical Technology Subcommittee**

Introduction and Overview Ajaz Hussain, Ph.D.  
Update from Science Board  
Objectives for subcommittee  
Selection process for the subcommittee

Committee Discussion

3:30 Break

3:45 **Update of other Subcommittees and CDER Guidances Committee**  
Nonclinical Studies Subcommittee James MacGregor, Ph.D.  
Drug Safety and Risk Management Subcommittee Martin Himmel, M.D.

4:15 Adjourn

(Note: 4:15 - 5:30 Training for ACPS Members)

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### AGENDA

Day 2: Thursday, November 29, 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	<b>Dermatopharmacokinetics</b>	
	Introduction to the issues	Dale Conner, Pharm.D.
	Data Presentations	Thomas Franz, M.D. Lynn Pershing, Ph.D. Mamata Gokhale, Ph.D.
	Committee Discussion Invited Guests Lynn Drake, M.D. Jonathan Wilkin, M.D. Les Benet, Ph.D.	Dale Conner, Pharm.D.
10:45	Break	
11:00	Open Public Hearing	
12:00	Lunch	
1:00	<b>Individual Bioequivalence</b>	
	Introduction to the topic and discussion topics	Larry Lesko, Ph.D.
1:15	Background and Concepts of Individual Bioequivalence	Mei-Ling Chen, Ph.D.
1:30	Results from Replicate Design Studies in NDA's and FDA database	Mei-Ling Chen, Ph.D.
1:45	Results from Replicate Design Studies in ANDA's	Rabi Patnaik, Ph.D.
2:00	FDA Research Plan	Stella Machado, Ph.D.

2:10 Discussion by Committee Members and  
Invited Guests

Les Benet, Ph.D.  
Sandy Bolton, Ph.D.  
Lazlo Endrenyi, Ph.D.  
Nevine Zariffa, Ph.D.  
Avi Yacobi, Ph.D.

2:30 Break

2:45 Continued Discussion on Individual Bioequivalence

4:30 Adjourn