

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE  
October 21 - 22, 2003  
CDER Advisory Committee Conference Room  
5630 Fishers Lane  
Rockville, MD

**AGENDA**

Day 1: Tuesday, October 21, 2003

- 8:30 Call to Order Art Kibbe, Ph.D., Chair  
Conflict of Interest Hilda Scharen, Exec. Sec.
- 8:45 Introduction to Meeting Helen Winkle, Director OPS
- 9:00 **Subcommittee Reports**  
Manufacturing Judy Boehlert, Ph.D.  
Clinical Pharmacology Jürgen Venitz, M.D., Ph.D.  
Pharmacology/Toxicology
- 10:00 **Draft PAT Guidance – Update** Ajaz Hussain, Ph.D.  
Questions/Discussion
- 10:30 Break
- 10:45 **Parametric Tolerance Interval Test for Dose Content Uniformity**  
Overview and Issues Ajaz Hussain, Ph.D.
- 11:30 **Open Public Hearing**
- 12:30 **Lunch**
- 1:30 **Parametric Tolerance Interval Test for Dose Content Uniformity cont.**  
Approaches for resolving identified issues Wallace Adams, Ph.D.  
IPAC-RS Presentations  
(Break 2:30 – 2:45)  
Committee Discussion and Recommendations
- 4:30 **Adjourn**

10/09/03

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Day 2: Wednesday, October 22, 2003

- 8:30 Call to Order Art Kibbe, Ph.D., Chair
- Conflict of Interest Hilda Scharen, Exec.Sec.
- 8:45 **Risk-based CMC Review Proposals**
- Current thinking Yuan-Yuan Chiu, Ph.D.  
Vilayat Sayeed, Ph.D.
- Focus on "process understanding" Ajaz Hussain, Ph.D.
- Issues and challenges Moheb Nasr, Ph.D.
- Committee Discussion
- 10:15 Break
- 10:45 **Nomenclature**
- Proposals for resolving issues and challenges Moheb Nasr, Ph.D.
- FDA Perspective
- USP Perspective
- Committee discussion
- 12:00 **Lunch**
- 1:00 **Open Public Hearing**
- 2:00 **Research for Generics - Bioequivalence of Topical Products**
- Generic Drug Research Program Lawrence Yu, Ph.D.
- Dermatopharmacokinetics: Improvement of methodology for assessing bioequivalence of topical products Annette L. Bunge, Ph.D.

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A case study of the effects of physical and rheological properties of deployment of topical products

David Katz, Ph.D.

Bioequivalence of topical products: FDA Perspective

Jonathan Wilkin, MD

(3:00 – 3:15 Break)

4:45 **Conclusion and Summary Remarks**

Ajaz Hussain Ph.D.

5:00 **Adjourn**