

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

May 7-8, 2002
CDER Advisory Committee Conference Room
5630 Fishers lane
Rockville, MD

AGENDA

Day 1: Tuesday, May 7, 2002

- 8:30 Call to Order Vincent H. L. Lee, Ph.D., Acting Chair
- Conflict of Interest Kathleen Reedy, Exec. Sec
- 8:45 Introduction to Meeting Helen Winkle, Acting Director OPS
- 9:00 **Future Sub-committees**
- Introduction and Overview Ajaz Hussain, Ph.D. Deputy Director, OPS
- Clinical Pharmacology
 - Pharmacology/Toxicology
 - Other
- Committee Discussions
- 9:45 Break
- 10:00 **Draft Guidance: Food Effect BE Studies**
- Introduction and Overview Dale Conner, Pharm.D. OPS/OGD
- Science Background and Issues Ameeta Parekh, Ph.D. OPS/OCPB
- Invited Guests
Aziz Karim, Ph.D. Takeda
Ian Wielding, Ph.D. Pharmprofiles
- 11:30 Open Public Hearing
- 12:30 Lunch
- 1:30 **Biopharmaceutics Classification System - Next Steps**
- Introduction and Overview Lawrence Yu, Act. Deputy Director for Science, OGD/OPS
- Presentations Gordon Amidon, Ph.D. Univ. Michigan
Jack Cook, Ph.D. Pfizer
- 3:15 Break
- 3:30 Committee Discussions
- 4:30 Adjourn

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Day 2: Wednesday, May 8, 2002

- 8:30 Call to Order Vincent H. L. Lee, Ph.D., Acting Chair
Conflict of Interest Kathleen Reedy, Exec. Sec
- 8:45 **Process Analytical Technology**
Introduction and Overview Ajaz Hussain, Ph.D. Deputy Director, OPS
Sub-Committee Report and Next Steps Tom Layloff, Ph.D.
Committee Discussions
- 10:30 Break
- 10:45 **Rapid Microbial Testing - Update**
Introduction and Overview David Hussong, Ph.D. OPS
Bryan Riley, Ph.D. OPS
Presentation Michael S. Korczynski, Ph.D. Mikkor
Committee Discussions
- 11:30 Open Public Hearing
- 12:30 Lunch
- 1:30 **Blend Uniformity**
Introduction and Overview Ajaz Hussain, Ph.D., Deputy Director, OPS
Presentations Tobias Massa, Ph.D. Eli Lilly
Thomas Garcia, Ph.D. Pfizer
Committee Discussions
- 2:45 Break
- 3:00 **Regulatory Issues related to crystal habits - polymorphism**
Introduction and Overview Yuan-yuan Chiu, Director ONDC
ONDC Issues Steve Miller, Ph.D. OPS/ONDC
OGD Issues Richard Adams, Ph.D. OPS/OGD

Other Regulatory perspectives

Harry G. Brittain, Ph.D.
Center for Pharmaceutical Physics

Invited Guests

Kenneth R Morris, Ph.D. Purdue

Committee Discussions

4:30 **OPS Updates and Topics for the next meeting**

5:00 Adjourn