



**Food and Drug Administration  
Center for Drug Evaluation and Research**

**ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)**

**October 5-6, 2006**

CDER Advisory Committee Conference Room  
5630 Fishers Lane  
Rockville, MD

**TENTATIVE AGENDA**

(Scheduled Presentation Times May Change Due to Open Public Hearing Requirements)

**Day 1: Thursday, October 5, 2006**

- 8:30 **Call to Order** Carol Gloff, Ph.D.  
Acting Chair, ACPS
- Conflict of Interest Statement** Mimi Phan, Pharm.D.  
Designated Federal Officer, ACPS
- 8:40 **Introduction to Meeting and OPS Update**
- 9:00 **ICH Quality Topics Update**
- 10:00 **Break**
- ICH Quality Topics Update (continued)**  
**Committee Discussion and recommendations**
- 12:00 **Lunch**
- 1:00 **Open Public Hearing**
- 2:00 **Implementing Quality-by-Design:  
Status, Challenges, and Next Steps**
- 3:00 **Break**
- Implementing Quality-by-Design:  
Status, Challenges, and Next Steps (continued)**  
**Committee Discussion and Recommendations**
- 5:00 **Adjourn**

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**Day 2: Friday, October 6, 2006**

- 8:30 **Call to Order** Charles Cooney, Ph.D.  
Chair, ACPS
- Conflict of Interest Statement** Mimi Phan, Pharm.D.  
Designated Federal Officer, ACPS
- 8:40 **Highly Variable Drugs -- Bioequivalence Issues**
- 10:00 **Break**
- Highly Variable Drugs -- Bioequivalence Issues  
(Continued)**
- Committee Discussions and Recommendations**
- 11:15 **Awareness topic -- Risk Management for  
Complex Pharmaceuticals**
- Committee Discussions**
- 12:00 **Lunch**
- 1:00 **Open Public Hearing**
- 2:00 **Critical Path Initiative**
- Committee Discussion and Recommendations**
- 3:00 **Break**
- Implementation of Definitions for Topical  
Dosage Forms**
- Committee Discussion and Recommendations**
- Nanotechnology -- Issues and Definitions  
Committee Discussion and Recommendations**
- 4:45 **Conclusion and Summary Remarks**
- 5:00 **Adjourn**