

# **Food and Drug Administration**

**Center for Drug Evaluation and Research**

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

**October 25-26, 2005**

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: Tuesday, October 25, 2005**

- 8:30 **Call to Order** Charles Cooney, Ph.D.  
Chair, ACPS
- Conflict of Interest Statement** Mimi Phan  
Executive Secretary, ACPS
- 8:45 **Introduction to Meeting and OPS Update**
- 9:15 **Establishing Drug Release or Dissolution Specifications – Quality-by-Design (QbD) Approach**
- 10:00 Break
- 11:00 **Open Public Hearing**
- 12:00 Lunch
- 1:00 **Establishing Drug Release or Dissolution Specifications – QbD Approach (Continued)**
- 3:00 Break  
**Committee Discussions and Recommendations**
- 4:00 **Parametric Tolerance Interval Test for Dose Content Uniformity**  
**Committee Discussion and Recommendations**
- 5:00 **Adjourn**

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**Day 2: Wednesday, October 26, 2005**

- 8:30 **Call to Order** Charles Cooney, Ph.D.  
Chair, ACPS
- Conflict of Interest Statement** Mimi Phan  
Executive Secretary, ACPS
- 8:45 **Alcohol-induced Dose Dumping**
- 9:45 **Break**
- 10:00 **Implementation of Quality-by-Design (QbD)  
Principles in CMC Review**  
**Committee Discussion and Recommendations**
- 12:00 **Lunch**
- 1:00 **Open Public Hearing**
- 2:00 **Office of Pharmaceutical Science Research  
Programs - Developing a Review and Assessment  
Program**  
**Committee Discussion and Recommendations**
- 3:00 **Break**
- 3:15 **Awareness Topic: Enhancing the  
Pharmaceutical Education System**  
**Committee Discussion and Recommendations**
- 4:30 **Conclusion and Summary Remarks**
- 5:00 **Adjourn**