

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

DRAFT

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)

May 3-4, 2005

CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Tuesday, May 3, 2005

- 8:30 **Call to Order** Charles Cooney, Ph.D.
Chair, ACPS
- Conflict of Interest Statement** Hilda Scharen, M.S.
Executive Secretary, ACPS
- 8:45 **Introduction to Meeting**
OPS Update
- 9:15 **Establishing Drug Release or Dissolution
Specifications**
- 10:30 Break
- 12:00 Lunch
- 1:00 **Open Public Hearing**
- 2:00 **Establishing Drug Release or Dissolution
Specifications (Continued)**
- 3:30 Break
- Committee Discussions and Recommendations**
- 4:30 **Subcommittee Reports**
Clinical Pharmacology Subcommittee Jürgen Venitz, M.D., Ph.D.
Chair, Clinical Pharmacology Subcommittee
- 5:00 **Adjourn**

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AGENDA

Day 2: Wednesday, May 4, 2005

- 8:30 **Call to Order** Charles Cooney, Ph.D.
Chair, ACPS
- Conflict of Interest Statement** Hilda Scharen, M.S.
Executive Secretary, ACPS
- 8:45 **Parametric Tolerance Interval Test
for Dose Content Uniformity**
Current update on the Working Group
- 9:15 **Product Design and Pharmaceutical Equivalence**
- 10:30 Break
- 12:00 Lunch
- 1:00 **Open Public Hearing**
- 2:00 **Product Design and Pharmaceutical Equivalence
(Continued)**
- Committee Discussion and Recommendations**
- 3:00 Break
- 3:15 **Criteria for Establishing a Working Group for
Review and Assessment of OPS Research
Programs**
- Committee Discussion and Recommendations**
- 4:30 **Conclusion and Summary Remarks**
- 5:00 **Adjourn**