

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

November 16, 2000
University of Maryland, Shady Grove Campus
9640 Gudelsky Drive
Rockville, MD 20850

AGENDA

Day 2: Thursday, November 16, 2000

8:30 Call to Order/Conflict of Interest Stephen Byrn, Ph.D., Chair

8:35 Welcome, Introduction Helen Winkle

8:45 **Guidance Updates**

Biopharmaceutics Classification System (BCS) Ajaz Hussain, Ph. D.

General Bioavailability/Bioequivalence Vinod P. Shah, Ph. D.

Average, Population, and Individual
Approaches to Establishing Bioequivalence Mei-Ling Chen, Ph.D.

9:45 **Break**

Clinical Pharmacology

10:00 Modeling and Simulation Introduction Larry Lesk

10:10 The Applications of Simulation in Drug Development

10:25 A Framework of Modeling and Simulation in Regulatory Decision Peti

10:45 Committee Discussion

12:00 **Lunch**

1:00 Open Public Hearing

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Day 2 (continued): Thursday, November 16, 2000

2:00 FDA Research Report
Product Quality Research Institute
Ajaz Hussain, Ph.D.

2:30 Committee Discussion

3:00 **Break**

Generics Issues

3:15 Failed Bio Studies
Dale Conner, PharmD.

3:45 Committee Discussion

Adjourn