

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

November 15, 2000
University of Maryland, Shady Grove Campus
9640 Gudelsky Drive
Rockville, MD 20850

AGENDA

Day 1: Wednesday, November 15, 2000

8:30	Call to Order / Conflict of Interest	Chair
8:45	Welcome	Helen Winkle
	Chemistry, Manufacturing, and Controls	
9:00	314.70 Update	Nancy Sager
9:10	Risk Management Initiative	Helen Winkle
9:25	Reducing the Regulatory Burden Concept, What and How	Yuan-yuan Chiu, Ph.D.
9:45	Innovator Industry Perspective	Tobias Massa, Ph.D.
10:05	Generic Industry Perspective	Debra Miran
10:25	Break	
10:40	Committee Discussion	
12:00	Lunch	
1:00	Open Public Hearing	
2:00	Subcommittee Report: Orally Inhaled and Nasal Drug Products	Wallace P. Adams, Ph.D. Guirag Poochikian, Ph.D.
2:30	Committee Discussion	

3:00 Break

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Day 1 (continued): Wednesday, November 15, 2000

3:15 Subcommittee Report:
Nonclinical Studies

John Doull, M.D., Ph.D.
James MacGregor, Ph. D.

3:45 Committee Discussion

Adjourn