ORALLY INHALED AND NASAL DRUG PRODUCTS SUBCOMMITTEE OF THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

April 26, 2000
CDER Advisory Committee Conference Room 1066
5630 Fishers Lane
Rockville, MD

DRAFT AGENDA

8:30	Call to Order/Chairman's Remarks	Vincent H. L. Lee, Ph.D.
8:40	Introduction and Objectives	Eric Sheinin, Ph.D.
	Chemistry, Manufacturing and Controls: Content Uniformity	
8:55	Current FDA Practices for NDAs	Guirag Poochikian, Ph.D.
9:10	Alternative Statistical Approaches	Walter W. Hauck, Ph.D.
9:30	Subcommittee Discussion	
10:00	**Break**	
	Bioavailability (BA) and Bioequivalence (BE)	
10:15	Current FDA BA/BE Background and Issues	Wallace P. Adams, Ph. D.
	In Vitro BA and BE Testing	
10:30	Profile Analysis of Cascade Impactor Data: Proposed FDA Approach	Yi Tsong, Ph.D.
11:00	Profile Analysis of Cascade Impactor Data: An Alternative View	Andrew R. Clark, Ph.D.
11:30	DPIs: In Vitro Tests for Performance and Comparability	David Ganderton, Ph.D.
12:00	Subcommittee Discussion	

12:30	**Lunch**	
1:30	Open Public Hearing	
	Data Related to BE Testing of Nasal Sprays, and Comments on the BE Studies of Nasal Sprays for Systemic Action	Abdul Zahir, Ph.D.
	Uniqueness of Lingual Spray Delivery	Donald P. Cox, Ph.D.
	Others - TBA	
	In Vivo BA and BE	
2:30	Clinical Studies for Local Delivery of Nasal Aerosols and Sprays	Izabela Roman, M.D., Ph.D.
2:50	Clinical Studies for Local Delivery of Orally Inhaled Corticosteroids	Richard C. Ahrens, M.D.
3:10	**Break**	
3:25	Subcommittee Discussion	
3:50	PK and PD Studies for Systemic Exposure of Locally Acting Drugs	
3:50	Current FDA PK Practices	Venkata R. S. Uppoor, Ph.D.
4:00	Industry View	Lester I. Harrison, Ph.D.
4:20	Academic View	Hartmut Derendorf, Ph.D.
4:40	Subcommittee Discussion	
	Adjourn	