ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

SEPTEMBER 23-24, 1999
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Thursday, September 23, 1999

8:30	Call to Order/Conflict of Interest	Robert Taylor, M.D., Ph.D.

Average and Individual BE Criteria to Compare BE Measures

8:45	Introduction	Roger L. Williams, M.D.
9:15	1. Clinical Perspective	Tom Gretter, M.D.
	2. Pharmaceutical Scientist Perspective	William Barr, Ph.D.
	3. Expert Panel Report	Leslie Z. Benet, Ph.D.

10:15 Break

10:45 Population and Individual Bioequivalence Working Group

Motivation	Walter Hauck, Ph.D.
Criteria and Update of Guidance	Mei-Ling Chen, Ph.D.
Mechanistic Understanding	Larry Lesko, Ph.D.
Replicate and Non-Replicate Datasets	Roger Williams, M.D.
General BA/BE Guidance/Orally Administered Drugs	Vinod Shah, Ph.D.

12:00 Lunch

1:00	Open Public Hearing	

2:00 Committee Discussion

Introduction to Discussion Topics Roger Williams, M.D.

Discussion Topic 1

Is it reasonable and appropriate for FDA to recommend replicate study designs to assess bioequivalence for specified drug products?

Discussion Topic 2

The Advisory Committee is asked to comment on inclusion and exclusion criteria for those drug products where replicate study designs would be recommended, if the answer to Topic 1 is affirmative.

Discussion Topic 3

Are there science and technical reasons why the proposed individual bioequivalence criterion should not be used to allow market access for specified drug substances and drug products as noted in the FDA general guidance?

3:00 Break

3:30 Committee Discussion Cont.

Discussion Topic 4

The proposed criterion allows scaling of the bioequivalence limit (goalpost) by the within-subject variance of the reference product. To avoid large mean T and R differences, constraints on the allowable mean difference may be placed. The Advisory Committee is asked to consider and endorse this approach.

Discussion Topic 5

The FDA proposal, as well as the Expert Panel, recommends BE studies in certain types and numbers of subjects. The Advisory Committee is asked to comment on these recommendations.

Discussion Topic 6

The Advisory Committee is asked to comment on plans for further research programs and projects associated with use of average and individual criteria to allow comparison of bioavailability measures.

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Friday, September 24, 1999

8:30	Call to Order/Conflict of Interest	Robert Taylor, M.D., Ph.D.

Clinical Pharmacology Policy Topics

8:35	Exposure-Response Introduction/Overview	Roger Williams, M.D.
	Purpose/Goal	Larry Lesko, Ph.D.
	Expert Panel=s Perspectives	Don Stanski, M.D.
	Open Public Hearing	
	Committee Discussion	
10:15	Break	
10:45	Drug-Drug Interaction Introduction	Roger Williams, M.D.
	Drug-Drug Interaction Guidance	Shiew-Mei Huang, Ph.D.
	Committee Discussion	
12:00	Lunch	

Nonclinical Studies Subcommittee Report on Research Topics

1:00	Overview	James MacGregor, Ph.D. Jack Reynolds, D.V.M.
	Open Public Hearing	
	Committee Discussion	
3:00	Break	
3:30	Committee Function and Awards	Roger Williams, M.D.

Adjourn