Food and Drug Administration

Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)

October 5-6, 2006

CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 2: Friday, October 6, 2006

8:30	**Call to Order**	Charles Cooney, Ph.D. Chair, ACPS
	Conflict of Interest Statement	Mimi T. Phan, Pharm.D., RP.h. Designated Federal Officer, ACPS
8:40	**Highly Variable Drugs -- Bioequivalence Issues**	
	(1) Topic Introduction	Lawrence Yu, Ph.D. Director for Science, Office of Generic Drugs (OGD), Office of Pharmaceutical Science (OPS), CDER, FDA
	(2) Therapeutic Considerations of Highly Variable Drugs	Leslie Benet, Ph.D. Professor of Biopharmaceutical Sciences University of California San Francisco
	(3) Bioequivalence of Highly Variable Drugs	Kamal K. Midha, Ph.D. Pharmalytics Research Institute, University of Saskatchewan, Canada
	(4) Evaluation of a Scaling Approach for Highly Variable Drugs	Sam Haidar, Ph.D. Lead Pharmacologist, OGD, OPS, CDER, FDA
10:00	Break	
	(5) FDA's Proposal	Barbara Davit, J.D., Ph.D. Deputy Director, Division of Bioequivalence (DBE), OGD, OPS, CDER, FDA
	Committee Discussions and Recommendations	
11:15	**Awareness topic -- Risk Management for Complex Pharmaceuticals**	Steven Kozlowski, M.D. Director, Office of Biotechnology Products (OBP), OPS, CDER, FDA
	Committee Discussions	
12:00	Lunch	
1:00	Open Public Hearing	

(Scheduled Presentations Times May Change Due to Open Public Hearing Requirements)

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Day 2: Friday, October 6, 2006 (continued)

2:00 **Critical Path Initiative**
(This Topic was not discussed during the meeting and has been deferred to a future ACPS meeting)

(1) Agency Overview	Shirley Murphy, M.D. Director, Office of Translational Sciences (OTS), CDER, FDA
(2) OPS Implementation of Critical Path Inititiative	Keith Webber, Ph.D. Deputy Director, OPS, CDER, FDA
OPS Next Steps	Helen Winkle Director, Office of Pharmaceutical Science (OPS), CDER, FDA

Committee Discussion and Recommendations

3:00 Break

Implementation of Definitions for Topical Dosage Forms

Introduction and FDA Strategy	Lucinda Buhse, Ph.D. Director, Division of Pharmaceutical Analysis (DPA), Office of Testing and Research (OTR), OPS, CDER, FDA

Committee Discussion and Recommendations

Nanotechnology -- Issues and Definitions

(1) Topic Introduction/Overview	Nakissa Sadrieh, Ph.D. Science and Research Staff, OPS, CDER, FDA
(2) Applicability of Existing Regulations to the Development of a Dendrimer Nanotechnology-based Pharmaceutical	Jeremy Paull, Ph.D. Vice President, Regulatory Affairs and Quality Assessment, Starpharma Pty., Ltd.
(3) Nanotechnology in Emerging Medical and Consumer Products: Opportunities and Risks	Russell M. Lebovitz, M.D., Ph.D. Managing Partner, SUMA Partners

Committee Discussion and Recommendations

4:45 **Conclusion and Summary Remarks** — Helen Winkle

5:00 **Adjourn**