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 1: Thursday, October 5, 2006

8:30	**Call to Order**	Carol Gloff, Ph.D. Acting Chair, ACPS
	Conflict of Interest Statement	Mimi T. Phan, Pharm.D., RP.h. Designated Federal Officer, ACPS
8:40	**Introduction to Meeting and Office of Science (OPS) Update**	Helen Winkle Director, OPS, CDER, FDA
9:00	**International Conference Harmonisation (ICH) Quality Topics Update**	
	(1) Topic Introduction	Moheb Nasr, Ph.D. Director, Office of New Drug Quality Assessment (ONDQA), OPS, CDER, FDA
	(2) Q8 – Pharmaceutical Development	John Berridge, Ph.D. Rapporteur, ICH Q8 and consultant to Pfizer Ltd. (Representing Pharmaceutical Research & Manufacturers of America/The European Federation of Pharmaceutical Industries Associations/Japan Pharmaceutical Manufacturers Association)
	(3) Q9 – Quality Risk Management	H. Gregg Claycamp, Ph.D. Director, Scientific Support Staff, Office of New Animal Drug Evaluation (ONADE), Center for Veterinary Medicine (CVM), FDA
10:00	Break (15 minutes)	
	(4) Q10 – Pharmaceutical Quality Systems	Joseph Famulare Acting Deputy Director, Office of Compliance (OC), CDER, FDA
	(5) Q4B – Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria	Robert H. King, Sr. Special Assistant for Science, OPS, CDER, FDA (Rapporteur, ICH Q4B)
	Committee Discussion and Recommendations	
12:00	Lunch	

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Day 1: Thursday, October 5, 2006 (continued)

1:00 **Open Public Hearing**

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

2:00 **Implementing Quality-by-Design: Status, Challenges, and Next Steps**

(1) Topic Introduction and an FDA Perspective	Moheb Nasr, Ph.D.
(2) ONDQA Initiatives	Chi-Wan Chen, Ph.D. Deputy Director, ONDQA, OPS, CDER, FDA
(3) Office of Generic Drugs Initiatives (OGD)	Lawrence Yu, Ph.D. Director for Science,OGD, OPS, CDER, FDA
(4) Office of Biotechnology Products (OBP) Initiatives	Steven Kozlowski, M.D. Director, OBP, OPS, CDER, FDA

Break (15 minutes)

(5) Generic Pharmaceutical Association (GPhA) Perspectives	Gordon Johnston, R.Ph., M.S. Vice President, Regulatory Affairs, GPhA
(6) PhRMA Perspectives	Robert G. Baum, Ph.D. Executive Director, Global Regulatory Chemisty, Manufacturing & Controls Policy, Pfizer Global Research & Development (Representing PhRMA)
(7) Summary of Current Plan Status -- Challenges and Next Steps	Helen Winkle

Committee Discussion and Recommendations

5:00 **Adjourn**

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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	

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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**