

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

## ***Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)***

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

July 27, 2011

### AGENDA

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*The committee will discuss current strategies for the FDA's Office of Pharmaceutical Science (OPS) implementation of Quality by Design (QbD) principles within its review office, incorporating an update on the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) activities. The committee will also receive awareness presentations on FDA's current partnering with the United States Pharmacopeia (USP), principally to discuss the Monograph Modernization Program.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Elizabeth Topp, Ph.D.</b> Acting Chair, ACPS-CP
8:05 a.m.	Conflict of Interest Statement	<b>Yvette Waples, Pharm.D.</b> Designated Federal Officer, ACPS-CP
8:10 a.m.	Welcome and Opening Remarks	<b>Helen Winkle</b> Director Office of Pharmaceutical Science (OPS) CDER, FDA
8:15a.m.	<b>Topic 1: Implementation of Quality by Design (QbD) – Current Perspectives on Opportunities and Challenges</b>	
	Topic Introduction and ICH Update	<b>Moheb Nasr, Ph.D.</b> Director, Office of New Drug Quality Assessment (ONDQA), OPS, CDER, FDA
	The Impact of Quality by Design (QbD) on Manufacturing and Product Quality – Innovator Industry Perspective	<b>Gerry Migliaccio, M.S.</b> Pfizer, Inc. – Representing the Pharmaceutical Research and Manufacturers of America
	Can We Do Without QbD in Generics?	<b>Yatindra Joshi, Ph.D.</b> Teva USA – Representing the Generic Pharmaceutical Association
	Regulatory Assessment of Applications Containing QbD Elements – European Union (EU) Perspective	<b>Evdokia Korakianiti, Ph.D.</b> European Medicines Agency
10:00 a.m.	<b>BREAK</b>	
10:15 a.m.	Regulatory Assessment of Applications Containing QbD Elements – FDA Perspective	<b>Sarah Pope Miksinski, Ph.D.</b> Branch Chief, Branch 2 Division of New Drug Quality Assessment I ONDQA, OPS, CDER, FDA
10:45 a.m.	Open Public Hearing Session	

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### AGENDA (cont.)

11:15 a.m.	Topic Wrap-up	<b>Moheb Nasr, Ph.D.</b>
11:25 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	<b>LUNCH</b>	
1:00 p.m.	<b>Topic 2: USP Interaction – Monograph Modernization Program and Other Initiatives</b>	
	Topic Introduction: FDA Monograph Modernization Task Group (MMTG)	<b>Larry Ouderkirk</b> Consumer Safety Officer Office of Manufacturing & Product Quality Office of Compliance (OC), CDER, FDA
	Over-the-Counter (OTC) Monographs: Improving Quality Assessment Standards	<b>Reynold Tan, Ph.D.</b> Interdisciplinary Scientist, Division of Nonprescription Regulation Development Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
	USP Perspectives: USP Monograph Modernization Initiative – Small Molecules	<b>Karen Russo, Ph.D.</b> Vice President, Small Molecules United States Pharmacopeia (USP)
	USP Perspectives: USP Monograph Modernization Initiative – Excipients	<b>Catherine Sheehan, M.S.</b> Director, Excipients United States Pharmacopeia (USP)
	USP Monograph Modernization: The OTC Industry Initiatives	<b>Rachael Roehrig, Ph.D.</b> Director, Technical & Scientific Affairs Consumer Healthcare Products Association
3:15 p.m.	<b>BREAK</b>	
3:30 p.m.	Open Public Hearing Session	
4:00 p.m.	FDA/USP Science Collaboration	<b>Jon Clark, M.S.</b> Associate Director for Program Policy OPS, CDER, FDA
4:20 p.m.	Summary Remarks	<b>Helen Winkle</b>
5:00 p.m.	<b>ADJOURNMENT</b>	