

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

DRAFT AGENDA

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 | TBA
Acting Chair, ACPS-CP |
| 8:05 a.m. | Conflict of Interest Statement | Yvette Waples, Pharm.D.
Designated Federal Officer, ACPS-CP |
| 8:10 a.m. | Introduction/Background | FDA |
| 8:15a.m. | Topic 1: Implementation of Quality by Design (QbD) – Current Perspectives on Opportunities and Challenges | |
| | Topic Introduction and ICH Update | |
| | The Impact of Quality by Design (QbD) on Manufacturing and Product Quality – Innovator Industry Perspective | |
| | Can We Do Without QbD in Generics? | |
| | Regulatory Assessment of Applications Containing QbD Elements – European Union (EU) Perspective | |
| 10:00 a.m. | BREAK | |
| 10:15 a.m. | Regulatory Assessment of Applications Containing QbD Elements – FDA Perspective | |
| 10:45 a.m. | Open Public Hearing Session | |
| 11:15 a.m. | Topic Wrap-up | |
| 11:25 a.m. | Questions to the Committee/Committee Discussion | |
| 12:00 p.m. | LUNCH | |

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DRAFT AGENDA (cont.)

1:00 p.m. **Topic 2: USP Interaction – Monograph Modernization Program and Other Initiatives**

FDA Monograph Modernization Task Group (MMTG)
Overview

Over-the-Counter (OTC) Monographs: Improving Quality
Assessment Standards

USP Perspectives: USP Monograph Modernization
Initiative – Small Molecules

USP Perspectives: USP Monograph Modernization
Initiative – Excipients

USP Monograph Modernization: The OTC Industry
Initiatives

3:15 p.m. **BREAK**

3:30 p.m. Open Public Hearing Session

4:00 p.m. Topic Wrap-up and Additional Update on Interaction
Activities

4:20 p.m. Summary Remarks

5:00 p.m. **ADJOURNMENT**