

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

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

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

White Oak Conference Center, Silver Spring, Maryland

August 8, 2012

AGENDA

During the first session, the committee will discuss the uses and limitations of in vitro dissolution testing and propose future direction for evaluation including possible research. During the second session, the committee will receive an update on the FDA's recently posted draft guidances for industry on biosimilar products. This will be an awareness topic and there will not be formal Committee discussion or recommendation.

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| 8:00 a.m. | Call to Order and Introduction of Committee | Elizabeth Topp, Ph.D.
Acting Chairperson, ACPS-CP |
| 8:05 a.m. | Conflict of Interest Statement | Yvette Waples, Pharm.D.
Designated Federal Officer, ACPS-CP |
| 8:15 a.m. | Welcome and Introductory Remarks | Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science (OPS)
CDER, FDA |

Topic 1: Uses and Limitations of *In Vitro* Dissolution Testing

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| 8:30 a.m. | <u>FDA PRESENTATIONS</u> | |
| | Uses and Limitations of <i>In Vitro</i> Dissolution Testing: Topic Introduction and Overview | Lawrence X. Yu, Ph.D.
Deputy Director for Science and Chemistry Office of Generic Drugs (OGD), OPS, CDER, FDA |
| | Dissolution Testing: Evolving Dissolution Apparatus | Lucinda (Cindy) Buhse, Ph.D.
Director, Division of Pharmaceutical Analysis
Office of Testing and Research (OTR)
OPS, CDER, FDA |
| | Dissolution Testing: Evolving Dissolution Media for Predicting <i>In Vivo</i> Performance | Arzu Selen, Ph.D.
Biopharmaceutics Research Lead, Office of New Drug Quality Assessment (ONDQA)
OPS, CDER, FDA |
| 9:30 a.m. | Clarifying Questions from Committee | |
| 9:45 a.m. | <u>GUEST SPEAKER PRESENTATION</u> | |
| | Oral Bioperformance & 21st Century Dissolution Testing | Gregory E. Amidon, Ph.D.
Research Professor of Pharmaceutical Sciences
University of Michigan College of Pharmacy
Ann Arbor, Michigan |

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AGENDA (cont.)

- 10:10 a.m. Clarifying Questions from Committee
- 10:15 a.m. **BREAK**
- 10:30 a.m. **FDA PRESENTATION**
- Dissolution Testing and Quality-by-Design **Lawrence X. Yu, Ph.D.**
- 10:55 a.m. Clarifying Questions from Committee
- 11:00 a.m. Open Public Hearing Session
- 12:00 p.m. **LUNCH**
- 1:00 p.m. **FDA PRESENTATION**
- Topic Wrap-up and Future Directions **Lawrence X. Yu, Ph.D.**
- 1:15 p.m. Questions to the Committee/Committee Discussion
- Topic 2: Biosimilars – An Update**
[This is an awareness topic and there will not be formal Committee discussion]
- 2:00 p.m. Call to Order and Introduction of Committee **Elizabeth Topp, Ph.D.**
Acting Chairperson, ACPS-CP
- 2:05 p.m. Conflict of Interest Statement **Yvette Waples, Pharm.D.**
Designated Federal Officer, ACPS-CP
- 2:10 p.m. **FDA PRESENTATIONS**
- Biosimilars – An Update **Steven Kozlowski, M.D.**
Focused on Quality Considerations
Director
Office of Biotechnology Products (OBP)
OPS, CDER, FDA
- Quality Considerations for Biosimilars **Marjorie Shapiro, Ph.D.**
Lab Chief, Laboratory of Molecular and
Developmental Immunology (LMDI)
Division of Monoclonal Antibodies
OBP, OPS, CDER, FDA
- 2:35 p.m. Clarifying Questions from Committee

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AGENDA (cont.)

2:45 p.m. **PhRMA PRESENTATION**

A PhRMA Member View on Biosimilars
Analytical and Quality Considerations

Robert J. Mattaliano, Ph.D.
Group VP, Biologics Development
Genzyme Corporation
Framingham, Massachusetts

3:10 p.m. Clarifying Questions from Committee

3:15 p.m. **GPhA PRESENTATION**

Update on Biosimilars

Mark McCamish, M.D., Ph.D.
Global Head Biopharmaceutical Development
Sandoz International, GmbH
Holzkirchen, Germany

3:40 p.m. Clarifying Questions from Committee

3:45 p.m. **BREAK**

4:00 p.m. Open Public Hearing Session

4:30 p.m. **FDA PRESENTATION**

Topic Wrap-up and Current Status

Steven Kozlowski, M.D.

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