

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 26, 2011

AGENDA

The committee will discuss presentations by the Office of Generic Drugs (OGD) on bioequivalence issues and quality standards relative to narrow therapeutic index (NTI) drug products as a class. In response to feedback during the April 13, 2010, Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) meeting, the committee will further discuss the definition and list of NTI drugs, as well as proposed bioequivalence standards for these products. The committee will also receive awareness presentations relevant to OGD's ongoing focus on quality and safety of generic drug products. Presentations will outline current activities seeking to better understand the impact of formulation and quality on the performance of generic drug products and current thinking related to potential regulatory pathways for these issues.

8:00 a.m.	Call to Order and Introduction of Committee	Elizabeth Topp, Ph.D. Acting Chair, ACPS-CP
8:05 a.m.	Conflict of Interest Statement	Yvette Waples, Pharm.D. Designated Federal Officer, ACPS-CP
8:15 a.m.	Introduction/Background	Helen Winkle Director Office of Pharmaceutical Science (OPS) CDER, FDA
8:30 a.m.	Topic 1: Bioequivalence (BE) and Quality Standards for Narrow Therapeutic Index (NTI) Drug Products	
	Topic Introduction: Approaches to Demonstrate Bioequivalence of Narrow Therapeutic Index Drugs	Lawrence Yu, Ph.D. Deputy Director for Science and Chemistry Office of Generic Drugs (OGD) OPS, CDER, FDA
	Narrow Therapeutic Index Drugs: An Approach to Bioequivalence and Interchangeability	Kamal K. Midha, Ph.D. University of Saskatchewan
	Evaluation of Scaling Approaches to Demonstrate BE of NTI Drugs – OGD Simulation Efforts	Donald Schuirmann Mathematical Statistician Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Pharmaceutical Quality of NTI Drug Products	Wenlei Jiang, Ph.D. Pharmacologist, OGD, OPS, CDER, FDA
10:15 a.m.	BREAK	
10:30 a.m.	FDA Proposal for Bioequivalence of Generic Narrow Therapeutic Index Drugs	Barbara M. Davit, Ph.D. Acting Director, Division of Bioequivalence II OGD, OPS, CDER, FDA

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AGENDA (cont.)

- 11:00 a.m. Open Public Hearing Session
- 12:00 p.m. **LUNCH**
- 1:00 p.m. Topic Wrap-up **Lawrence Yu, Ph.D.**
- 1:15 p.m. Questions to the Committee/Committee Discussion
- 2:00 p.m. **Topic 2: Impact of Formulation and Quality on the Safety and Performance of Generic Drug Products**
- Topic Introduction: Quality and Safety of Generic Drug Products **Keith Webber, Ph.D.**
Deputy Director, OPS and
Acting Director, OGD, OPS
CDER, FDA
- Postmarketing Drug Safety: Considerations for Abbreviated New Drug Applications (ANDAs) **Laurie Muldowney, M.D.**
Medical Officer, OPS, CDER, FDA
- Equivalence by Design – Consumer Concern **Vilayat Sayeed, Ph.D.**
Director, Division of Chemistry III
OGD, OPS, CDER, FDA
- 3:15 p.m. **BREAK**
- 3:30 p.m. Regulatory Research to Support the Office of Generic Drugs **Mansoor Khan, R.Ph., Ph.D.**
Director
Division of Pharmaceutical Quality Research
Office of Testing and Research
OPS, CDER, FDA
- Impact of Formulation and Quality on Safety and Acceptance of Generic Drug Products **Gordon Johnston, R.Ph., M.S.**
Representing the Generic Pharmaceutical Association (GPhA)
- 4:30 p.m. Open Public Hearing Session
- 5:00 p.m. Topic Wrap-up and Future Directions **Keith Webber, Ph.D.**
- 5:10 p.m. **ADJOURNMENT**