University of Maryland Center of Excellence in Regulatory Science and Innovation

Science that speeds health innovation

Questioning the Bioequivalence Standards for Antiepileptic Drugs: Implications for Regulation of Narrow Therapeutic Index Drugs

Mark your calendars for Questioning the Bioequivalence Standards for Antiepileptic Drugs: Implications for Regulation of Narrow Therapeutic Index Drugs, a conference sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Food and Drug Administration.

Approximately 85 percent of prescriptions dispensed are generic drugs. These drugs have saved billions of dollars since 1984, with few documented cases of inequivalence. However, the FDA's approach for determining the bioequivalence between generic and brand products has met with some controversy since the establishment of the Abbreviated New Drug Application (ANDA) process by the Hatch-Waxman Amendments.

This conference, scheduled for **Monday, May 12, 2014** at the FDA's White Oak Campus will discuss the effectiveness of current regulatory standards governing generic drug approval, including the most appropriate and acceptable approach for assessing generic bioequivalence to ensure therapeutic equivalence. Because it has been argued that current bioequivalence standards may not be sufficient in special patient populations (e.g., generic brittle epilepsy patients) using antiepileptic drugs (AEDs), the focus will be AED bioequivalence in epilepsy patients. The ongoing project for AED approval for pediatrics for NDA will also be discussed. Conclusions drawn from this conference may be relevant for the regulatory oversight of other therapeutic categories as well, such as immunosuppressant drugs.

For more information, please visit www.pharmacy.umaryland.edu/AED.

Registering by mail? Please detach this form and submit it to the address below. All participants can also register online at www.pharmacy.umaryland.edu/AED.

Questioning the Bioequivalence Standards for Antiepileptic Drugs: Implications for Regulation of Narrow Therapeutic Index Drugs

University of Maryland School of Pharmacy
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☐ Federal Government Employee (FREE)
☐ Other Participant ($50.00)

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CONFERENCE AGENDA

May 12, 2014

9:00-9:15 a.m.
Opening Remarks
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
Food and Drug Administration

9:15-9:45 a.m.
Results of Bioequivalence in Epilepsy Patients (BEEP) Study
James Polli, PhD
Shangraw/Noxell Endowed Chair in Industrial Pharmaceutics
Co-Principal Investigator, M-CERSI
University of Maryland School of Pharmacy

Tricia Ting, MD
Associate Professor of Neurology
University of Maryland School of Medicine

9:45-10:15 a.m.
Equivalence Among Generic AEDs (EQUIGEN) Study
Michel Berg, MD
Associate Professor of Neurology
University of Rochester School of Medicine and Dentistry

10:15-10:45 a.m.
Ensuring Safety and Efficacy of Generic Anti-Epileptic Drugs: FDA OGD Perspectives
Wenlei Jiang, PhD
Pharmacologist
Science Staff
Office of Generic Drugs
Food and Drug Administration

10:45-11:00 a.m.
Break

11:00-11:30 a.m.
Physician Practices and Implications for NTI Classification
William Clarke, PhD
Associate Professor of Pathology
Johns Hopkins University

Michael Cohen-Wolkowiez, MD
Associate Professor of Pediatrics
Duke University School of Medicine

11:30-12:00 p.m.
Panel Discussion
Panelists: Drs. Polli, Ting, Berg, Jiang, Clarke, and Cohen-Wolkowiez

12:00-1:00 p.m.
Lunch

1:00-1:30 p.m.
Dose Sensitivity Considerations for AEDs
James Cloyd, PharmD
Professor of Experimental and Clinical Pharmacology
University of Minnesota College of Pharmacy

1:30-2:00 p.m.
Industrial Perspective: NTI Considerations in Ongoing Product Quality
Jack Cook, PhD
Vice President, Clinical Pharmacology Specialty Care
Pfizer, Inc.

2:00-2:30 p.m.
Extrapolating Efficacy of AEDs from Adults to Pediatrics: An Ongoing Critical Path Project
Angela Men, MD, PhD
Clinical Pharmacology Team Leader for Neurology Products
Food and Drug Administration

2:30-2:45 p.m.
Break

2:45-3:15 p.m.
Modified Release AED Generic Standards
Gregory Krauss, MD
Professor of Neurology
Johns Hopkins University School of Medicine

3:15-3:45 p.m.
Panel Discussion
Panelists: Drs. Cloyd, Cook, Men, and Krauss

3:45-4:00 p.m.
Closing Remarks
Robert Lionberger, PhD
Acting Deputy Director for Science
Office of Generic Drugs
Food and Drug Administration