Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
Department of Health and Human Services

Generic Drug User Fee Amendments of 2012 Regulatory Science Initiatives:
Request for Public Input for FY 2018 Generic Drug Research
Public Workshop

Public Comment Period - Presenters

Session I: Equivalence of complex products

"Non-Biological Complex Drugs – Challenges for approval and post-approval standards"
Jon de Vlieger, PhD
Secretary to the NBCD Working Group
Non-Biological Complex Drugs Working Group

"Gaps that remain in bioequivalence (BE) evaluation of complex drugs: how global experience with IV iron generics can inform approaches to advancing in BE guidance in the U.S."
Amy Barton Pai, PharmD
Associate Professor of Pharmacy
Department of Clinical Pharmacy, University of Michigan

"Advanced drug product characterization techniques"
Kenneth R. Morris, PhD
Professor
NIPTE and Long Island University

"BE, efficacy and safety consideration for injectable complex formulations"
Duxin Sun, PhD
J.G. Searle Endowed Professor
University of Michigan, College of Pharmacy

Session II: Equivalence of locally-acting products

"Product Performance Tools for Establishing Equivalence; Combining Formulation Function with Effect"
Sid Bhoopathy, PhD
Pharmaceutical Consultant
Absorption Systems

"Classification of topical drug products – A way forward to reducing regulatory burden"
Vinod P. Shah, PhD
Pharmaceutical Consultant
VPS Consulting, LLC

"The Complex Biology of Vision - Equivalence Strategies for Complex Ophthalmic Products"
Vatsala Naageshwaran, MS
Vice President Corporate development

Absorption Systems

"Association for Accessible Medicines (AAM) View on GDUFA Regulatory Science"
Lisa Parks, R.Ph
Vice President, Sciences & Regulatory Affairs
Association for Accessible Medicines

Session III: Therapeutic equivalence evaluation and standards

"NIPTE Center of Excellence for Abuse Deterrent Opioid Technologies: Assessment of current and future research needs in generic drug regulation of ADF formulations"
Mansoor Khan, PhD
Professor
NIPTE and Texas A&M University

"IPEC-Americas recommendations for increasing collaboration and transparency with drug ingredient suppliers"
David R. Schoneker, MS
Vice Chair for Science and Regulatory Policy
IPEC-Americas

"New Scientific Directions in Oral Bioequivalence: Implications for Product Development and QC Standards (QbD, PAT)"
Gordon L. Amidon, PhD
Professor of Pharmacy
The University of Michigan, College of Pharmacy

"Stochastic Frameworks for Variability in Oral Dissolution-Absorption and Predictability"
James G. Brasseur, PhD
Research Professor
University of Colorado, Boulder

"Public Health Crisis: Access to Generics for Patients with Cardiovascular Disease"
Robert Page, PharmD, MSPH
Professor of Clinical Pharmacy
American Heart Association

Session IV: Computational and analytical tools

"Computational modeling work in pulmonary drug targeted delivery"
Yu Feng, PhD
Assistant Professor
Chemical Engineering at Oklahoma State University
"FDA Supported Grant: Pharmacokinetic and Pharmacodynamic (PK-PD) Studies of Cardiovascular Drugs"

Scott Mosley, PharmD
Postdoctoral Fellow

Department of Pharmacotherapy and Translational Research, University of Florida College of Pharmacy

"New Prior Knowledge as a Public Mechanism for Development and Education"

Kenneth R. Morris, PhD
Professor
NIPTE and Long Island University