FY 2017 Generic Drug Research Public Workshop Presentations

Session I: Equivalence of complex products

- Product Characterization and In Vitro Testing for Establishing Equivalence of Complex Products, Xiaohui(Jeff) Jiang, FDA
- Equivalence of Complex Products Cyclosporine Ophthalmic Emulsion, Robert A. Bellantone, Physical Pharmaceutica LLC
- Challenges with the Demonstration of Statistical Non-Inferiority of Irritation for Transdermal Drug Delivery Systems Using the OGD Bioguidance Method, Russ Rackley, Mylan Pharmaceuticals, Inc.
- Non-Biological Complex Drugs – Challenges for approval and post-approval standards, Jon de Vlieger, 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, University of Michigan
- Advanced drug product characterization techniques, Kenneth R. Morris, NIPTE and Long Island University
- Bioequivalence (BE), Safety and Efficacy Consideration for Injectable Complex Formulations, Duxin Sun, University of Michigan

Session II: Equivalence of locally-acting products

- Equivalence of Locally-Acting Drug Products, Markham C. Luke, FDA
- Product Performance Tools for Establishing Equivalence; Combining Formulation Function with Effect, Sid Bhoopathy, Absorption Systems
- Classification of topical drug products – A way forward to reducing regulatory burden, Vinod P. Shah, VPS Consulting, LLC
- The Complex Biology of Vision - Equivalence Strategies for Complex Ophthalmic Products, Vatsala Naageshwaran, Absorption Systems

Session III: Therapeutic equivalence evaluation and standards

- FDA Research Update, Myong-Jin Kim, FDA
- GDUFA Amendments of 2012 Regulatory Science Initiatives: Request for Public Input for FY 2018 Generic Drug Research, Siva Vaithiyalingam, Cipla USA, Inc.
- 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, NIPTE and Texas A&M University
- IPEC-Americas recommendations for increasing collaboration and transparency with drug ingredient suppliers, David R. Schoneker, IPEC-Americas

- New Scientific Directions in Oral Bioequivalence: Implications for Product Development and QC Standards (QbD, PAT), Gordon L. Amidon, University of Michigan
- Stochastic Frameworks for Variability in Oral Dissolution-Absorption and Predictability, James G. Brasseur, University of Colorado Boulder

Session IV: Computational and analytical tools

- Quantitative Methods and Modeling to Support GDUFA Regulatory Science Research Program, Liang Zhao, FDA
- Industry Perspective on Application of Physiologically based Absorption Modeling in Generic Drug Research, Amitava Mitra, Sandoz Inc.
- Computational modeling work in pulmonary drug targeted delivery, Yu Feng, Oklahoma State University
- FDA Supported Grant: Pharmacokinetic and Pharmacodynamic (PK-PD) Studies of Cardiovascular Drugs, Scott Mosley, University of Florida
- New Prior Knowledge as a Public Mechanism for Development and Education, Kenneth R. Morris, NIPTE and Long Island University