

Bi-Annual Industry Regulatory Science Working Group Meeting Minutes February 10, 2020 1:00 PM to 2:30 PM White Oak Bldg. 51, Room 3300

Attendees:

FDA
Tiana Barnes
Raphael Brykman
Howard Chazin
Stephanie Choi
Jessie Floura
Sau (Larry) Lee
Robert Lionberger
Markham Luke
Suneela Prodduturi
Jason Rodriguez
Katherine Tyner
Yan Wang

Lei Zhang

Liang Zhao

Industry

Henri Akouka, Teva Rafael Antunes, PBOA

Kurt Attermeier, Fresenius Kabi Karthik Balasubramanian, Teva Biserka Cetina-Cizmek, Teva

Dawn Culp, Mylan

Claire Dabreu-Hayling, Teva

Gregg De Rosa, Teva John DiLoreto, BPTF David Gaugh, AAM Gary Henniger, Teva Kiran Krishnan, Apotex Jagdish Lande, Fresenius Kabi Jinsong Liu, Fresenius Kabi

Mark Liu, Mylan Ripen Misri, Apotex Lisa Parks, AAM Russ Rackley, Mylan Gil Roth, PBOA Ron Selders, Mylan Gina Sirianni, Apotex

Gina Sirianni, Apotex Scott Tomsky, Teva Yu Chung Tsang, Apotex

Arunya Usayapant, Fresenius Kabi Molly Ventrelli, Fresenius Kabi

Roisin Wallace, Mylan

1:00 pm - 1:05 pm: Introductions

1:05 pm – 2:30pm: Planning for the FY2020 Generic Drug Regulatory Science Initiatives Public Workshop

 Dr. Rob Lionberger, Director of the Office of Research and Standards (ORS) within Office of Generic Drugs (OGD), led a discussion on topics to be discussed at the FY2020 Generic Drug Regulatory Science Initiatives Public Workshop to be held on May 4th, 2020. Four breakout sessions will be held in the afternoon, in the following areas:



- 1. Post Market Surveillance of Generic Drugs
- 2. Drug Device Combination Products
- 3. In Vitro Bioequivalence Methods
- 4. Data Analysis and Model-Based Bioequivalence
- Dr. Howard Chazin, Director of the Clinical Surveillance Safety Staff in OGD, and Dr.
 Jason Rodriguez, Laboratory Chief in the Division of Complex Drug Analysis in the Office
 of Testing and Research/Office of Pharmaceutical Quality, presented FDA observations on
 challenges relating to the post market surveillance of generic drugs. The following points
 were discussed:
 - Analytical Methods for response to emerging issues (example detection of nitrosamines in various drug products)
 - Can real word evidence or data from post-market surveillance be used to provide confidence in generic substitution to patients and health care providers
 - How can the industry and the FDA better communicate to patients and healthcare providers to assure generic drug substitutability?
 - o Allowable differences in certain generic drug or drug/device products and how they relate to postmarketing safety concerns
- Dr. Markham Luke, Director of the Division of Therapeutic Performance in ORS/OGD, presented FDA observations on challenges relating to drug device combination products. The following points were discussed:
 - o Issues related to characterizing the performance of drug delivery systems
 - Issues related to the design of comparative human factors studies to demonstrate that brand and generic products with allowable differences in the device constituent part are therapeutic equivalents
 - Exploring how certain differences in device design or device use (e.g. number of steps – per labeling) could impact on measurable performance differences for combination products for their intended user
 - Evaluating certain patented design attributes for combination products and whether they make a difference for drug delivery
- Dr. Yan Wang, Acting Team Leader in the Division of Therapeutic Performance in ORS/OGD, presented FDA observations on challenges relating to in vitro bioequivalence methods. The following points were discussed:
 - Particle size and surface characterization methods and in vitro-in vivo correlations for suspension drug products
 - In vitro methods for inhalation drug products
 - Novel analytical techniques
 - Computational methods to support/complement in vitro methods
 - o IVPT and Q3 characterization for topical products
- Dr. Liang Zhao, Director of the Division of Quantitative Methods and Modeling in ORS/OGD, presented FDA observations on challenges relating to data analysis and modelbased bioequivalence. The following points were discussed:



- o Challenges in industry implementing PBPK/absorption models to support more efficient BE methods (such as alternative to clinical endpoint studies)
- o Statistical expertise in implementing new BE approaches
- O How to evaluate data from in vitro studies and which in vitro studies are clinically relevant

Action item: FDA will incorporate the points above for discussion during the public workshop.