U.S. FOOD & DRUG ADMINISTRATION

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	**Industry**
Tiana Barnes	Henri Akouka, Teva
Raphael Brykman	Rafael Antunes, PBOA
Howard Chazin	Kurt Attermeier, Fresenius Kabi
Stephanie Choi	Karthik Balasubramanian, Teva
Jessie Floura	Biserka Cetina-Cizmek, Teva
Sau (Larry) Lee	Dawn Culp, Mylan
Robert Lionberger	Claire Dabreu-Hayling, Teva
Markham Luke	Gregg De Rosa, Teva
Suneela Prodduturi	John DiLoreto, BPTF
Jason Rodriguez	David Gaugh, AAM
Katherine Tyner	Gary Henniger, Teva
Yan Wang	Kiran Krishnan, Apotex
Lei Zhang	Jagdish Lande, Fresenius Kabi
Liang Zhao	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
	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?
  - 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:
  - 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
  - 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 model-based bioequivalence. The following points were discussed:

- Challenges in industry implementing PBPK/absorption models to support more efficient BE methods (such as alternative to clinical endpoint studies)
- Statistical expertise in implementing new BE approaches
- 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.