U.S. FOOD & DRUG ADMINISTRATION

Bi-Annual Industry Regulatory Science Working Group Meeting Minutes
September 17, 2019
1:30 PM to 3:00 PM
White Oak Bldg. 32, Room 1333

Attendees:

FDA	**Industry**
Tiana Barnes	John DiLoreto, BPTF
Stephanie Choi	Kiran Krishnan, AAM (Apotex)
Jessie Floura	Lisa Parks, AAM
Darby Kozak	Gil Roth, PBOA
Sau (Larry) Lee	Wayne Talton, AAM (Mylan)
Robert Lionberger	Scott Tomsky, AAM (Teva)
Markham Luke	Molly Ventrelli, AAM (Fresenius Kabi)
Jason Rodriguez	Elizabeth White, EFCG (Evonik)
Katherine Tyner	

1:30 pm – 1:35 pm: Introductions

1:35 pm – 3:00 pm: FY 20 Research Initiatives; Discussion and feedback from Industry on initiatives

Dr. Rob Lionberger, Director of the Office of Research and Standards (ORS) within Office of Generic Drugs (OGD), led a discussion with Industry representatives on science and research priority initiatives for FY 2020. New priority areas were not identified for FY 2020, but industry provided input on specific areas of research needs relating to the FY 2019 initiatives. The group discussed priority initiatives as organized into the following categories: Complex Active Ingredients, Formulations, or Dosage Forms, Complex Routes of Delivery, Complex Drug -Device Combinations, and Tools and Methodologies for BE and Therapeutic Equivalence Evaluation. Industry's comments were as follows:

1. Complex Active Ingredients, Formulations, or Dosage Forms
    a. There is a need for clear guidance on tools for characterization as well as monograph standards and research on selection and identification of the optimal number of batches for characterization.
    b. What are acceptable limits to demonstrate equivalence for products requiring immunogenicity studies?
    c. Explanation of the expectations on method validation
    d. Expand the scope of identifying critical quality attributes (CQAs) to ophthalmic suspensions

2. Complex Routes of Delivery
    a. Guidelines for post-approval changes for product categories for which a SUPAC (Scale-Up and Post-Approval Change) guidance is not available.
3. Complex Drug-Device Combinations
    a. No additional comments but industry will continue to consider other research areas that can be explored in the future
4. Tools and Methodologies for BE and Therapeutic Equivalence Evaluation
    a. Expand the biowaiver concept to include parenteral products
    b. Explore and expand options for demonstrating bioequivalence using in vitro techniques
    c. Develop alternative approaches to address outliers in bioequivalence studies when the causes are not related to inadequate or poor in vivo performance of the test formulation
    d. Develop alternative approaches to study design to attain steady state for BE assessment for long acting injectable products. Especially for those products that require a lengthy period of time for patients to reach steady state in multi-dose BE studies

Action item: FDA will incorporate the points above in the FY2020 priorities or propose them for discussion during the FY2020 public workshop.

Dr. Lionberger introduced two non-agenda items to the group; Research Reports Output and May 2019 Regulatory Science Workshop Feedback

1. Dr. Lionberger reported that the FY2018 Research Report has been made available on the FDA website. FDA anticipates publishing the FY2019 Research Reports in a timelier fashion.
2. Dr. Lionberger requested feedback from Industry on the May 2019 Regulatory Science Public Workshop. Industry will provide any immediate feedback it has, including process improvement and topics, to FDA in the coming weeks. Improvements for the May 2020 Regulatory Science Public Workshop will also be on the agenda for the next meeting of this group
    a. FDA encouraged generic industry to be more engaged in providing feedback and comments during the Regulatory Science Public Workshop, and suggested generic companies to get together to identify broader scientific/regulatory issues (e.g., those common to a drug class) that warrant research to facilitate product development and more efficient and effective regulatory evaluation.

- The industry working group members also indicated that scientific publications are valuable. In addition to the yearly posting on publications resulting from research, FDA will post a FY18 report on research outcomes that describe how research has impacted the development and review of generic drugs.