

Bi-Annual Industry Regulatory Science Working Group Meeting Minutes  
November 1, 2018  
10:30 AM to 12:00 PM  
White Oak Bldg. 32, Room 1309

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**Attendees:**

**FDA**

Tiana Barnes  
Stephanie Choi  
Jessie Floura  
Robert Lionberger  
Markham Luke  
Katherine Tyner  
Lei Zhang  
Liang Zhao

**Industry**

John DiLoreto, BPTF  
David Gaugh, AAM  
Kiran Krishnan, AAM (Apotex)  
Lisa Parks, AAM  
Gil Roth, PBOA  
Wayne Talton, AAM (Mylan)  
Scott Tomsky, AAM (Teva)  
Molly Ventrelli, AAM (Fresenius Kabi)

10:30 am – 10:35 am: Introductions

10:35 am – 11:35 am: Discussion and acknowledgement of comments from the FY2018 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), provided a research update on the FY2018 initiatives and described research metrics that could be useful for outcome reporting. He also walked through the two agenda topics that were discussed at the public workshop:
  - Session I: Evaluation of FY2018 Generic Drug Research Priorities
  - Session II: Considerations for FY2019 Generic Drug Research Priorities
- Dr. Liang Zhao, Director of Division of Quantitative Method and Modeling (DQMM) within ORS and Dr. Markham Luke, Director of Division of Therapeutic Performance (DTP) within ORS presented both generic drug industry and academic input, as well as comments that were submitted to the docket
- Industry and FDA working group members agreed that the FY2018 Generic Drug Research Priorities address all input and comments received from the May 24, 2018 workshop
- Dr. Rob Lionberger provided additional discussion on research areas listed in the FY2018 Generic Drug Research Priorities but that were not mentioned in the public comments. He also sought feedback regarding whether further research on expanding BCS Class 3 waivers would provide value to industry.

Action item: FDA will add this as a question to the upcoming FY2019 Generic Drug Regulatory Science Initiatives Public Workshop on May 1, 2019 to encourage additional comments from industry in this area.

11:35 am – 11:55 am: Discussion of the FY2019 Generic Drug Research Priorities List

- An overview of the FY2019 Generic Drug Research Priorities List was presented to the working group for discussion and comment. Additional input was sought to determine if these priorities cover all critical issues to industry. All the industry working group members agreed that these priorities sufficiently covered all critical issues to industry.
  
- Dr. Rob Lionberger discussed Translation and Transparency as the final topic of the meeting
  - Translation of research into guidance and product development
    - There was discussion on the challenges for industry in implementing new analytical methods described in guidance.
    - Action item: FDA will add this as a question to the upcoming FY2019 Generic Drug Regulatory Science Initiatives Public Workshop on May 1, 2019 to encourage additional comments from industry in this area.
  - Transparency of research results and outcomes
    - There was discussion on other possible ways besides publications for FDA to be more transparent in sharing research results.
    - Industry indicated that webinars and workshop presentations are extremely valuable.
    - Example FDA organized workshops include:
      - Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review” (October 2-3, 2017)
      - Demonstrating Equivalence of Generic Complex Drug Substances and Formulations: Advances in Characterization and In Vitro Testing (October 6, 2017)
      - Overcoming Barriers to the Development of, and Improving Patient Access to, Topical Dermatological Generic Drug Products (October 20, 2017)
      - New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products (January 9, 2018)
      - SBIA Complex Generic Drug Products Conference (September 12-13, 2018)
      - DIA Complex Drug-Device Generic Combination Products Meeting (October 9-10, 2018)