U.S. FOOD & DRUG ADMINISTRATION

# Bi-Annual Industry Regulatory Science Working Group Meeting Minutes
February 25, 2019
1:30 PM to 3:00 PM
White Oak Bldg. 32, Room 1321

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**Attendees:**

| **FDA** | **Industry** |
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| Tiana Barnes | John DiLoreto, BPTF |
| Stephanie Choi | David Gaugh, AAM |
| Lucy Fang | Kevin Hawkins, AAM (Teva) |
| Jessie Floura | Kiran Krishnan, AAM (Apotex) |
| Darby Kozak | Lisa Nilsson, AAM (Teva) |
| Larry Lee | Lisa Parks, AAM |
| Robert Lionberger | Gil Roth, PBOA |
| Markham Luke | Mihir Shanbhag, AAM (Apotex) |
| Jason Rodriguez | Andrew Shaw, AAM (Mylan) |
| Katherine Tyner | Cornell Stamoran, PBOA (Catalent) |
| Lei Zhang | Wayne Talton, AAM (Mylan) |
| | Scott Tomsky, AAM (Teva) |
| | Patrick Vallano, AAM (Mylan) |
| | Molly Ventrelli, AAM (Fresenius Kabi) |
| | Roisin Wallace, AAM (Mylan) |

1:30 pm – 1:35 pm: Introductions

1:35 pm – 3:00 pm: Planning for the FY2019 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), described the three topics that have been included in the Federal Register Notice for the FY19 public workshop which will be held on May 1, 2019. The three main topics (including sub-topics) for discussion during the public workshop are:
    1. FY2019 regulatory science initiatives, including specific products or actions that FDA should consider as it implements those initiatives, including, for example:
        - The value to the generic drug product industry in expanding the Biopharmaceutics Classification Systems Class III waivers to include non-Q1/Q2 formulations
        - Scientific gaps that impact the prediction of the results of fed bioequivalence studies
        - Challenges for industry in implementing new analytical or computational methods that arise from regulatory science initiatives

2. Recently approved new drug applications that may pose scientific challenges to the future development of generic drug products referencing those applications
3. Regulatory science initiatives that FDA should begin to consider in FY 2019, including, for example:
    - Scientific challenges in the evaluation of sensitization for transdermal systems
    - The development of alternative approaches to in vivo bioequivalence studies to evaluate product equivalence

- Dr. Lionberger also summarized the GDUFA regulatory science priority initiatives for FY19 which were posted at the beginning of the fiscal year. He sought feedback on whether the industry working group members agreed with the three proposed topic areas for discussion at the public workshop and whether there were any additional topics that industry would like to discuss.
- The industry working group members agreed that these three proposed topic areas should be discussed at the public workshop and also indicated that the following points would be of interest:
    1. Scientific barriers to using the BCS waiver process and the Q1/Q2 requirement for both Class 1 and Class 3 drugs
    2. Scientific challenges in bridging of foreign reference products
    3. Implementation of new analytical methods and technologies such as MDRS
    4. Method validation for new analytical methods
    5. More affordable alternatives to FEV1 studies
    6. Standards for extractables/leachables for container closure systems
    7. Requirements for human factor studies for drug-device combination products

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

- 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.