Bi-Annual FDA-Industry Regulatory Science Working Group Meeting Minutes
March 12, 2021
11:30 AM to 12:45 PM
Virtual Zoom Meeting

Attendees:

FDA	**Industry**
Tiana Barnes	John DiLoreto
Rachel Dunn	David Gaugh
Lucy Fang	Brian McCormick
Jessie Floura	Lisa Parks
Gloria Fu	Gil Roth
Mitch Frost	Molly Ventrelli
Likan Liang	
Robert Lionberger	
Markham Luke	
Sameer Raney	
Lei Zhang	
Liang Zhao	

11:30 am – 11:35 am: Introductions

11:35 am – 12:30 pm: Preparation of the upcoming FY 2021 Generic Drug Science and Research Initiatives Public Workshop on June 23, 2021

Dr. Robert Lionberger, Director of the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD), steered the discussion about an upcoming FY 2021 Generic Drug Science and Research Initiatives Public Workshop to be held in virtual on June 23, 2021, including the goal and expectation of the workshop, an early Save-the-Date announcement, the format of the workshop, and an introduction of the Center for Research on Complex Generics (CRCG):

- A Save-the-Date announcement for the FY 2021 Generic Drug Science and Research Initiatives Public Workshop is available at https://www.fda.gov/drugs/news-events-human-drugs/fy-2021-generic-drug-science-and-research-initiatives-public-workshop-06232021-06232021
- The goal of this year's public workshop is to have a dialogue with industry and to solicit feedback from industry on for the following 5 topic areas of potential relevance to generic drug product development:

    - What research is needed to determine how formulation differences in generic injectable products (that are not qualitatively (Q1) and quantitatively (Q2) the same as their reference listed drug products) affect the substitutability of these products?
    - What research is needed to prepare for generic versions of oligonucleotide drug products (e.g., siRNA, chemically modified, antisense oligonucleotides)?
    - What research relating to artificial intelligence (including machine learning) and/or the use of big data toolsets may facilitate and modernize the development of generic products?
    - What research is needed to bridge the gap between existing scientific insights from GDUFA-funded research (e.g., related to product characterization techniques or modeling and simulation tools) and the development of suitable test procedures, study designs, model integrated evidence, and/or approaches for developing generic products?
    - What research is needed to support best practices and convergence of global bioequivalence standards?
- The focus of the topics is to identify science and research initiatives rather than to discuss regulatory policy.
- A brief update on the Center for Research on Complex Generics (CRCG):
    - CRCG has actively engaged with the generic drug industry, collecting input through a series of interviews with dozens of industry representatives to help the FDA understand product planning strategies and technical challenges of generic drug product development
    - CRCG will present details of insights from these interviews at the workshop
- FY 2021 Generic Drug Science and Research Initiatives Public Workshop will be a one-day virtual meeting with two sections:
    - Morning section includes opening remark, two presentations from FDA, three talks involving case studies given by industry speakers and a panel discussion
    - Afternoon section includes three breakout sessions

Dr. Robert Lionberger invited FDA workshop planning committee members to provide a brief overview of the breakout sessions planned for the afternoon:

- Dr. Liang Zhao, Director of the Division of Quantitative Methods and Modeling in ORS/OGD, presented the framework and topics for breakout session #1, Model-Integrated Evidence for Generic Drug Development
- Dr. Markham Luke, Director of the Division of Therapeutic Performance in ORS/OGD, presented the framework and topics of breakout session #2, Complex Product Characterization and Analysis
- Dr. Mitchell Frost, Team Leader in the Division of Therapeutic Performance in ORS/OGD, presented the framework and topics of breakout session #3, General Issues with Generic Products. *Title of this Breakout session has been updated based on feedback provided at this meeting: 'In Vitro and In Vivo Bioequivalence Approaches: Challenges and Opportunities'*

12:30 pm – 12:45 am: Feedback and suggestions from industry members of the FDA-Industry Regulatory Science Working Group

- *Industry members asked clarification questions, and generally agreed with the planned topics and agenda arrangement and provided comments and feedback to the workshop agenda*

Dr. Robert Lionberger proposed the following action Items from the meeting:

- Industry members of the FDA-Industry Regulatory Science Working Group would assist with industry speaker and panelist nominations
- FDA would provide industry members some additional information about the breakout sessions to assist in the identification of appropriate industry speakers