Bi-Annual Industry Regulatory Science Working Group Meeting
September 24, 2021
1:00 PM to 2:30 PM
Zoom Meetings

Minutes

1:00 PM – 1:05 PM: Introductions

Invited Attendees**:**

FDA	**FDA** (*continued*)	**Industry**
Tiana Barnes	Sue-Chih Lee	John DiLoreto
Heather Boyce	Robert Lionberger	David Gaugh
William Chong	Markham Luke	Kiran Krishnan
Rachel Dunn	Sam Raney	Brian McCormick
Karen Feibus	Fallon Smalls	Lisa Parks
Jessie Floura	Angela Stark	Gil Roth
Mitch Frost	Miyoung Yoon	Molly Ventrelli
Gloria Fu	Lei Zhang	
Xiaohua Huang	Liang Zhao	

1:05 PM – 1:30 PM: Discussion of Fiscal Year (FY) 2021 GDUFA Public Workshop Sessions

- Plenary Session: Overview by Robert Lionberger, PhD
- Breakout Session 1: Overview by Liang Zhao, PhD
- Breakout Session 2: Overview by Markham Luke, MD, PhD
- Breakout Session 3: Overview by Mitch Frost, MD
- General Discussion All

Dr. Robert Lionberger, Director of the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD), at the U.S. Food and Drug Administration (FDA) steered a discussion about the virtual fiscal year (FY) 2021 Generic Drug Science and Research Initiatives Public Workshop that was held on June 23, 2021 ('the FY 2021 Workshop'). He described the role of the Center for Research on Complex Generics (CRCG) and highlighted notable industry comments.

Dr. Liang Zhao, Director of the Division of Quantitative Methods and Modelling within ORS/OGD, steered a discussion about Breakout Session 1 during the FY 2021 Workshop.

Dr. Markham Luke, Director of the Division of Therapeutic Performance I within ORS/OGD, steered a discussion about Breakout Session 2 during the FY 2021 Workshop.

Dr. Mitch Frost, Deputy Director of the Division of Therapeutic Performance II within ORS/OGD, steered a discussion about Breakout Session 3 during the FY 2021 Workshop.

There was general discussion from the meeting attendees that the FY 2021 Workshop topics and discussions were well aligned with current issues and challenges impacting generic drug development, and that the focus of the public workshop was forward-looking about ongoing and upcoming challenges.

1:30 PM – 1:45 PM: Discussion of Draft FY 2022 Priorities

Dr. Sam Raney, Associate Director for Science in ORS/OGD, steered a discussion about the draft FY 2022 Priorities:

Dr. Robert Lionberger noted that FY 2022 would be the fifth year of the GDUFA II program, and that the revisions to the research priorities were modest in scope. He envisioned that the FY 2022 Workshop would likely consider larger shifts in the research priorities, as part of a broader scope of challenges for the subsequent five years of the GDUFA Science and Research program.

Dr. Kiran Krishnan, Senior Vice President of Global Regulatory and Medical Affairs for Apotex Corporation, initiated a general discussion about nitrosamines, noting that, while issues related to nitrosamines are not unique to generics, these issues disproportionately affect generics. It was noted that several public comments during the plenary session of the FY 2021 Workshop had described generic industry challenges related to nitrosamines. Dr. Robert Lionberger commented that CDER offices would work collaboratively to address issues related to nitrosamines, and that industry suggestions to revise to the draft FY 2022 Priorities were welcome.

1:45 PM – 2:15 PM: Discussion of FY 2022 GDUFA Public Workshop (May 9-10, 2022)

Dr. Robert Lionberger initiated a discussion about the FY 2022 Workshop (scheduled for May 9-10, 2022), and requested assistance from the working group to identify major topic areas and industry participants for the FY 2022 Workshop. He suggested that the tentative theme of the workshop could focus on the next five years of the GDUFA Science and Research Program. Potential workshop topics were detailed in the meeting agenda. Briefly, these included:

- Global Nature of Generic Drug Industry
- Excipient Effects
- Drug-Device Combination Products
- Implementing the Science in Product Development and ANDA Submissions
- Implementing Practical and Efficient Model-Integrated Bioequivalence Approaches
- Other

Dr. Brian McCormick, Vice President - Chief Regulatory Counsel, Head of Global Regulatory Policy at Teva Pharmaceuticals, initiated comments from industry that the Global Nature of Generic Drug Industry would be a great topic; meeting attendees expressed that it would be helpful for the generic drug industry around the world to be better aligned and coordinated.

Dr. Lisa Parks, Vice President of Sciences and Regulatory Affairs at the Association for Accessible Medicines, steered a discussion about the scope of a topic on excipient effects, with comments from Dr. Robert Lionberger that the FY 2022 Workshop topics would focus on scientific matters and could explore the pharmacology and toxicology considerations for approved vs. novel excipients, potentially including discussions about strategies for ANDA applicants to be able to utilize novel excipients.

Dr. Lisa Parks initiated a discussion about the format of the FY 2022 Workshop, with comments from Dr. Kiran Krishnan that an option for an in-person component to the meeting would add value, and comments from other industry participants who concurred, but also noted that the virtual environment had the advantage of convenient access for attendees as well as presenters who would otherwise need to travel from distant places. Dr. Robert Lionberger commented that the workshop format was not yet finalized, however, the option to attend virtually would definitely be offered, and the FDA has secured the Great Room at the FDA White Oak campus as a physical venue for a potential in-person component to the workshop; An uncertainty is that FDA is currently unable to anticipate what the guidelines will be for limits on in-person gatherings in May of 2022.

2:15 PM – 2:25 PM: Discussion of Center for Research on Complex Generics (CRCG)

Dr. Sam Raney requested feedback about how the CRCG is serving the generic drug industry. Dr. Lisa Parks, Dr. Kiran Krishnan, Dr. Brian McCormick and others commented that the CRCG has been an effective extension of FDA outreach, taken industry feedback seriously, enhanced industry's ability to provide input and feedback to the FDA, helped to identify appropriate topic areas for the FY 2021 Workshop based upon collecting industry feedback, and that the FDA-CRCG workshops being organized were useful.

Dr. Sam Raney requested feedback about how the CRCG should contribute to the FY 2022 Workshop. *Dr. Brian McCormick and others commented that it would be helpful for the CRCG to continue working with industry to solicit and collate feedback about challenges for generic drug development, and to help with the selection of sessions, coordination of presentations by specific industry presenters, and identification of industry panelists. On a related note, industry members commented that there was a great deal of material covered during the FY 2021 Workshop, and it might be better to distribute that content across 2 days for the FY 2022 Workshop.*

2:25 PM – 2:30 PM: Review of Meeting Outcomes and Proposed Action Items

Dr. Sam Raney and Dr. Lisa Parks clarified the action items and target due dates.