U.S. FOOD & DRUG ADMINISTRATION

Bi-Annual Industry Regulatory Science Working Group Meeting Minutes
October 6, 2020
2:00 PM to 3:30 PM
WebEx

Attendees:

FDA	**Industry**
Tiana Barnes	Rafael Antunes, EFCG
Raphael Brykman	John DiLoreto, BPTF
Howard Chazin	David Gaugh, AAM
Sam Raney	Jinsong Liu, Fresenius Kabi
Jessie Floura	Gil Roth, PBOA
Sau (Larry) Lee	Gina Sirianni, Apotex
Robert Lionberger	Yu Chung Tsang, Apotex
Markham Luke	Molly Ventrelli, Fresenius Kabi
Jason Rodriguez	Noor Araim, Acella/Sovereign
Yan Wang	
Lei Zhang	
Liang Zhao	

2:00 pm – 2:05 pm: Introductions

2:05 pm – 2:45pm: Draft FY21 Research Priorities

- Dr. Rob Lionberger, Director of the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD), led a discussion on a summary of the FY2021 draft research priorities by walking through the updates to the proposed FY2021 priorities based on feedback from industry through bi-annual meetings, the public workshop in May 2020 and public comments.
- Industry representatives agreed with the updates to the current priorities for the implementation of FY2021 research priorities (aligned with their priorities).

2:45pm – 3:05pm – Center for Research on Complex Generics Grant

- Dr. Rob Lionberger introduced Dr. Sam Raney, Team Leader for Topical Dermatologic and Transdermal Products, Division of Therapeutic Performance (DTP) within the Office of Research and Standards (ORS). Dr. Sam Raney will serve as the Project Lead of the FY2020-funded grant to establish a Center for Research on Complex Generics (CRCG). FDA Awarded a five-year grant to the University of Maryland and the University of Michigan. The center aims to enhance research collaborations with the generic industry to further the FDA's mission of increasing access to safe and effective generic drug products. The goal will be pursued through collaborative research, training, and exchange of resources between FDA, the generic industry and stakeholders. Dr. Sam Raney introduced the

website: http://www.complexgenerics.org/ for industry representatives to refer to for additional details

- Industry members are encouraged to collaborate and were asked to provide names of people with whom James Polli at University of Maryland and Anna Schwendeman at University of Michigan may begin discussions

3:05pm – 3:25pm – Feedback on the May 2020 workshop structure and briefly discuss the planning of the June 2021 workshop

- Dr. Robert Lionberger and Jessie Floura shared format of the May 2020 public workshop, and industry representatives conveyed that the format structure was good. The June 2021 public meeting will follow a similar structure and additional details will be shared at the next Bi-Annual Industry Regulatory Science Working Group meeting. At the next meeting, industry representatives will provide input on hot topics, potential panels and industry speakers for the next public workshop on June 23, 2021.

3:25pm – 3:30pm – Action Items and Wrap Up

Action item:

1. Post the FY2021 GDUFA Science and Research Priorities once all FDA approvals are confirmed.
2. Industry representatives to share with Tiana the names of people with whom James Polli and Anna Schwendeman can collaborate regarding the Center for Research on Complex Generics (CRCG).
3. FDA will share additional details for the FY2021 Generic Drug Regulatory Science Initiatives Public Workshop at the next Bi-Annual Industry Regulatory Science Working Group Meeting.
4. FDA will incorporate the points above for discussion during the public workshop on June 23, 2021.