

**Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2021 Generic Drug Research
Public Workshop**

May 4, 2020
Virtual Meeting

Agenda

8:30 – 8:45 am Opening Remarks
Sally Choe, Ph.D.
Director
Office of Generic Drugs (OGD), CDER, FDA

8:45 – 9:00 am Introduction
Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS)
OGD/CDER/FDA

Session I: Overview of FY19-20 GDUFA Research Activities

9:00 – 9:15 am
Howard Chazin, M.D., M.B.A.
Director, Clinical Safety Surveillance Staff
OGD/CDER/FDA
“Post Market Surveillance of Generic Drugs: Opportunities for GDUFA Research”

9:15 – 9:30 am
Kimberly Witzmann, M.D.
Acting Deputy Director, Office of Bioequivalence
OGD/CDER/FDA
“GDUFA Regulatory Science and Research on Generic Drug-Device Combination Products”

9:30 – 9:45 am
Darby Kozak, Ph.D.
Acting Deputy Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
“GDUFA Regulatory Science Research on In Vitro Bioequivalence Methods”

9:45 – 10:00 am
Liang Zhao, Ph.D., M.B.A.
Director, Division of Quantitative Methods and Modeling
ORS/OGD/CDER/FDA
“Quantitative Methods and Modeling to Support GDUFA Regulatory Science Research Program”

10:00 – 10:20 am Break

10:20 – 10:40 am

Lei Zhang, Ph.D.

Deputy Director

ORS/OGD/CDER/FDA

“Newly Approved Complex Drug Products and Potential Challenges to Generic Drug Development”

10:40 – 11:40 am

Industry Leaders’ Roundtable

Panel Discussion

11:40 am – 12:40 pm

Lunch

Session II: Breakouts

12:40 – 3:00 pm

Breakout 1: Post-market Surveillance of Generic Drugs

Moderators: Howard Chazin, M.D., MBA and Jason Rodriguez, Ph.D.

Breakout 2: Combination Products

Moderator: Markham Luke, M.D., Ph.D.

Breakout 3: In Vitro Bioequivalence Methods

Moderator: Yan Wang, Ph.D.

Breakout 4: Data Analysis and Model-Based Bioequivalence

Moderator: Liang Zhao, Ph.D., M.B.A.

3:00 – 3:20 pm

Break

Session III: Wrap-up

3:20 – 4:20 pm

Summary from Breakouts

4:20 – 4:30 pm

Closing Remarks

Robert Lionberger, Ph.D.

Director

ORS/OGD/CDER/FDA