Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2020 Generic Drug Research
Public Workshop

May 1, 2019
FDA White Oak Campus,
10903 New Hampshire Ave.
Bldg. 31, Rm. 1503 Sections B&C
Silver Spring, MD 20993

Agenda

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

8:45 – 8:55 am — Introduction
Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS)
OGD/CDER/FDA

Session I: Implementation of FY 19 Generic Drug Research Priorities

8:55 - 9:05 am
Sid Bhoopathy, Ph.D.
Chief Operating Officer, Absorption Systems
"Impact of Excipients on BCS Class 3 Drug Product Dissolution and Permeability"

9:05 - 9:15 am
Siva Vaithiyalingam, Ph.D.
Vice President, Regulatory Affairs North America, Cipla
"BCS Class 3 Waivers: Expansions Beyond Q1/Q2"

9:15 – 9:35 am — Panel Discussion

9:35 – 9:45 am
Arian Emami Riedmaier, Ph.D.
Senior Scientist, Translational Modeling, Abbvie
"Predicting Food Effect: Applications in Clinical Drug Development"

9:45 – 9:55 am
Amitava Mitra, Ph.D.
Associate Director, Clinical Development, Sandoz
"An Industry Perspective on Successful Prediction of Food Effect and Fed BE Studies"

9:55 – 10:05 am
Gregg DeRosa, Ph.D.
Senior Vice President, Generic Clinical R&D and Internal Clinics, Teva

Andrew Shaw, Ph.D.
Senior Director, Pharmacokinetics and Drug Metabolism, Mylan
"Reducing the Burden of Proof – Re-evaluating the Necessity of Fed Bioequivalence Studies"

10:05 – 10:15 am
Zhanglin Ni, Ph.D.
Staff Fellow, Division of Quantitative Methods and Modeling (DQMM)
ORS/OGD/CDER/FDA
"Scientific Gaps that Impact the Prediction of Fed BE Studies"

10:15 – 10:35 am Panel Discussion

10:35 – 10:50 am **Break**

10:50 – 11:10 am *Public Comment Period*

11:10 – 11:20 am
Darby Kozak, Ph.D.
Team Leader, Division of Therapeutic Performance (DTP)
ORS/OGD/CDER/FDA
"*Advantages and Challenges in Implementing New Analytical Methods that Arise from Regulatory Science Initiatives"*

11:20 – 11:30 am
Liang Zhao, Ph.D., M.B.A.
Director
DQMM/ORS/OGD/CDER/FDA
"*Challenges for Industry in Implementing New Computational Methods that Arise from Regulatory Science Initiatives"*

11:30 – 11:50 am Panel Discussion

11:50 am – 12:50 pm **Lunch**

<u>Session II: New drug approvals that pose scientific challenges to generic product development</u>

12:50 – 1:05 pm
Lei Zhang, Ph.D.
Deputy Director
ORS/OGD/CDER/FDA
"Newly Approved Complex Drug Products and Potential Challenges to Generic Drug Development"

1:05 – 1:20 pm
Jason Rodriguez, Ph.D.
Branch Chief, Division of Pharmaceutical Analysis
Office of Testing and Research, Office of Pharmaceutical Quality, CDER, FDA
"Development of Enhanced Analytical Tools for Evaluation of Complex Generic Products"

1:20 – 1:40 pm *Public Comment Period*

1:40 – 2:00 pm — Panel Discussion

2:00 – 2:15 pm — **Break**

Session III: Considerations for Future Regulatory Science Initiatives

2:15 – 2:25 pm
Walter Wigger-Alberti, M.D.
CEO and Clinical Advisor Dermatology, Bioskin GmbH
"Specific Challenges in the Evaluation of Irritation and Sensitization for Transdermal Systems: A Dermatological Appraisal Focusing on Scoring and Application"

2:25 – 2:35 pm
Lisa Nilsson, M.Sc.
Associate Director, Device R&D, Teva
"Challenges Faced in the Development of the User Interface for Generic and Biosimilar Combination Products"

2:35 – 2:45 pm
Joga Gobburu, Ph.D., M.B.A.
Professor of Pharmacy, Practice and Science
Director, Center for Translational Medicine, University of Maryland, School of Pharmacy
"A Potential Role for Innovative Bayesian and PBPK Approaches to Generic Drug Development"

2:45 – 2:55 pm
Kiran Krishnan, Ph.D.
Senior Vice President, Global Regulatory Affairs, Apotex
"Demonstrating US Reference Standard and Foreign Reference Standards Sameness"

2:55 – 3:15 pm — *Public Comment Period*

3:15 – 4:20 pm — Panel Discussion

4:20 – 4:30 pm — Closing Remarks
Robert Lionberger, Ph.D.
Director
ORS/OGD/CDER/FDA