Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2019 Generic Drug Research
Public Workshop

May 24, 2018
FDA White Oak Campus,
10903 New Hampshire Ave.
Bldg. 31, Rm. 1503 Sections B&C
Silver Spring, MD 20993

Agenda

8:30 – 8:40 am — Opening Remarks
Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS)
Office of Generic Drugs (OGD), CDER, FDA

8:40 – 9:05 am
Lei Zhang, Ph.D.
Deputy Director, ORS
OGD/CDER/FDA
"FDA Research Update on the FY18 Initiatives"

9:05 – 9:20 am
Stephanie Choi, Ph.D.
Acting Associate Director for Science, ORS
OGD/CDER/FDA
"Research Metrics for GDUFA II Mandated Outcome Reporting"

<u>Session I: Evaluation of FY 18 Generic Drug Research Priorities</u>

9:20 – 9:30 am
Theofanis Mantourlias, Ph.D.
Head of Formulation Development, Fresenius Kabi Austria
"Complex Drug Products"

9:30 – 9:40 am
Prasad Peri, Ph.D.
Senior Director, RA CMC, Respiratory and Devices, Teva
"Inhalation Drug Products"

9:40 – 9:50 am
Michael Roberts, PhD, DSc
Professor of Therapeutics and Pharmaceutical Science
School of Pharmacy and Medical Sciences, University of South Australia
Professor of Clinical Pharmacology and Therapeutics, Diamantina Institute, University of Queensland
Senior Principal Research Fellow with the Australian National Health & Medical Research Council
"Topical Products: When Does a Difference Matter?"

9:50 – 10:00 am
Guenther Hochhaus, Ph.D.
Professor
College of Pharmacy, University of Florida
"What are the Knowledge Gaps that Need to be Filled Before One Can Approve Generic Inhalation Drugs on In Vitro and PK Studies Alone?"

10:00 – 10:15 am **Break**

10:15 – 11:15 am *Public Comment Period*

11:15 – 12:15 pm Panel Discussion

12:15 – 1:15 pm **Lunch**

Session II: Considerations for FY 19 Generic Drug Research Priorities

1:15 – 1:35 pm
Xiaohui Jiang, Ph.D.
Deputy Director, Division of Therapeutic Performance, ORS
OGD/CDER/FDA
"Potential Research Challenges for Newly Approved Complex RLDs"

1:35 – 1:45 pm
Amin Rostami, Ph.D.
Professor, University of Manchester
Senior Vice President of R&D and Chief Scientific Officer, Certara
"Individual Physiology, Biology, Anatomy and Their Interplay with Formulation: Impossible Permutations of Conditions to be Studied for Bioequivalence"

1:45 – 1:55 pm
Howard Chazin, M.D., M.B.A.
Director, Clinical Safety and Surveillance Staff
OGD/CDER/FDA
"Challenges in Safety Surveillance for Generic Drugs"

1:55 – 2:10 pm **Break**

2:10 – 3:10 pm *Public Comment Period*

3:10 – 4:10 pm Panel Discussion

4:10 – 4:20 pm Closing Remarks
Kathleen "Cook" Uhl, M.D.
Director
OGD/CDER/FDA