Generic Drug User Fee Amendments of 2012 Regulatory Science Initiatives:
Request for Public Input for FY 2018 Generic Drug Research
Public Workshop

May 3, 2017
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

Session I: Equivalence of complex products

8:40 – 8:55 am
Xiaohui (Jeff) Jiang, PhD
Deputy Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"FDA Research Update"

8:55 – 9:05 am
Robert Bellantone, PhD
President and CSO
Physical Pharmaceutica, LLC
"Industry Perspective on Generic Drug Research Needs"

9:05 – 9:15 am
Vincent P. Andolina, BS
Vice President, Regulatory Affairs
AuroMedics Pharma, LLC
"Industry Perspective on Generic Drug Research Needs"

9:15 – 9:25 am
Russ Rackley, PhD
Head, Global PKDM at Mylan Pharmaceuticals, Inc.
"Industry Perspective on Generic Drug Research Needs"

9:25 – 9:40 am — *Public Comment Period*

9:40 – 10:15 am — Panel Discussion

10:15 – 10:25 am — **Break**

Session II: Equivalence of locally-acting products

10:25 – 10:45 am
Markham C. Luke, MD, PhD
Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA
"FDA Research Update"

10:45 – 11:00 am *Public Comment Period*

11:00 – 12:00 pm Panel Discussion

12:00 – 1:00 pm **Lunch**

Session III: Therapeutic equivalence evaluation and standards

1:00 – 1:20 pm
Myong Jin Kim, PharmD
Deputy Director, Division of Quantitative Methods and Modeling
ORS/OGD/CDER/FDA
"FDA Research Update"

1:20 – 1:40 pm
Siva Vaithiyalingam, PhD
Vice President, Regulatory Affairs, North America
Cipla USA, Inc.
"Industry Perspective on Generic Drug Research Needs"

1:40 – 1:55 pm *Public Comment Period*

1:55 – 2:35 pm Panel Discussion

2:35 – 2:45 pm **Break**

Session IV: Computational and analytical tools

2:45 – 3:05 pm
Liang Zhao, PhD
Director, Division of Quantitative Methods and Modeling
ORS/OGD/CDER/FDA
"FDA Research Update"

3:05 – 3:25 pm
Amitava Mitra, PhD
Associate Director, Clinical Development
Sandoz, Inc.
"Industry Perspective on Generic Drug Research Needs"

3:25 – 3:40 pm	*Public Comment Period*
3:40 – 4:20 pm	Panel Discussion
4:20 – 4:30 pm Kathleen “Cook” Uhl, M.D. Director OGD/CDER/FDA	Closing Remarks