U.S. FOOD & DRUG ADMINISTRATION

# Public Meeting on
# Biosimilar User Fee Act (BsUFA)
# Reauthorization
# Agenda
**October 20, 2016**

8:30 – 9:00 am **Registration**

9:00 – 9:05 am **Welcome**

**Amanda Roache,** Center for Drug Evaluation and Research, FDA
*Office of Strategic Programs*

9:05 – 9:15 am **Opening Remarks**

**Robert Califf, MD,** Commissioner of Food and Drugs, FDA

9:15 – 9:35 am **BsUFA Background and Reauthorization Process**

**Theresa Mullin, PhD,** Center for Drug Evaluation and Research, FDA
*Director, Office of Strategic Programs*

9:35 – 10:30 am **FDA Presentation on Proposed Commitments for BsUFA II**

**Program Enhancements - Leah Christl, PhD,** Associate Director for Therapeutic Biologics OND Therapeutic Biologics and Biosimilars Team (TBBT), Center for Drug Evaluation and Research, FDA

**Finance Enhancements – Josh Barton,** Operations Research Analyst, Center for Drug Evaluation and Research, FDA

10:30 – 10:45 am **Break**

10:45 – 11:10 am **Panel 1 –Patient/Public Health Advocate Perspectives**

**Andrew Spiegel,** Executive Director, Global Colon Cancer Association

**Diana Zuckerman,** President, National Center for Health Research

**Leigh Purvis,** Director, Health Services Research, AARP Public Policy Institute

**Sally Greenberg,** Executive Director, National Consumers League

11:10 – 11:30 am **Panel 2 – Health Care Professionals Perspectives**

**Angus B. Worthing,** MD, American College of Rheumatology

**Jillanne Schulte**, Director, Federal Regulatory Affairs, Government Affairs Division, American Society of Health-System Pharmacists

**Mary Jo Carden,** Vice President, Government and Pharmacy Affairs Academy of Managed Care Pharmacy

**11:30 – 12:30** **Lunch**

12:30 – 1:00 pm **Panel 3 – Regulated Industry Perspectives**

**David R. Gaugh,** RPh Senior Vice President, Sciences and Regulatory Affairs, GPhA and the Biosimilars Council

**Sasha Haverfield,** Senior Vice President, Science and Regulatory Advocacy, PhRMA

**Kay Holcombe,** Senior Vice President for Science Policy, BIO

**Juliana M. Reed,** Vice President, Government Affairs, Coherus Biosciences, President, The Biosimilars Forum

1:00 – 1:45 pm **Open Public Comment**

1:45 - 2:00 pm **Closing Remarks**

**Theresa Mullin, PhD,** Center for Drug Evaluation and Research, FDA
*Director, Office of Strategic Programs*