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