Public Meeting on Biosimilar User Fee Act (BsUFA) Reauthorization
December 18, 2015

8:00 – 9:00 am	**Registration**
9:00 – 9:05 am	**Welcome** Terry Toigo, MBA, RPh Meeting Moderator & Associate Director for Drug Safety Operations Center for Drug Evaluation and Research, FDA
9:05 – 9:15 am	**Opening Remarks** Janet Woodcock, MD Director Center for Drug Evaluation and Research, FDA
9:15 – 9:30 am	**BsUFA Background and Reauthorization Process** Leah Christl, PhD, Associate Director for Therapeutic Biologics OND Therapeutic Biologics and Biosimilars Team (TBBT) Center for Drug Evaluation and Research, FDA
9:30 – 10:00 am	**Panel 1 – Consumer/Patient Perspectives** Leigh Purvis Director, Health Services Research AARP Public Policy Institute, Health Team Eric Hargis, CEO Colon Cancer Alliance Andrew Spiegel, Esq. Chair, Digestive Disease National Coalition
10:00 – 10:30 am	**Panel 2 – Health Care Professionals Perspectives** Mary Jo Carden Vice President, Government and Pharmacy Affairs Academy of Managed Care Pharmacy Angus Worthing, MD American College of Rheumatology Christopher J. Topoleski Director, Federal Regulatory Affairs American Society of Health-Systems Pharmacists
10:30 – 10:50 am	**Break**

10:50 – 11:30 am	**Panel 3 – Regulated Industry Perspectives** Kay Holcombe Senior Vice President for Science Policy BIO Juliana M. Reed Vice President, Government Affairs Coherus Biosciences President, The Biosimilars Forum David R. Gaugh, RPh Senior Vice President, Sciences and Regulatory Affairs GPhA and the Biosimilars Council Michael Levy Deputy Vice President, Scientific and Regulatory Advocacy PhRMA
11:30 – 11:40 am	**Panel 4 – Scientific and Academic Expert Perspectives** Antonio Moreira, PhD Vice Provost for Academic Affairs UMBC
11:40 – 11:55 pm	**Closing Remarks** Theresa Mullin, PhD Director, Office of Strategic Programs Center for Drug Evaluation and Research, FDA
11:55 – 12:30 pm	**Open Public Comment**