Public Meeting on Biosimilar User Fee Act (BsUFA) Reauthorization

November 19, 2020

9:00 – 9:05 am	**Welcome and Introduction**
	Maria Barhams Sagoua, Center for Drug Evaluation and Research, FDA *Lean Management Staff*
9:05 – 9:15 am	**Opening Remarks**
	Patrizia Cavazzoni, Center for Drug Evaluation and Research, FDA *Acting Center Director*
9:15 – 9:30 am	**BsUFA Background and Reauthorization Process**
	Andrew Kish, Center for Drug Evaluation and Research, FDA *Director, Office of Program and Strategic Analysis*
9:30 – 10:00 am	**Panel 1 – Consumer/Patient Perspectives**
	Monica Mallampalli, HealthyWomen *Senior Advisor, Scientific and Strategic Initiatives*
	Anna Hyde, Arthritis Foundation *Vice President of Advocacy and Access*
	Marjana Marinac, JDRF International *Senior Director, Regulatory Affairs*
10:00 – 10:30 am	**Panel 2 – Health Care Professionals Perspectives**
	Angus Worthing, American College of Rheumatology *Member, Board of Directors*
	Bhavesh Shah, Boston Medical Center Health System *Senior Director of Hematology/Oncology and Specialty Pharmacy*
	Lisa Kennedy Sheldon, Oncology Nursing Society *Clinical and Scientific Affairs Liaison*
10:30 – 10:50 am	**Break**

10:50 – 11:30 am **Panel 3 – Regulated Industry Perspectives**

Julie Reed, Biosimilars Forum
President

Cory Wohlbach, Association for Accessible Medicines
Global Vice President, Biosimilar Regulatory Affairs, Teva Pharmaceuticals

Cartier Esham, Biotechnology Innovation Organization
Executive Vice President, Emerging Companies

Lucy Vereshchagina, Pharmaceutical Research and Manufacturers of America
Vice President, Science and Regulatory Advocacy

11:30 – 11:40 pm **Panel 4 – Scientific and Academic Expert Perspectives**

Inmaculada Hernandez, University of Pittsburgh School of Pharmacy
Assistant Professor of Pharmacy and Therapeutics

11:40 – 11:50 am **FDA Remarks**

Sarah Yim, Center for Drug Evaluation and Research, FDA
Director, Office of Therapeutic Biologics and Biosimilars

11:50 – 12:20 pm **Public Comments**

12:20 – 12:30 pm **Closing Comments**

Maria Barhams Sagoua, Center for Drug Evaluation and Research, FDA
Lean Management Staff