Public Meeting on Biosimilar User Fee Act (BsUFA) Reauthorization

November 2, 2021

9:00 a.m. **Welcome and Introduction**

Tasha Ray, Center for Drug Evaluation and Research, FDA
Meeting Moderator, Program Evaluation and Implementation Staff, Office of Program and Strategic Analysis, Office of Strategic Programs

9:05 a.m. **Opening Remarks**

Patrizia Cavazzoni, Center for Drug Evaluation and Research, FDA
Center Director

9:10 a.m. **BsUFA Background and Reauthorization Process**

Andrew Kish, Center for Drug Evaluation and Research, FDA
Director, Office of Program and Strategic Analysis, Office of Strategic Programs

9:25 a.m. **BsUFA III Agreement Overview**

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

Laurie Graham, Center for Drug Evaluation and Research, FDA
Director, Division of Internal Policies and Programs, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality

Steven Kozlowski, Center for Drug Evaluation and Research, FDA
Director, Office of Biotechnology Products, Office of Pharmaceutical Quality

Joshua Barton, Center for Drug Evaluation and Research, FDA
Director, Resource Capacity Planning Staff, Office of Program and Strategic Analysis, Office of Strategic Programs

10:00 a.m. **Break**

10:20 a.m. **Industry Comments**

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

Meaghan Smith, Biosimilars Forum
Executive Director

Camelia Thompson, Biotechnology Innovation Organization
Senior Director, Science & Regulatory Affairs

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

11:00 a.m. **Open Public Comment**

11:30 p.m. **Closing Remarks**