Public Meeting on the Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act

March 22, 2022

9:30 – 9:35 am	**Welcome and Introduction** **Mark Ascione, MBA/MEM,** Center for Drug Evaluation and Research, FDA *Meeting Facilitator, Program Evaluation and Implementation Staff*
9:35 – 10:20 am	**Presentation of the Assessment** **Valerie Overton,** Eastern Research Group *Vice President*
10:20 – 10:35 am	**FDA Perspective** **Sarah Yim, MD,** Center for Drug Evaluation and Research, FDA *Director, Office of Therapeutic Biologics and Biosimilars*
10:35 – 11:35 am	**Industry Perspectives** **David Gaugh, PhD,** Association for Accessible Medicines (AAM) *Senior Vice President, Sciences & Regulatory Affairs* **Camelia Thompson, PhD,** Biotechnology Innovation Organization (BIO) *Senior Director, Science and Regulatory Team* **Rachel Turow, JD, MPH,** Teva Pharmaceuticals *Associate General Counsel, Regulatory Law & Policy; Head, U.S. Regulatory Policy* *Speaking on behalf of the Biosimilars Forum* **Jessica Tyson, PhD, MPH,** Pharmaceutical Research and Manufacturers of America (PhRMA) *Senior Director, Science and Regulatory Advocacy*
11:35 – 12:25 pm	**Q&A and Open Public Comment**
12:25 – 12:30 pm	**Closing**