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

January 27, 2021

9:30 – 9:35 am	**Welcome and Introduction** **Maria Barhams Sagoua**, Center for Drug Evaluation and Research, FDA *Meeting Facilitator, Lean Management 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,** Center for Drug Evaluation and Research, FDA *Director, Office of Therapeutic Biologics and Biosimilars*
10:35 – 11:15 am	**Industry Perspectives** **Hillel P. Cohen, Ph.D.,** Sandoz Biopharmaceuticals (a Novartis Company), *Executive Director, Scientific Affairs* (on behalf of the Biosimilars Council, a division of the Association for Accessible Medicines) **Juliana Reed,** Biosimilars Forum and Pfizer Biosimilars *President and Vice President* **Camelia Thompson, Ph.D.,** Biotechnology Innovation Organization (BIO) *Senior Director, Science and Regulatory Affairs* **Jessica Tyson,** Pharmaceutical Research and Manufacturers of America (PhRMA) *Director, Science and Regulatory Advocacy*
11:15 – 11:30 am	**Break**
11:30 – 12:25 pm	**Q&A and Open Public Comment**
12:25 – 12:30 pm	**Closing**