Public Meeting on the Recommendations for Biosimilar User Fee Act (BsUFA) Reauthorization

October 26, 2026

9:00 – 9:05 am	**Welcome and Introduction** **Danielle Villata**, Center for Drug Evaluation and Research (CDER), FDA *Meeting Moderator*
9:05 – 9:10 am	**Opening Remarks** **Grace Graham**, Office of the Commissioner, FDA *Deputy Commissioner for Policy, Legislation, and International Affairs*
9:10 – 9:20 am	**BsUFA Background and Overview of Recommendations** **Andrew Kish**, CDER, FDA *Director, Office of Program and Strategic Analysis*
9:20 – 9:55 am	**Program: Proposed Enhancements** **Sarah Yim**, CDER, FDA *Director, Office of Therapeutic Biologics and Biosimilars (OTBB)* **Mustafa Ünlü**, CDER, FDA *Director, Biosimilar Regulatory Review Staff, OTBB* **Sau (Larry) Lee**, CDER, FDA *Deputy Director, Office of Pharmaceutical Quality* **Andrew Kish**, CDER, FDA *Director, Office of Program and Strategic Analysis* *Senior Director, Science and Regulatory Advocacy*

Ryan Kaat, Pharmaceutical Research and Manufacturers of America (PhRMA)
Assistant General Counsel, Law

Juliana Reed, The Biosimilars Forum
Executive Director

Giuseppe Randazzo, Association for Accessible Medicines (AAM)
Senior Vice President of Sciences and Regulatory Affairs

Steve Berman, Biotechnology Innovation Organization (BIO)
Vice President, Science and Regulatory Affairs Strategy

9:55 – 10:30 am **Finance: Proposed Enhancements**

Kristopher Hoover, Office of Finance, Budget, and Acquisitions, FDA
Data Scientist, Resource Capacity Planning Branch

Sean Hilscher, Pharmaceutical Research and Manufacturers of America (PhRMA)

Juliana Reed, The Biosimilars Forum
Executive Director

Scott Kuzner, Association for Accessible Medicines (AAM)
Senior Director of Sciences and Regulatory Affairs

Steve Berman, Biotechnology Innovation Organization (BIO)
Vice President, Science and Regulatory Affairs Strategy

10:30 – 10:45 am **Break**

10:45 – 11:45 am **Public Stakeholder Perspectives**

11:45– 11:55 am **Public Comment**

11:55 – 12:00 pm **Closing Remarks**

Andrew Kish, CDER, FDA
Director, Office of Program and Strategic Analysis