



Public Meeting on Biosimilar User Fee Act (BsUFA) Reauthorization

December 3, 2025

9:00 am – 9:05 am	Welcome and Introduction Jonathan Collins , Center for Drug Evaluation and Research, FDA <i>Meeting Moderator</i>
9:05 – 9:10 am	Opening Remarks Mike Davis , Center for Drug Evaluation and Research, FDA <i>Deputy Center Director</i>
9:10 – 9:30 am	BsUFA Background and Reauthorization Process Andrew Kish , Center for Drug Evaluation and Research, FDA <i>Director, Office of Program and Strategic Analysis</i>
9:30 – 10:00 am	Regulated Industry Perspectives Juliana Reed , The Biosimilars Forum <i>Executive Director</i> Scott Kuzner , Biosimilars Council <i>Senior Director, Sciences and Regulatory Affairs</i> Sean Hilscher , PhRMA <i>Senior Director, Science and Regulatory Advocacy</i>
10:00 – 10:15 am	Break
10:15 – 11:30 am	Public Comment
11:30 – 11:35 am	Closing Remarks

Jonathan Collins, Center for Drug Evaluation and Research,
FDA
Meeting Moderator