



**U.S. FOOD & DRUG**  
ADMINISTRATION

# Public Meeting on Biosimilar User Fee Act (BsUFA) Reauthorization

December 3, 2025

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

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