Biosimilar User Fee Amendments (BsUFA) Reauthorization

Stakeholder Meeting with FDA

April 27, 2026 | 2:00 - 3:30 pm

Virtual Format

MEETING PURPOSE

This meeting was the first in a planned series of monthly public stakeholder consultation meetings held as part of the Biosimilar User Fee Act (BsUFA) IV reauthorization process. The meeting was convened to inform FDA's development of BsUFA IV performance commitments through structured input from representatives of patient and consumer advocacy groups.

MEETING SUMMARY

On April 27, 2026, FDA convened the first BsUFA IV Public Stakeholder Consultation Meeting, bringing together representatives from patient and consumer advocacy organizations. FDA presented BsUFA program background, reauthorization context, and a summary of previously submitted public stakeholder perspectives. The meeting concluded with an open discussion and polling exercise in which stakeholders prioritized topics for the two remaining monthly consultation meetings.

BsUFA Reauthorization Overview and Program Background

FDA opened the meeting with an overview of the BsUFA IV reauthorization process, walking stakeholders through the statutory requirements governing consultation with patient and consumer advocacy groups, the current negotiation timeline, and the structure and purpose of this monthly meeting series. FDA also provided background on the BsUFA program, covering its history and evolution across three reauthorizations, the current fee structure and revenue breakdown, program workload and performance trends, and an update on CDER and CBER staffing. To facilitate actionable input from the consultation meetings, FDA clarified that modifications to the BsUFA III commitment letter and amendments to the BsUFA user fee statutory sections are in scope; however, amendments to other sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act), such as section 505, are out of scope of BsUFA IV negotiations.

BsUFA IV Public Stakeholder Perspectives Summary

FDA summarized the public comments received during the December 3, 2025 public meeting and docket (Docket No. FDA-2015-N-3326), which included input from industry respondents, trade organizations, and private citizens. Public comments clustered around three broad themes: review process efficiency, transparency and guidance, and inspections and manufacturing. FDA noted that this summary would help prioritize topics for the remaining two consultation meetings.

Identifying Priority Meeting Series Topics (Open Discussion and Poll)

FDA presented a list of potential topics for the expected remaining two monthly consultation meetings and invited stakeholders to rank them via a polling exercise. Topics included hiring, interchangeability, resource capacity planning, financial transparency, meeting management, regulatory science, supplements, chemistry, manufacturing, controls (CMC), use-related risk analysis (URRA), human factors, and 351(k) review processes. Following the poll, FDA facilitated a discussion in which stakeholders highlighted several areas of interest. On interchangeability, stakeholders stressed the need for patient education and greater transparency around interchangeability determinations. On resource capacity planning and hiring, stakeholders questioned whether FDA has sufficient staff to meet growing biosimilar demand and asked for more transparency around workload prioritization decisions. On regulatory science, stakeholders sought clearer standards for batch-to-batch variability. On CMC and inspections, stakeholders underscored the importance of post-market surveillance alongside pre-approval inspections. More broadly, stakeholders expressed a strong desire to understand how their organizations can actively support FDA in bringing safe and effective biosimilars to market. FDA committed to helping direct that desire toward areas within the scope of BsUFA.

Next Steps

The next Public Consultation Meeting is scheduled for May 29, 2026, and will focus on the highest-priority topics identified through today's poll and discussion. All meeting minutes and negotiation updates will continue to be posted publicly on FDA's website.

PARTICIPANTS

STAKEHOLDERS

Chad Worz	American Society of Consultant Pharmacists
Hayley Dempsey	Arthritis Foundation
Janet Krommes	Doctors for America
Justin Leventhal	The American Consumer Institute
Kim Czubaruk	Cancer Care
Kim McClellan	Recurrent Respiratory Papillomatosis Foundation
Mike Hess	COPD Foundation
Mike Jones	n/a
Nicole Boschi	National MS Society
Nissa Shaffi	Allergy & Asthma Network
Noah Austin	U.S. PIRG
Patricia Kelmar	U.S. PIRG
Shion Chang	National Health Council
Tania Calle	Healthy Women

FDA

Andrew Kish	CDER
Danielle Villata	CDER
Emanuela Lacana	CDER
Joel Welch	CDER
Joshua Ostrer	OCC
Kimberly Taylor	CDER
Kristopher Hoover	CDER
Marianne Terrot	OCC
Mustafa Unlu	CDER
Nina Brahme	CDER
Sara Abdollahi	CDER
Sarah Ikenberry	CDER
Sarah Yim	CDER
Sonday Kelly	CBER
Stacey Ricci	CDER
Thamar Bailey	CDER