Biosimilar User Fee Act (BsUFA) Reauthorization

Stakeholder Meeting with FDA

May 29, 2026 | 10:00 am - 12:00 pm

Virtual Format

MEETING PURPOSE

This meeting was the second 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 provide stakeholders an overview on selected BsUFA IV performance commitments and gather structured input from patient and consumer advocacy group representatives.

MEETING SUMMARY

On May 29, 2026, FDA convened the second BsUFA IV Public Stakeholder Consultation Meeting, bringing together representatives from patient and consumer advocacy organizations. FDA presented on biosimilar and interchangeable products, the regulatory science pilot program, and finance and staffing. The meeting concluded with an opportunity for stakeholders to ask questions about BsUFA processes, negotiation meeting minutes, and topics presented.

Biosimilar and Interchangeable Products

FDA provided an overview of biosimilar and interchangeable terminology and FDA's evolving scientific expectations for biosimilars. FDA emphasized its growing confidence in comparative analytical assessments, particularly well-designed in vitro assays, that have enabled a shift away from the expectation of certain clinical studies while maintaining approval standards. FDA noted that its review of BsUFA products remains comprehensive, encompassing manufacturing and controls, comparative analytical data, clinical pharmacology, human factors, device performance, and labeling, all conducted in parallel by interdisciplinary review teams. FDA stated that review process and timeline improvements to support first cycle approval are under discussion in BsUFA IV negotiations, including aligning the interchangeability supplement review timeline with updated scientific expectations, streamlining obtaining feedback on product development, and taking a more proactive approach to identifying and resolving facility-related issues before they become stumbling blocks for applicants.

In addition, FDA shared its portfolio of biosimilar education resources for health care providers and patients that are available through FDA's public website as well as courses through Medscape. FDA encouraged participants to help disseminate these resources through their networks. FDA

said the Agency is developing a new stakeholder toolkit to increase biosimilar awareness and support informed decision-making among patients and healthcare providers. FDA said the targeted resources will equip providers with tools and communication strategies to navigate biosimilar switches and substitution conversations, while empowering patients to make informed choices in collaboration with their care teams, ultimately driving greater biosimilar adoption. Finally, FDA presented on the Purple Book, highlighting its role as a key resource for information on FDA-licensed biological products, including biosimilar and interchangeable designations.

Regulatory Science Pilot Program

FDA provided an overview of the BsUFA III Regulatory Science Pilot Program, which was established to address gaps in knowledge and promote science-based biosimilar development. FDA stated that the program focuses on two areas: improving the efficiency of biosimilar product development and advancing the development of interchangeable products. FDA said that the pilot objectives have been accomplished and that from the Agency's perspective, it is appropriate to end the regulatory science pilot program. FDA noted that internal laboratories, review staff and external funding mechanisms remain available to address specific biosimilar research questions should they arise in the future. FDA indicated that discussions with industry are still ongoing and that no final decision has been reached.

Finance and Staffing

FDA presented on the landscape of finances and staffing for the BsUFA program. FDA displayed data indicating that the program is financially heathy, growing, and secure. FDA noted that user fee amounts have been trending downward, reducing the financial commitment for sponsors and encouraging continued biosimilar development. FDA acknowledged that CDER and CBER have experienced significant workforce losses. The impact on the BsUFA program, however, is relatively limited.

A stakeholder asked questions focused on the accuracy and methodology of FDA's forecasting models, the short-term outlook for submission volumes, and how workforce losses were calculated relative to the BsUFA program specifically. FDA clarified that the best-performing model from among multiple forecasting approaches is used for projections, that submission volumes are expected to continue increasing in the near term, and that the full-time employee (FTE) loss data reflect BsUFA-funded proportions of broader organizational losses rather than specific positions within the biosimilar program.

Next Steps

The next Public Consultation Meeting is scheduled for June 29, 2026, and will include a status update on ongoing negotiations and details on next steps in the reauthorization process. All meeting minutes and negotiation updates will continue to be posted publicly on FDA's website.

PARTICIPANTS

STAKEHOLDERS

Bryant Robinson	National MS Society
Chad Worz	American Society of Consultant Pharmacists
Hayley Dempsey	Arthritis Foundation
Janet Krommes	Doctors for America
Justin Leventhal	The American Consumer Institute
Mike Hess	COPD Foundation
Mike Jones	n/a
Noah Austin	U.S. PIRG
Samantha Seers	National Consumers League
Shion Chang	National Health Council

FDA

Andrew Kish	CDER
Danielle Villata	CDER
Emanuela Lacana	CDER
Emily Ewing	CDER
Joel Welch	CDER
Jonathan Collins	CDER
Joshua Barton	CDER
Joshua Ostrer	OCC
Kimberly Taylor	CDER
Kristopher Hoover	CDER
Marianne Terrot	OCC
Mustafa Unlu	CDER
Nikolay Nikolov	CDER
Nina Brahme	CDER
Paul Phillips	CDER
Sarah Ikenberry	CDER
Thamar Bailey	CDER