Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

June 16, 2026 | 9:30 am–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss draft commitment letter language for facility inspections, data fidelity, Modernizing Biologics License Application (BLA) Review, the third-party assessment, and supplements and review sections of the BsUFA III commitment letter.

PARTICIPANTS

FDA		INDUSTRY	
Sonday Kelly	CBER	Giuseppe Randazzo	AAM
Andrew Kish	CDER	Jessica Greenbaum	AAM (Sandoz)
Derek Smith	CDER	Cory Wohlbach	AAM (Teva Pharmaceuticals)
Don Henry	CDER	Derek Scholes	BIO
Emanuela Lacana	CDER	Lina AlJuburi	BIO (Sanofi)
Irene Chan	CDER	Hillel Cohen	Biosimilars Forum
Joel Welch	CDER	Juliana Reed	Biosimilars Forum
Kimberly Taylor	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
Kristopher Hoover	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Larry Lee	CDER	Kristy Lupejkis	PhRMA
Laurel Goldberg	CDER	Ryan Kaat	PhRMA
Mahesh Ramanadham	CDER	Sean Hilscher	PhRMA
Mustafa Unlu	CDER	Leah Christl	PhRMA (Amgen)
Nina Brahme	CDER		
Paul Phillips	CDER		
Sarah Ikenberry	CDER		
Sarah Yim	CDER		
Thamar Bailey	CDER		
Joshua Ostrer	OCC		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA and Industry aligned on draft commitment letter language regarding facility inspections and BLA transfers. FDA and Industry also aligned on modifying sections of the BsUFA IV commitment letter and FDA agreed to discontinue discussion of their data fidelity proposal. FDA presented draft commitment letter language regarding reassigning missed goal dates and revised language on the third-party assessment. Industry followed up on the supplements commitment letter language.

Approach to Draft Facility Inspections Commitment Letter Language

During the June 9th meeting, FDA presented draft facility inspection commitment letter language and Industry raised several clarifying questions regarding the implementation of FDA's facility inspections proposal.

During the June 16th meeting, FDA presented revised language to ensure consistency with a similar proposal FDA proposed and committed to during Prescription Drug User Fee Act negotiations. Industry then asked implementation related questions, including regarding the proposed post-action meetings and if they were intended to adhere to the existing Biosimilar Biological Product Development Type 1 meeting framework, as suggested in the draft language. FDA reaffirmed that the Post-PLI Meeting is not appropriate for all observations, and Industry encouraged FDA to take a flexible and transparent approach during implementation.

Following a caucus, FDA acknowledged that the post-action meeting was not intended to operate as a Type 1 meeting and presented revised commitment letter language that would establish a new Chemistry, Manufacturing, and Controls (CMC) facility specific meeting type for post-action meetings to ensure clarity about how these meetings would function. FDA said the new meeting type would not have a performance goal and noted that additional implementation considerations would be captured in guidance.

Industry said they are aligned on the draft commitment letter language.

FDA Data Fidelity Proposal Follow Up

During the May 12th meeting, Industry and FDA agreed to temporarily pause discussion on the data fidelity proposal while the group continues to negotiate FDA's inspections-related proposal.

During the June 16th meeting, FDA and Industry agreed to discontinue discussion on this proposal.

Approach to Draft Modernizing BLA Review Commitment Letter Language

During the June 11th meeting, FDA responded to Industry's Modernizing BLA Review subproposal regarding BLA transfer requests, noting that the Agency would need a minimum of 180 days to

complete license revocation and reissuance after receiving a request to transfer a 351(k) BLA. During the June 16th meeting, Industry agreed to FDA's proposed 180-day timeline and FDA agreed to draft commitment letter language.

During the June 9th meeting, Industry presented a Modernizing BLA Review reassigning missed goal dates counterproposal, which would commit the Agency to increased communication with sponsors in the event a goal date is missed. During the June 16th meeting, FDA presented draft commitment letter language based on Industry's counterproposal. Industry asked clarifying questions and said they would provide feedback on the proposed language in a future meeting.

Approach to BsUFA IV Draft Commitment Letter

During the June 11th meeting, FDA proposed removing the "Promoting Best Practices in Communication Between FDA and Sponsors During Application Review," "Advancing Development of Interchangeable Biosimilar Biological Products," and "Information Technology Goal" sections of the BsUFA III commitment letter in BsUFA IV as neither FDA nor Industry had proposals in these areas, and they are no longer relevant. FDA also proposed modifying the "Improving FDA Hiring and Retention of Review Staff" commitment letter section to acknowledge FDA's commitment to share updates on restaffing efforts.

During the June 16th meeting, Industry said they were aligned with FDA's proposed language modifications.

Approach to Draft Third-Party Assessment Commitment Letter Language

During the June 9th meeting, FDA presented draft third-party assessment language. During the June 16th meeting, FDA presented revised language and Industry asked clarifying questions.

Following a caucus, FDA and Industry discussed additional revisions to the language, noting aspects of BsUFA IV commitments that could be reported as part of the assessment versus via other reporting mechanisms. FDA agreed to provide a cost estimate for the evaluation and follow-up on BsUFA IV commitment reporting in a future meeting.

Approach to Supplements Draft Commitment Letter Language

During the June 11th meeting, FDA responded to Industry's proposed revisions to the draft supplements commitment letter language and Industry agreed to provide feedback at a future meeting.

During the June 16th meeting, Industry asked clarifying questions and said they would propose revised language during the following meeting.

Next Steps

The goal for the next meeting on June 18th is to discuss draft commitment letter language on supplements, Modernizing BLA Review, meeting management, the third-party assessment, imminent action, combination products, and provisional determinations and BsUFA IV reporting-related commitments.