Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

June 18, 2026 | 9:30 am–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss draft commitment letter language on supplements, Modernizing Biologics License Application (BLA) Review, meeting management, the third-party assessment, imminent action (IA), combination products, and provisional determinations and BsUFA IV reporting-related commitments.

PARTICIPANTS

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

MEETING SUMMARY

FDA and Industry aligned on draft commitment letter language regarding supplements, BLA transfer requests, and the third-party assessment. FDA and Industry tentatively agreed to the draft commitment letter language on reassigning missed goal dates, IA, and combination products. FDA and Industry discussed the Agency's proposed reporting commitments for BsUFA IV. FDA responded to Industry's proposed revisions to the draft meetings management commitment letter language. FDA proposed draft commitment letter language on provisional determinations.

Approach to Supplements Draft Commitment Letter Language

FDA proposed a minor revision to the draft commitment letter language on supplements. Industry said they accept FDA's edit and are aligned on the draft commitment letter language.

Approach to Modernizing BLA Review Draft Commitment Letter Language

FDA presented draft commitment letter language on Industry's Modernizing BLA Review subproposal regarding BLA transfer requests. Industry proposed a minor revision to FDA's proposed language. After further discussion, FDA and Industry said they were aligned on the draft commitment letter language on BLA transfer requests.

Industry presented revisions to the draft commitment letter language regarding their Modernizing BLA Review reassigning missed goal dates subproposal and FDA proposed additional revisions. After further discussion, Industry and FDA tentatively agreed on proposed revisions. Industry said they would confirm their perspective on the proposed revisions at a future meeting.

Approach to Meeting Management Draft Commitment Letter Language

Industry proposed revisions to the draft commitment letter language on meeting management, which included several clarifying edits to distinguish Biosimilar Initial Advisory (BIA) meeting expectations from Biosimilar Biological Product Development (BPD) Type 2b meeting expectations. Industry and FDA also discussed other elements of the meetings proposals, including regarding the follow-up opportunity.

Following a caucus, FDA proposed eliminating the BIA meeting category to facilitate clarity. FDA reiterated their previous point shared during the April 14th meeting, that sponsors often provide detailed information about their entire proposed development program, which exceeds the BIA meeting scope of providing "general advice." FDA noted that, should the BIA meeting category be removed, sponsors' first interaction with the Agency would occur within the Type 2b meeting framework, which offers Industry more detailed advice. FDA clarified that all Type 2b meetings would have a 90-day timeline (in contrast to the existing 75-day timeline for BIA meetings). FDA

also noted that Industry and the Agency are in alignment on removing the BPD fee, which the Agency believes was a motivator for Industry to request a BIA meeting rather than a BPD Type 2b meeting.

Industry agreed to consider FDA's proposal to remove the BIA meeting and provide feedback at a future meeting.

Approach to Third-Party Assessment Draft Commitment Letter Language

FDA presented a cost estimate for the third-party assessment and proposed a revision to the scope of the assessment described in the draft commitment letter language to account for supplements subject to the new imminent action process. After further discussion, FDA and Industry said they were aligned on the draft commitment letter language for the third-party assessment.

Approach to Imminent Action (IA) Draft Commitment Letter Language

Industry presented revisions to FDA's draft commitment letter language on IA and FDA proposed additional revisions. After further discussion, Industry tentatively agreed to FDA's proposed revisions and agreed to follow up on this proposal during a future meeting.

Approach to Combination Products Draft Commitment Letter Language

FDA responded to Industry's proposed revisions to the draft commitment letter language on combination products. FDA proposed further revisions to the draft language. After further discussion, Industry tentatively agreed to the draft commitment letter language and agreed to follow up on this proposal during a future meeting.

Approach to Provisional Determinations (PD) Draft Commitment Letter Language

FDA presented draft PD commitment letter language. Industry agreed to review the draft commitment letter language and provide feedback at a future meeting.

Approach to BsUFA IV Reporting Commitments

FDA presented an approach to reporting commitments for major amendments, IA, new target action dates, PD, and BLA transfer requests. Industry asked clarifying questions about FDA's proposed reporting commitments and proposed a more detailed commitment on reporting for major amendments.

After further discussion, FDA presented a counterproposal to move more detailed metrics on major amendments to the third-party assessment. FDA also proposed slightly expanding the

scope of their proposed major amendment reporting commitment. Industry agreed to respond to FDA's counterproposal in a future meeting.

Next Steps

The goals for the next meeting on June 23rd will be to discuss the BsUFA IV reporting commitments and the draft commitment letter language on reassigning missed goal dates, IA, combination products, meeting management, provisional determinations, and the structure of the BsUFA IV commitment letter.