Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

June 23, 2026 | 9:30 am–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss the BsUFA IV reporting commitments and the draft commitment letter language on reassigning missed goal dates, imminent action (IA), combination products, meeting management, provisional determinations (PDs), and the structure of the BsUFA IV commitment letter.

PARTICIPANTS

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

MEETING SUMMARY

FDA and Industry aligned on draft commitment letter language regarding IA, combination products, BLA transfer requests, reassigning missed goal dates, and the third-party assessment. FDA and Industry also aligned on an approach to reporting on BsUFA IV commitments and a structure for the BsUFA IV commitment letter. Industry provided feedback on FDA's proposed PDs commitment letter language and FDA's proposed revisions to the draft meeting management commitment letter language.

Approach to Imminent Action (IA) Draft Commitment Letter Language

During the June 18th meeting, Industry tentatively agreed to draft commitment letter language on IA. During the June 23rd meeting, Industry confirmed their alignment on the draft language.

Approach to Combination Products Draft Commitment Letter Language

During the June 18th meeting, Industry tentatively agreed to draft commitment letter language on combination products. During the June 23rd meeting, Industry confirmed their alignment on the draft language.

Approach to Modernizing BLA Review Draft Commitment Letter Language

During the June 18th meeting, Industry tentatively agreed to draft commitment letter language on Industry's Modernizing BLA Review subproposal regarding BLA transfer requests and reassigning missed goal dates.

During the June 23rd meeting, Industry proposed a minor revision to the BLA transfer requests language, which FDA accepted. Industry then confirmed their alignment on the draft language regarding BLA transfer requests and reassigning missed goal dates.

Approach to Third-Party Assessment Draft Commitment Letter Language

During the June 18th meeting, FDA and Industry aligned on draft commitment letter language on the third-party assessment. During the June 23rd meeting, Industry proposed a minor revision to the draft language, which FDA accepted.

Approach to BsUFA IV Reporting Commitments

During the June 18th meeting, FDA proposed slightly expanding the scope of their proposed major amendment reporting commitment.

During the June 23rd meeting, Industry shared their alignment with FDA's reporting proposal and FDA agreed to incorporate reporting language into the BsUFA IV commitment letter.

Approach to Provisional Determinations (PDs) Draft Commitment Letter Language

Industry presented revisions to FDA's proposed draft PD commitment letter language and FDA proposed additional revisions. Industry inquired about PD reporting metrics, noting that there are no performance goals associated with PD amendments. Industry said additional PD metrics, including data on PD amendment timelines, would be helpful to understand whether the process is working as intended.

Following a caucus, FDA proposed including the PDs in the third-party assessment in lieu of reporting on PDs on a routine basis.

After further discussion, Industry agreed to include PDs in the third-party assessment and said they were aligned with draft commitment letter language incorporating PDs in the third-party assessment.

Approach to Meeting Management Draft Commitment Letter Language

During the June 18th meeting, 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. In turn, FDA proposed eliminating the BIA meeting category to facilitate clarity. FDA noted that, should the BIA meeting category be removed, sponsors' first interaction with the Agency would occur within the Type 2b meeting framework.

During the June 23rd meeting, Industry shared their alignment with eliminating the BIA meeting but noted that BIA meetings are scheduled 15 days earlier than a BPD Type 2b meeting, representing time lost for sponsors. Industry then inquired whether FDA would consider incorporating language into the commitment letter to state that the FDA will send preliminary responses for Type 2a and Type 4 meetings to Industry 5 days ahead of the meeting. Industry said, in their experience, the Agency typically sends preliminary responses two days ahead of meetings, which can be challenging for global companies in different time zones. Industry also requested additional clarity on the scope and timing of the follow-up opportunity, noting that in certain instances a follow-up meeting is more efficient than scheduling an additional meeting.

Following a caucus, FDA noted that Industry's concern regarding the timing of preliminary responses has not been previously raised and, in FDA's view, would constitute a new proposal. FDA also said that the Agency is not aware of any issues regarding the timing of preliminary responses for Type 2a and Type 4 meetings. FDA said they would need time to research the relevant data and therefore does not agree with modifying the preliminary response timeline language in the commitment letter. Regarding the follow-up opportunity, FDA noted that the Agency already agreed to expand the use of the follow-up opportunity to include instances when a response is provided after meeting minutes or a written response has been issued, and that

further expanding the follow-up opportunity beyond clarifying questions would not be consistent with PDUFA nor feasible for review staff.

Industry acknowledged FDA's feedback and reiterated their alignment on eliminating the BIA meeting. FDA said they would provide revised commitment letter language in a future meeting.

Approach to BsUFA IV Draft Commitment Letter

FDA proposed a structure for organizing sections of the BsUFA IV commitment letter. Industry shared tentative agreement with the proposed structure.

Following the meeting, Industry shared their alignment on the proposed structure via email.

Next Steps

The goals for the next meeting on June 25th will be to discuss draft commitment letter language on provisional determinations and meeting management, the BsUFA IV draft commitment letter, and the finance commitment letter and statutory language.