Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

June 30, 2026 | 9:30 am–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss draft commitment letter language on provisional determinations (PDs) and finance, review the BsUFA IV draft commitment letter, and discuss the finance statute.

PARTICIPANTS

FDA		INDUSTRY	
Sonday Kelly	CBER	Giuseppe Randazzo	AAM
Andrew Kish	CDER	Scott Kuzner	AAM
Emanuela Lacana	CDER	Jessica Greenbaum	AAM (Sandoz)
Joel Welch	CDER	Cory Wohlbach	AAM (Teva Pharmaceuticals)
Joshua Barton	CDER	Steve Berman	BIO
Kimberly Taylor	CDER	Lina AlJuburi	BIO (Sanofi)
Kristopher Hoover	CDER	Hillel Cohen	Biosimilars Forum
Larry Lee	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		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA and Industry aligned on PD commitment letter language, finance commitment letter language, and finance statutory language. FDA and Industry discussed additional modifications to the BsUFA IV commitment letter.

Approach to Provisional Determinations (PDs) Draft Commitment Letter Language

During the June 25th meeting, FDA and Industry aligned on most of the draft PD commitment letter language. Following the meeting, FDA proposed additional revisions to the draft language to increase clarity.

During the June 30th meeting, Industry accepted FDA's proposed revisions and said they are in alignment with the draft language.

Approach to BsUFA IV Draft Commitment Letter

FDA proposed several modifications to the "Program for Enhanced Review Transparency and Communication for Original 351(K) BLAs" and "Special Protocol Question Assessment and Agreement" sections of the BsUFA IV commitment letter to, in FDA's view, modernize the language to reflect current practice and expectations.

Following a caucus, Industry tentatively agreed to FDA's proposed language modifications and proposed additional revisions to the BsUFA IV commitment letter, including specifying that supplemental applications should be reported separately from other 351(k) applications for BsUFA IV commitments related to imminent action, missed goal dates, and major amendments. In addition, Industry proposed including language in the "Advancing Chemistry, Manufacturing, and Controls (CMC) Facility Assessment: A Risk-Based Lifecycle Approach" commitment letter section to commit the Agency to continue supporting the use of alternative tools to assess manufacturing facilities. Regarding meeting management, Industry requested clarification on whether the BsUFA III commitment to provide additional detail on the follow-up opportunity criteria has been fulfilled and, if not, whether the commitment should be carried over into the BsUFA IV commitment letter.

FDA accepted Industry's proposed revisions regarding reporting and alternative tools. Regarding the follow-up opportunity, FDA said that follow-up opportunities are available only for questions of a clarifying nature; however, questions raising new issues or new proposals would require a new meeting request, as stated in the draft BsUFA IV letter. FDA said it would not be feasible to document every scenario that would meet the criteria for a follow-up opportunity. FDA said the language detailing the follow-up opportunity criteria in the BsUFA IV commitment letter is in alignment with the language negotiated as part of the Prescription Drug User Fee Act (PDUFA) VIII agreement.

Industry reiterated their concerns regarding the level of detail provided for the follow-up opportunity criteria; however, they agreed to keep the draft BsUFA IV commitment letter language as is.

Approach to Finance Draft Commitment Letter and Statute

Industry proposed minor revisions to the FDA proposed finance commitment letter language. FDA accepted the proposed revisions and shared their alignment with the commitment letter language.

Regarding the finance statute, FDA responded to questions Industry shared prior to the meeting. Industry then raised concerns about the clarity of the statutory language detailing instances when a full fee would be assessed rather than a half fee. After further discussion, FDA proposed revised language, and Industry confirmed alignment with the proposed revisions.

Next Steps

FDA and Industry will finalize changes to the draft BsUFA IV commitment letter and finance statute.