Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 27, 2026 | 9:30 am – 11:30 am

Virtual Format

MEETING PURPOSE

To discuss draft supplements and Pediatric Research Equity Act (PREA) commitment letter language and FDA's imminent action proposal, updated counterproposal to Industry's Modernizing BLA Review subproposal, and provisional determinations proposal.

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	Derek Scholes	BIO
Kimberly Taylor	CDER	Lina AlJuburi	BIO (Sanofi)
Kristopher Hoover	CDER	Bee Reed	Biosimilars Forum
Larry Lee	CDER	Hillel Cohen	Biosimilars Forum
Mustafa Unlu	CDER	Juliana Reed	Biosimilars Forum
Nikolay Nikolov	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
Nina Brahme	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Paul Phillips	CDER	Kristy Lupejkis	PhRMA
Sarah Ikenberry	CDER	Ryan Kaat	PhRMA
Sarah Yim	CDER	Sean Hilscher	PhRMA
Stacey Ricci	CDER	Leah Christl	PhRMA (Amgen)
Thamar Bailey	CDER		
Joshua Ostrer	OCC		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA and Industry aligned on draft PREA commitment letter language. FDA then responded to Industry's feedback on the Agency's proposed draft supplements commitment letter language and provided feedback on Industry's imminent action counterproposal. Next, FDA presented an updated counterproposal to Industry's modernizing BLA review proposal regarding transparency of approved 351(k) BLAs. FDA then briefly followed up on the Agency's provisional determinations proposal and presented the status of ongoing negotiations.

Approach to Draft Pediatric Research Equity Act (PREA) Commitment Letter Language

During the May 21st meeting, Industry presented revised language, noting that their revisions were minor and intended to establish consistency across the commitment letter. During the May 27th meeting, FDA said they accept Industry's edits and are aligned on the draft commitment letter language.

Approach to Draft Supplements Commitment Letter Language

During the May 19th meeting, FDA presented draft supplement commitment letter language and Industry asked the Agency to consider including language from the BsUFA III commitment letter in the Category 1 supplement description to ensure submissions seeking licensure for an additional indication that do not include new data sets other than analytical in vitro data can still receive a 4-month clock. During the meeting, FDA also said they would consider modifying the draft language to clarify specific terms.

During the May 27th meeting, FDA said the Agency has never encountered a situation where in vitro data was needed to add an indication, noting that the language appears to pertain to a hypothetical situation. FDA said if there were to be an instance where additional data were needed to support an indication, the submission would likely fit the criteria for a Category 2 supplement, which will have a 6-month review performance goal. In response to the terminology clarification, FDA said the Agency does not believe additional clarification to the commitment letter is required. Industry asked additional questions regarding Category 2, seeking clarification on which changes fall within Category 2 versus those that would be categorized as a CMC supplement.

Following a caucus, Industry said they agree with not including the in vitro data language in the commitment letter and said they would provide a response on the Category 2 supplement language in a future meeting.

FDA Feedback on Industry Imminent Action (IA) Counterproposal

FDA requested clarity on several aspects of Industry's IA counterproposal, which was presented on May 21st. In response, Industry confirmed that IA authority could apply to resubmissions as

well as original 351(k) applications and supplements, though the "small issues" criterion would not apply to supplements. Industry also provided an example to illustrate what may qualify as "additional information," beyond labeling, provided to FDA in the context of a late-cycle reference product labeling change, citing updated extrapolation information. Industry clarified that the proposed language for the REMS-related IA provision was not intended to restrict using the major amendment pathway (e.g., for amendments that include a REMS with elements to assure safe use).

Regarding Industry's inquiry about how the Agency would apply IA in situations where approval as a biosimilar would be possible by the goal date even though approval as an interchangeable would not be possible on the goal date due to blocking first interchangeable exclusivity (FIE), FDA confirmed that if FIE expired within 60 days of the goal date, they would administratively split the application, and FDA would approve the BLA as biosimilar on the action date and apply IA for the interchangeability aspect of the application. FDA would approve the BLA as interchangeable when blocking FIE expires instead of issuing a provisional determination. FDA also inquired about Industry's proposed quarterly frequency of public reporting on the Agency's IA use, noting that the third-party assessment would evaluate and report on IA utilization. Industry clarified that they considered, among other things, how GDUFA reports on the use of IA.

FDA agreed to begin drafting IA commitment letter language.

FDA Counterproposal to Industry's Modernizing BLA Review – Approved BLAs Transparency Proposal

During the May 21st meeting, FDA presented a counterproposal, noting that FDA cannot commit to redacting and publishing action packages for 351(a) BLAs and supplements. FDA said the Agency can only commit to redacting action packages for 351(k) BLAs as previously shared. FDA also noted that additional resources would be needed and provided a resource estimate. In response, Industry inquired about whether FDA's proposed resource estimate and feasibility considerations would shift if the proposed redaction timelines were extended.

During the May 27th meeting, FDA presented a reduced resource estimate and said, with this reduction, the Agency would be able to publish redacted 351(k) BLA action packages within 120 days of licensure, as opposed to the originally proposed 60-day timeline.

Following a caucus, Industry shared their appreciation for the revised resource estimate but said they would prefer to direct resources toward proposals that would provide greater impact. In turn, FDA and Industry agreed to discontinue discussion on this proposal.

FDA Revised Provisional Determinations (PDs) Proposal

During the May 21st meeting, FDA presented a revised PD proposal to include details about the process for submitting amendments to applications in PD status. During the May 27th meeting,

FDA reaffirmed that the Agency's PD proposal, including the additional amendments process, would require resources.

Industry acknowledged the Agency's resource requirement and inquired more broadly about possible implications of incorporating the term "provisional determination" into the BsUFA IV commitment letter, noting that the Agency has not defined this terminology in other public documents. FDA said the Agency intends to publish guidance or a manual of policies and procedures (MAPP) about PDs.

BsUFA IV Negotiations Progress Check

FDA presented the status of all of the ongoing proposals that were initially presented during the April 7th meeting. FDA and Industry reaffirmed their alignment on the draft PREA commitment letter language and mutual agreement to discontinue discussion on the Modernizing BLA Review subproposal related to approved BLAs transparency.

Next Steps

The goal for the next meeting on June 9th will be to continue discussing combination products, enhancing review efficiency as related to Risk Evaluation and Mitigation Strategies (REMS), facility inspections, meetings management, and the third-party assessment.