Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 21, 2026 | 9:30 am – 11:30 am

Virtual Format

MEETING PURPOSE

To discuss Industry's exclusivity determinations proposal, Industry's imminent action counterproposal, FDA's revised provisional determinations proposal, FDA's response to Industry's modernizing Biologics License Application (BLA) review proposal, and Industry's feedback on FDA's draft Pediatric Research Equity Act (PREA) commitment letter language.

PARTICIPANTS

FDA		INDUSTRY	
Sonday Kelly	CBER	Giuseppe Randazzo	AAM
Andrew Kish	CDER	Scott Kuzner	AAM
Emanuela Lacana	CDER	Jessica Greenbaum	AAM (Sandoz)
Emily Ewing	CDER	Cory Wohlbach	AAM (Teva Pharmaceuticals)
Irene Chan	CDER	Derek Scholes	BIO
Joshua Barton	CDER	Lina AlJuburi	BIO (Sanofi)
Kimberly Taylor	CDER	Bee Reed	Biosimilars Forum
Kristopher Hoover	CDER	Hillel Cohen	Biosimilars Forum
Larry Lee	CDER	Juliana Reed	Biosimilars Forum
Mustafa Unlu	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Nikolay Nikolov	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 agreed to discontinue negotiation of Industry's exclusivity determinations proposal. Industry reviewed their perspectives on guardrails for use of imminent action, and FDA and Industry discussed whether imminent action would be available for supplements, as well as original applications. FDA presented a revised provisional determinations proposal, which Industry agreed to consider. FDA also presented an updated counterproposal to Industry's modernizing BLA review proposal regarding transparency of approved 351(k) BLAs. Finally, Industry shared revisions to the FDA's draft PREA commitment letter language.

Approach to Industry's Exclusivity Determinations Proposal

Industry acknowledged the extensive discussion of Industry's exclusivity determinations proposal at the negotiations meeting on May 19th, during which FDA suggested that the Agency and Industry may be at an impasse regarding this proposal. Industry noted that they agree with FDA's assessment that FDA and Industry are at an impasse and are therefore unable to come to a successful negotiation resolution. FDA and Industry agreed to discontinue discussion of the proposal. Industry thanked FDA for their willingness to consider options, acknowledging the multiple counterproposals each party brought forward over the last six weeks.

FDA Imminent Action (IA) Proposal

Industry presented a counterproposal to FDA's IA proposal, which would allow the Agency to work past the goal date for a Biologics License Application (BLA) or supplement by 60 days if it is reasonably likely to support an approval under specified circumstances. Industry noted that their proposal generally mirrors the guiding principles for invoking IA that FDA shared during the May 14th meeting, including that IA should only be exercised in limited circumstances and is not intended to function as a routine extension mechanism. Industry highlighted that their proposal includes additional clarification on the meaning of "small issues," FDA communication with the applicant about their intent to exercise imminent action, the option for applicants to proactively request that FDA consider using IA, the option for applicants to request the Agency to reconsider invoking IA, and public reporting requirements.

FDA asked clarifying questions about Industry's proposal, including the applicability of the reconsideration process. FDA also inquired about Industry's stated intent to limit the use of IA only to original applications, and not to supplemental applications. Industry inquired about how imminent action would function in cases where the goal date had been extended due to a major amendment. Industry also inquired about how FDA would apply imminent action 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.

After some discussion, Industry proposed that supplements be eligible for imminent action, but that the small issues provision would not apply for supplemental applications. As part of the discussion, Industry agreed to remove the proposed process for sponsors to request that FDA reconsider using imminent action. FDA and Industry discussed that, in cases of a goal date extension due to a major amendment, imminent action would apply to the extended goal date. FDA and Industry also acknowledged that the proposed third-party assessment would include evaluation of the Agency's imminent action utilization.

FDA agreed to consider Industry's proposed approach to imminent action. FDA also agreed to consider how imminent action would apply 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.

FDA's Revised Provisional Determination (PD) Proposal

During the May 5th meeting, FDA proposed that review of amendments submitted while an original 351(k) application is in PD status could be roughly modeled after the Generic Drug User Fee Act (GDUFA) processes for amending abbreviated new drug applications (ANDAs) in a tentative approval status.

During the May 21st meeting, FDA presented an updated proposal for amendments to original 351(k) applications in PD status. FDA proposed that substantive changes to applications in PD status should be submitted as amendments (hereinafter referred to as "PD amendments"), which would adopt the same timelines as if such amendment were a supplement to approved BLAs. In terms of process, FDA proposed that while FDA reviews a PD amendment, the Agency would convert the application's status from PD to pending. FDA could then reissue a PD, grant final approval, or issue a Complete Response Letter (CRL) following Agency review of the PD amendment, as appropriate. FDA noted that the Agency may defer some PD amendments in cases where exclusivity expiry is some time in the future and reviewing the PD amendment at such an early point could result in duplicative work later.

Industry asked clarifying questions and inquired about specific cases. FDA noted that some clarity on specific cases may be more appropriate for guidance than the commitment letter. Industry agreed to consider FDA's revised proposal.

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

During the May 12th meeting, FDA shared resources that would be required to support Industry's proposal for redacted action packages for 351(k) original applications, and Industry requested that FDA consider resources required to redact and publish action packages for 351(a) BLAs and supplements.

During the May 21st meeting, FDA reported that the resources required to redact action packages for 351(a) BLAs and supplements would be significant and that Industry's proposed redaction timelines would need to be extended. FDA shared concerns about the feasibility of hiring and training the staff that would be required and said the Agency can only commit to redacting action packages for 351(k) BLAs as previously shared.

Industry inquired about whether the resource requirement and feasibility considerations would shift if the proposed redaction timelines were extended. FDA agreed to consider this question. Industry indicated they needed to consider whether to maintain this proposal if 351(a) action packages were not included, as availability of these action packages can help facilitate biosimilar development.

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

During the May 19th meeting, FDA presented draft PREA commitment letter. During the May 21st meeting, Industry presented revised language, noting that their revisions were minor and intended to establish consistency across the commitment letter.

FDA indicated tentative alignment and agreed to consider Industry's proposed revisions.

Next Steps

The goal for the next meeting on May 27th will be to continue discussing combination products, enhancing review efficiency as related to Risk Evaluation and Mitigation Strategies (REMS), and supplements. FDA and Industry agreed to add other topics as appropriate.