Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 14, 2026 | 9:30 am – 11:30 am

Virtual Format

MEETING PURPOSE

To discuss draft language for FDA's proposal on regulatory science, FDA's proposal on imminent action, FDA's response to Industry's modernizing Biologics License Application (BLA) review proposal (as related to major amendments), and FDA's response to Industry questions about FDA's meetings proposal.

PARTICIPANTS

FDA		**INDUSTRY**	
First Last	*Center Acronym*	*First Last*	*Trade (Company)*
Katie Rivers	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
Joel Welch	CDER	Lina AlJuburi	BIO (Sanofi)
Josh Barton	CDER	Bee Reed	Biosimilars Forum
Kimberly Taylor	CDER		
Kristopher Hoover	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 Yim	CDER	Ryan Kaat	PhRMA
Stacey Ricci	CDER	Sean Hilscher	PhRMA
Thamar Bailey	CDER	Leah Christl	PhRMA (Amgen)
Joshua Ostrer	OCC		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA and Industry discussed draft commitment letter language for FDA's regulatory science proposal. FDA presented guiding principles for clarifying the scope of FDA's imminent action (IA) proposal. FDA also presented a counterproposal to Industry's proposal regarding major amendments and suggested that major amendments be included in the third-party assessment that FDA proposed on May 7th. Finally, FDA reviewed their responses to clarifying questions from Industry about meetings.

Approach to Draft Regulatory Science Commitment Letter Language

FDA and Industry discussed the draft commitment letter language for regulatory science. FDA indicated a preference for ensuring the language retains flexibility regarding information sharing pertaining to biosimilar research being funded by the agency and associated timelines. Industry reemphasized the importance of transparency and accountability for the use of BsUFA funds for research given the sunsetting of the regulatory science pilot program. FDA agreed to consider revisions that Industry proposed as part of the discussion about the draft language.

FDA Imminent Action (IA) Proposal

During the May 7th meeting, FDA and Industry agreed to propose potential guardrails to support a shared understanding of the scope of the "small issues" provision, which is the fourth component of FDA's imminent action proposal. During the meeting on May 14th, FDA presented proposed guiding principles for use of the small issues provision. FDA proposed that the Agency could invoke imminent action when the Agency believes it is possible to resolve minor outstanding issues that could not have been resolved earlier and when late-stage developments make it difficult to complete review by the goal date. FDA noted that the intent of imminent action is not to backload reviews.

Industry shared that although they are still considering potential guardrails, their thinking is directionally aligned with FDA. Industry agreed to share language for their proposed guardrails and a response to the guiding principles FDA shared at a future meeting.

FDA Counterproposal to Industry's Modernizing BLA Review – Major Amendments Proposal

As part of their Modernizing BLA Review proposal, Industry said that applications have received clock extensions for major amendments that do not fall under the examples of major amendments provided in the BsUFA III commitment letter. Industry proposed that more clarity is needed to enhance transparency and predictability. Industry also proposed a reconsideration process for major amendments.

During the meeting, FDA shared data describing instances of major amendment goal date extensions for 351(k) BLAs. FDA noted that in all cases, applicants were notified which

submission constituted a major amendment. FDA also shared that, from its perspective, all cases were reasonable determinations for major amendments and that in only a few cases the major amendments were not explicitly provided as examples in the BsUFA III commitment letter. FDA acknowledged Industry's interest in more detailed explanations for FDA's determination of submissions that constitute major amendments to enhance transparency; however, FDA said that a reconsideration process would not be an appropriate solution. FDA noted that a reconsideration process could introduce inefficiency by placing further strain on reviewers and would diverge from existing Prescription Drug User Fee Act (PDUFA) processes. FDA also noted that it is challenging to prospectively define criteria or provide an exhaustive list of examples for major amendments that could result in a clock extension. FDA said the Agency was willing to report on 351(k) BLA clock extensions and revisit the commitment letter's examples of major amendments that constitute clock extensions. FDA also proposed to include evaluation of major amendment clock extensions in the third-party assessment that FDA proposed on May 7th.

Industry requested clarity about the timeline and deliverables for the proposed third-party assessment. FDA noted they plan to share more details about the third-party assessment in an upcoming meeting.

FDA Meeting Management Proposal Clarification

FDA presented responses to Industry's clarifying questions about how FDA distinguishes between the Biosimilar Initial Advisory (BIA) and Type 2b meetings, currently and in FDA's proposed revision to the BIA meeting. FDA shared that current guidance states that targeted or extensive advice for specific aspects of a product development program is not appropriate for BIA meetings but does not specify that applicants should request Type 2b meetings instead. FDA also clarified that general advice would still be in scope for BIA meetings if FDA agrees that licensure under the 351(k) pathway is feasible.

Industry indicated they appreciated FDA's responses and noted that the proposal under discussion in the finance subgroup to eliminate the Biosimilar Biological Product Development (BPD) fee has direct implications on this meeting management proposal. Specifically, Industry stated that narrowing the scope of the BIA meeting may result in sponsors paying BPD fees for multiple programs to receive initial FDA feedback on the scope of data expected to support a demonstration of biosimilarity, which is a key part of early feasibility assessment for biosimilar candidate selection for Industry. Industry, therefore, recommended tabling the proposal until alignment is reached on the BPD fee proposal. FDA sought clarity as to whether eliminating the BPD fee would assuage Industry's concerns. Industry responded that it becomes less of an issue, but there are additional considerations, including Industry's position that language should be added to the commitment letter to acknowledge that comparative analytical data are not required to have a BPD Type 2b meeting. In addition, Industry said they would still appreciate clarity on the types of questions appropriate for each meeting type. Industry agreed to

provide additional details on the example meeting topics that they would like clarity on, and FDA agreed to draft language clarifying the scope of BIA and Type 2b meetings.

Next Steps

The goals for the next meeting on May 19th will be to continue discussing FDA's facility lifecycle proposal and Industry's inspections proposal, FDA's supplements proposals, Industry's Pediatric Research Equity Act (PREA) proposal, and FDA's draft language for the third-party assessment.