Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 9, 2026 | 9:30 am -11:30 am

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss FDA's and Industry's respective supplements proposals and Industry's Pediatric Research Equity Act (PREA) proposal.

PARTICIPANTS

FDA		INDUSTRY	
Sonday Kelly	CBER	Alisha Sud	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
Josh Barton	CDER	Lina AlJuburi	BIO (Sanofi)
Kimberly Taylor	CDER	Bee Reed	Biosimilars Forum
Kristopher Hoover	CDER	Juliana Reed	Biosimilars Forum
Larry Lee	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
Mustafa Unlu	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Nikolay Nikolov	CDER	Kristy Lupejkis	PhRMA
Nana Adjeiwaa-Manu	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 proposed a schedule for the presentation of each of FDA and Industry's BsUFA IV proposals. Following the proposal schedule discussion, FDA and Industry presented their proposed

supplements proposals and exchanged clarifying questions. Industry then presented their PREA proposal and FDA asked clarifying questions.

Proposal Schedule

FDA presented a proposed schedule to discuss all of the proposals that were first presented during the April 7th meeting. As part of the proposed schedule, FDA requested to increase the negotiations meeting frequency to improve the likelihood of completing technical negotiations by June 2026. Industry agreed to increase the meeting frequency. FDA and Industry also agreed to establish a subgroup to discuss FDA and Industry's respective financial proposals. Industry shared they would provide a revised proposal schedule ahead of the April 14th meeting.

FDA Supplements Proposal

FDA presented the details of their supplements proposal, asserting that certain categories created under BsUFA III have proven unnecessary or do not reflect the resource requirements for the timeframes needed for review, and some of the supplements FDA receives do not fit into the existing categories. In turn, FDA proposed eliminating the existing BsUFA III supplement categories (i.e., categories A through F) and establishing three new categories (i.e., Types 1, 2, and 3) with review timelines of either 4-, 6- or 10-months that align with the resources required to review the information and data submitted. FDA noted that their proposal addresses the gap in supplement categories and does not include a specified category for supplements including comparative efficacy studies (CES) because the Agency expects CES to rarely be included in supplements. With respect to Category A supplements, FDA shared that under their proposal the category would be eliminated and relevant considerations for supplements formerly under Category A would be captured in future guidance. Overall, FDA said they believe the revised supplement categories will result in shorter review timelines for the majority of supplements. FDA indicated it would provide data at a future meeting. FDA reported that their proposal would not require new resources.

Industry acknowledged that FDA's supplements proposal would result in the review timelines increasing for certain supplements, while other supplement timelines would decrease or remain the same. Industry requested clarity on why some of the categories would increase to 6 months from the current 4-month timeline and to 10 months from their current 4- or 6-month timelines, including why there should be a 10-month review clock when human factor (HF) validation or comparative use human factors (CUHF) studies are included in submissions. Industry also requested clarity on how submissions with efficacy study data would be classified in FDA's three-tiered approach and how supplements currently under Category A would be addressed during the period when the category has been eliminated and the proposed guidance has not been published.

Regarding the proposed increase in certain supplement review timelines, FDA said that supplements that introduce a new strength, dosage form, route of administration, or presentation (SDRP) and/or include HF validation studies or CUHF studies can be very challenging for FDA to review and require additional resources. FDA said that studies under the 351(k) pathway require different scientific approaches compared to the 351(a) pathway. FDA asserted that attempting to compare 351(a) timelines to 351(k) timelines can be inappropriate because they involve different statutory frameworks. Industry stated that HF validation studies are included in both 351(a) and 351(k) BLAs, though inclusion of an HF validation study in a 351(a) BLA would not result in a 10-month clock. FDA also noted that supplements to add new SDRPs have different signatory authority for 351(k) and 351(a) BLAs, which is one of the factors that can contribute to the need for longer timelines for 351(k) BLAs, and that it is not sustainable to maintain short review clocks for certain resource-intensive supplements given the current and expected supplement filing rates. FDA said that at current supplement filing rates, it is taking a tremendous amount of effort for the Agency to meet review timelines for certain resource-intensive supplements. FDA also acknowledged again that, under their proposed structure, some of the supplement review clocks would be reduced by 2 or 4 months.

Regarding efficacy data submissions, FDA said that in the unlikely event an efficacy study was submitted in a supplement, then the Agency would categorize the supplement under the existing non-biosimilar specific supplement categories. With respect to supplements currently under Category A, FDA stated that determinations of what should be submitted as prior approval supplements versus as "changes being effected" supplements are subject to existing regulations and that changes to the commitment letter on this topic are out of scope. FDA noted that they would provide a response about how supplements currently under Category A would be managed following the elimination of the category and prior to guidance publication in a future meeting.

Industry also sought clarity on whether FDA's proposed review timelines are based on the capacity of current staffing levels. FDA confirmed their supplement proposal is based on the Agency's projected capacity when fully staffed.

Industry Supplements Proposal

Industry presented the details of their supplements proposal, noting that Industry and FDA's proposals have a lot of overlap in the problems they aim to address. Industry said that the supplement categories established under BsUFA III have gaps which have resulted in unpredictable and inconsistent supplement classifications and, at times, longer timelines than 351(a) BLA supplement, notwithstanding the fact that 351(k) BLAs are intended to be an abbreviated licensure pathway, and timelines that are not commensurate with the review burden. In turn, Industry proposed classifying certain supplements as CBEs or, for prior approval supplements, a 4-month review clock for all supplements unless CESs are included in the submission. Supplements with CES would receive a 10-month review clock.

FDA said that some of the proposed 4-month timelines for supplements do not align with the workload required for review in the biosimilars program. FDA further noted that the inclusion of CES being the driver of the review length works under the Prescription Drug User Fee Agreement (PDUFA) because clinical studies are the pivotal study to demonstrate efficacy and safety. However, FDA stated that the same logic does not apply for biosimilars because comparative analytics are more central to demonstrating biosimilarity, with clinical studies being at most supportive data for the application, whereas for 351(a) BLAs clinical trial data are central to demonstrating efficacy and safety.

Industry also put forth a CBE-0 and CBE-30 CMC supplements related proposal, noting that currently an applicant will not know whether FDA agrees with their CMC supplement classification at the 30-day mark. Industry said this practice creates risk for timely implementation of changes. In turn, Industry proposed that FDA commit to communicating its agreement or non-agreement with the applicant's CMC supplement classification within 30 days and establish a performance goal for these communications. Industry provided an example of an instance where Industry received an initial supplement classification determination and the determination subsequently changed.

FDA noted that from the Agency's vantage point this proposal aims to address an issue that is rare and not specific to biosimilars.

Industry Pediatric Research Equity Act (PREA) Proposal

Industry presented the details of their PREA proposal, noting that, as reflected in final guidance, FDA has interpreted PREA to mean that applicants for proposed biosimilar products should address PREA requirements based on the nature and extent of pediatric information in the reference product. Industry said that the expectation that biosimilar applicants follow the same format and content in their initial pediatric study plans (iPSPs) as the iPSP for the reference product is not logical for the biosimilar and requires the inclusion of superfluous information. Industry said this results in a burdensome and complex process to prepare an iPSP, which can delay agreement. In turn, Industry proposed FDA commit to opening a public docket for stakeholder input on the development of a streamlined, biosimilar-specific iPSP template. Furthermore, Industry proposed FDA commit to providing agreement or written comments within 90 days of an iPSP submission that uses the streamlined template and commit to a performance goal on these communications. Industry also proposed FDA commit to publishing guidance on pediatric study plans for biosimilar products.

FDA shared that the Center for Drug Evaluation and Research guidance agenda includes a PSP guidance but noted continuing challenges with guidance development and that it is difficult to commit to specific timelines.

Industry said the intent for the proposal was to establish a timeline for the guidance's publication since this guidance has been on FDA's guidance agenda for a while.

Next Steps

The goal for the next meeting on April 14th will be to discuss a revised proposal schedule, Industry and FDA's respective meeting management proposals, and Industry's combination product proposals.