Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 14, 2026 | 9:30 am -1:30 pm

Virtual Format

MEETING PURPOSE

To discuss FDA's and Industry's respective meeting management proposals, and Industry's proposals on combination products and intercenter consultative review.

PARTICIPANTS

FDA		INDUSTRY	
Katie Rivers	CBER	Alisha Sud	AAM
Andrew Kish	CDER	Giuseppe Randazzo	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	Hillel Cohen	Biosimilars Forum
Larry Lee	CDER	Juliana Reed	Biosimilars Forum
Laurel Goldberg	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
Mustafa Unlu	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Nikolay Nikolov	CDER	Kristy Lupejkis	PhRMA
Paul Phillips	CDER	Ryan Kaat	PhRMA
Sarah Ikenberry	CDER	Sean Hilscher	PhRMA
Sarah Yim	CDER	Leah Christl	PhRMA (Amgen)
Stacey Ricci	CDER		
Thamar Bailey	CDER		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA reviewed Industry's feedback on the proposed schedule for the presentation of each of FDA's and Industry's BsUFA IV proposals. Following the proposal schedule discussion, Industry

presented their biologic-device combination products and intercenter consultative review proposals. FDA asked clarifying questions. Then, FDA and Industry presented their respective meeting management proposals and exchanged clarifying questions.

Proposal Schedule

FDA reviewed Industry's feedback on the proposed schedule to discuss all of the proposals that were first presented during the April 7th meeting. FDA and Industry agreed to modify a few aspects of the schedule to maximize the use of time during negotiations meetings.

Industry Biologic Device Combination Products Proposal

Industry presented the details of their biologic-device combination product proposal, noting that FDA's current regulatory framework is unique among health authorities in its approach to interchangeable combination products and as such assessing feasibility and de-risking development programs requires clear guidance and early engagement from FDA. In turn, Industry proposed several process changes to promote early strategic alignment with the FDA, including expanding the Biosimilar Biological Product Development (BPD) meeting scope to include user-interface discussions, allowing sponsors to raise interface/human factor questions prior to submitting related analyses or protocols, and allowing sponsors the ability to request Type 2b meetings concurrently with Use-Related Risk Analyses (URRAs), Comparative Analyses (CAs), or Human Factor (HF) protocols submission. Additionally, the proposals suggest FDA use Information Requests for minor submission deficiencies and extend the BsUFA III follow-up meeting mechanism to include clarifying questions about URRA/CA/HF Protocol feedback.

Industry also proposed technical changes to the commitment letter language, including clarifying that URRA encompasses comparative analyses and that HF Protocols and HF Validation Protocols are subject to existing goal dates regardless of submission type. Industry also proposed extending the FY27 performance goal for URRA and CA reviews to BsUFA IV.

In reference to the early engagement opportunities, FDA requested clarity on the types of questions Industry envisioned could be reasonably answered prior to the submission of URRA/CA/HF protocols. FDA agreed that early alignment and understanding on a combination product approach is mutually beneficial for FDA and Industry. However, the Agency noted differences in approach between a biosimilar product and that of its reference product can raise both scientific and policy questions that can be challenging to advise on without understanding the details of what is being proposed. FDA also noted that under the existing framework, comparative use human factors studies (CUHFS) protocols do not have a user fee goal date.

Industry provided examples of possible questions they might pose during early engagement opportunities, including questions about the conceptual design of a device, whether certain elements should be included in an HF protocol, advice on whether a URRA is necessary, and clarity on whether a HF protocol or CUHF protocol is necessary. As Industry explained , the

current process can require multiple stages of review before FDA can provide advice about a proposed device or HF/CUHF protocol. Industry stated the aim of the proposal is to create early opportunities for strategic alignment with the Agency before making a large investment and commitment to a development program, creating efficiencies for both industry and FDA.

FDA also requested clarity regarding Industry's proposal to submit HF protocols subject to a 60-day goal date to the Biologics License Application (BLA) pathway in addition to the Investigational New Drug (IND) pathway. FDA said that if Industry wants input during development, then information should be submitted during the IND phase. Industry explained that in certain circumstances, an applicant may develop a device after the original BLA is submitted or there may not be an open IND.

Industry Intercenter Consultative Review (ICCR) Process Proposal

During the April 7th meeting, Industry introduced a proposal titled "Enhance Review Efficiency," which comprises several subproposals including a proposal on intercenter consultative review (ICCR). During the April 14th meeting, Industry presented the details of their ICCR proposal, noting that intercenter consults play a significant role in the review of combination products. Industry proposed modifying the commitment letter language to state that all centers and divisions consulted for a program under the BsUFA review program would be subject to the same BsUFA timelines. Industry noted that the current commitment letter does not include specific language around the process for consultative reviews.

FDA requested clarity on the problem that Industry's ICCR process proposal aims to address. Industry said there have been instances when comments from consulted centers have not been shared with Industry in a timely fashion and instances where multiple information requests have been sent to Industry on similar topics. Industry said that it is not always clear if the offices consulted during the review of a combination product are responding in a timely enough fashion to make BsUFA review timelines. Industry noted that this proposal is consistent with the proposal raised during Prescription Drug User Fee Act VIII negotiations. FDA caucused and said they would provide a response in a future meeting.

FDA Meeting Management Proposal

FDA presented the details of their meeting management proposal, asserting that the majority of Biosimilar Initial Advisory (BIA) meeting requests extend beyond the meeting scope. FDA said sponsors often provide detailed information about their entire proposed development program, which exceeds the BIA meeting scope, which is to provide "general advice." In these instances, FDA said they offer Industry the ability to convert their meeting request to a Type 2b meeting, where they will receive more detailed advice. According to the FDA, 32 percent of BIA meeting requests were converted to Type 2b meetings in FY23–25. In turn, FDA proposed clarifying the

commitment letter language to note that BIA meeting requests should be limited to questions regarding whether licensure under the 351(k) pathway may be feasible for the proposed product. FDA also proposed clarifying the Type 2b meeting description to specify that these meetings should be requested for initial engagement with the Agency to discuss the expected content of the proposed development program when feasibility of licensure under the 351(k) pathway is not a concern.

Industry noted that the current expectation for BIA meetings is that preliminary analytical data would not be required to receive more detailed advice and achieve early alignment on general expectations. Industry also requested clarity on how FDA would address instances when sponsors submit meeting requests that don't align with the proposed revised meeting descriptions. In addition, Industry sought clarification on what FDA meant by "feasibility." Industry said a shared understanding is essential, as BIA meetings provide important opportunities to obtain advice prior to investing in a development program.

FDA said Type 2b meetings do not currently require preliminary analytical data and they would consider Industry's proposal to include explicit language in the Commitment Letter. However, FDA stated that some advice does need data so the meeting discussion would be limited by what is included in the meeting package. Regarding instances when sponsors submit meeting requests that don't align with the revised meeting descriptions, FDA said they would follow the existing process for meeting conversions. FDA said the Agency would reach out to the company and offer them the ability to convert their meeting request.

FDA also proposed modifying the current commitment letter to allow Industry to request a written response only (WRO) format for all meeting types. Currently, Industry can only request WRO format for BIA, Type 2a, and Type 2b meeting types. FDA noted that while many sponsors request face-to-face meetings, 35% of face-to-face meetings have been cancelled after sponsors receive preliminary responses from the Agency.

Industry requested clarity that FDA's proposal would only focus on expanding Industry's ability to request WROs opposed to expanding the FDA's ability to convert face-to-face meetings to WROs. FDA confirmed that their proposal only seeks to expand Industry's ability to request the WRO format.

Industry Meeting Management Proposal

Industry presented the details of their meeting management proposal, noting that under BsUFA III, sponsors experience delayed or incomplete communication. Industry said the follow-up opportunity mechanism outlined in BsUFA III is not clearly defined. Industry also said that applicants prepare full briefing packages even to obtain advice on narrow questions. In turn, Industry proposed (1) developing a streamlined WRO meeting package expectation for Type 2a meetings and (2) clarifying and expanding the follow-up meeting opportunity. Industry noted that as part of clarifying and expanding the follow up opportunity, they propose the FDA to

commit to a performance goal on these communications and commit to defining parameters for appropriate use of the follow-up opportunity.

Industry stated that, under the existing framework, Industry has no pathway to follow up on questions FDA has not answered in the normal meeting cycle and, instead, FDA responds to the question in a correspondence outside of the meeting cycle (an "off-cycle" response). Industry noted that the current follow-up opportunity mechanism does not allow for this type of follow-up as it is limited to clarification of WRO or meeting minutes. In turn, Industry also proposed updating the commitment letter to allow sponsors to expand the follow-up opportunity to include FDA communications responding to a meeting question after the minutes or WROs are issued. Industry also proposed adding the option for sponsors to request a Type 1 meeting, using the original briefing package and, as applicable, additional information as determined by the applicant, to enable a dialogue with FDA after receipt of an "off-cycle" response .

FDA acknowledged the need for clarity on the follow-up opportunity mechanism and recognized that PDUFA guidance contains additional detail on the follow-up opportunity compared to BsUFA guidance. The FDA noted that they would be interested in hearing whether additional clarity is needed. FDA also requested clarity on the challenges Industry is experiencing with the existing meeting package criteria and whether Industry's proposal would require the FDA to cross-reference prior meeting packages.

Regarding the Type 2a meeting package, Industry said that, for certain Type 2a WRO requests, many elements of the full meeting package would be unnecessary. Industry noted they would provide more details about how to streamline meeting requests and briefing packages, but that the overall aim for the proposal is to create less burdensome process. Industry clarified that FDA would have access to additional background through previously submitted meeting packages .

FDA requested additional clarity on how certain aspects of Industry's proposal would be implemented. Industry agreed to provide a response at a later date.

Next Steps

The goal for the next meeting on April 16th will be to discuss Industry's IND protocols proposal, FDA's Pediatric Research Equity Act (PREA) counterproposal, and Industry's and FDA's respective supplements proposals.