Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 23, 2026 | 9:00 am - 10:30 am

Virtual Format

MEETING PURPOSE

To discuss FDA's response to Industry's proposals on combination products, Inter-Center Consultative Review (ICCR), and Investigational New Drug (IND) protocols, and discuss Industry's response to FDA's request for additional clarity on Industry's FDA-Sponsor meetings proposal.

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Alisha Sud	AAM
Emanuela Lacana	CDER	Giuseppe Randazzo	AAM
Irene Chan	CDER	Scott Kuzner	AAM
Kimberly Taylor	CDER	Jessica Greenbaum	AAM (Sandoz)
Larry Lee	CDER	Cory Wohlbach	AAM (Teva Pharmaceuticals)
Mustafa Unlu	CDER	Derek Scholes	BIO
Nikolay Nikolov	CDER	Lina AlJuburi	BIO (Sanofi)
Nina Brahme	CDER	Bee Reed	Biosimilars Forum
Sarah Yim	CDER	Hillel Cohen	Biosimilars Forum
Stacey Ricci	CDER	Juliana Reed	Biosimilars Forum
Katie Rivers	CBER	Andrew Zacher	Biosimilars Forum (Amneal)
Thamar Bailey	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Joshua Ostrer	OCC	Sean Hilscher	PhRMA
Marianne Terrot	OCC	Leah Christl	PhRMA (Amgen)
Kristopher Hoover	CDER		
Nana Adjeiwaa-Manu	CDER		

MEETING SUMMARY

FDA presented a counterproposal to Industry's combination products and ICCR proposals. FDA and Industry discussed Industry's IND protocols proposal. Industry presented responses to FDA's clarifying questions regarding Industry's FDA-Sponsor meetings proposal.

FDA Combination Products and Inter-Center Consultative Review (ICCR) Counterproposal

FDA presented a counterproposal to Industry's combination products and ICCR proposals, which has the stated aim to promote early strategic alignment with the Agency. Regarding Industry's ICCR proposal, FDA stated that all Agency centers and divisions consulted for ICCRs are already subject to the same BsUFA timelines.

With respect to the combination products proposal, FDA noted that sponsors can already raise user interface and Human Factors (HF) questions in Biosimilar Biological Product Development (BPD) meetings without first submitting a protocol. However, FDA said such questions must be appropriately scoped so that they can be answered without reviewing a use-related risk analysis (URRA), comparative analyses (CAs), or HF protocols. Regarding Industry's subproposal for the Agency to use an Information Request (IR) instead of a Submission Incomplete letter when the initial submission has minor or correctible deficiencies, FDA stated that if there is limited missing information that the Agency believes can be quickly resolved, the Agency currently issues an IR rather than a Submission Incomplete letter on a case-by-case basis. FDA did not agree to Industry's subproposal for the Agency to revise HF Validation protocols to HF protocols, noting that the proposed revision would mean that the Agency would need to establish new performance goals for comparative use human factor studies (CUHFS).

The Agency indicated it was open to Industry's proposal for sponsors to request a Type 2b meeting to discuss a URRA, CA, or HF validation study protocol submission with specific questions, though FDA noted that CUHFS would not be included. FDA said review timelines would align with the existing 90-day timeframe for Type 2b meetings. FDA said they were willing to continue the current performance goal for URRA reviews to BsUFA IV and revise the commitment letter to clarify that URRA review includes review of comparative analyses, as Industry proposed. With respect to Industry's proposal for HF validation study protocols to be subject to existing goal dates even when submitted to the BLA and not the IND (which industry noted during the April 14th meeting would be to specifically address an administrative barrier and not intended to circumvent best practices for product development or leave evaluation of a protocol by FDA too late in the development cycle), the Agency agreed to clarify in the commitment letter that HF validation study protocols submitted to a Biologics License Application (BLA) will receive the same goal date as those submitted to an Investigational New Drug (IND), provided the protocol is not submitted at the time of submission of an application or supplement or to a pending application or supplement already in review.

Industry asked clarifying questions about the parameters of topics that FDA would consider under a BPD meeting, including under the proposed Type 2b meeting. Industry reiterated their experienced challenges with obtaining advice on user interface- and HF-related questions through the BPD process. FDA stated that the discussion at the Type 2b meeting would likely be more robust if sponsors submitted a URRA, CA or HF validation study protocol with their meeting request so that FDA would be able to appropriately evaluate their questions. Industry sought further clarity from FDA as to their expectations of what specific information would need to be

included in a meeting package to obtain feedback. After further discussion, Industry agreed to prepare examples of questions sponsors might ask during the proposed Type 2b meeting.

Industry stated that their combination product proposal was a high priority and requested that FDA consider the resources that might be needed. FDA agreed to provide a resource estimate at a future meeting.

FDA Investigational New Drug (IND) Protocols Proposal Response

In response to Industry's IND protocols proposal, FDA presented data on Agency response times to IND protocols. Industry asked a clarifying question about the scope of the data, including whether it covered only the initial IND or all IND protocols. FDA agreed to clarify the scope in a future meeting.

FDA asked Industry for more context on two scenarios Industry raised during the April 16th meeting: (1) sponsors seeking feedback on protocols when they do not have an open IND and (2) issues with receiving feedback on protocol amendments. Industry provided an example of comments on a protocol arriving well-after the Agency provided a safe-to-proceed decision, which in turn delayed their drug development process. Additionally, Industry provided examples of instances where FDA's feedback did not align with other global regulatory authorities, resulting in further delays.

FDA and Industry agreed to follow up on this proposal in a future meeting.

Industry Meeting Management Proposal Clarification

Industry presented responses to FDA's questions about Industry's FDA-Sponsor meetings proposal. In response to FDA's request for an example streamlined Type 2A WRO meeting request and briefing package, Industry proposed a meeting request and package that included administrative information and cross-references, along with a background section tailored to the specific questions. With respect to FDA's question on what performance criteria would mean in the follow-up opportunity proposal, Industry suggested having clear criteria for using the follow-up opportunity. In response to when a sponsor can request a Type 1 meeting, Industry proposed that an applicant could request the meeting within 20 days of receiving an "off cycle" response, which refers to an Agency response to a question that could not be addressed during the review cycle. Industry noted that sponsors could reference their previously submitted materials, and, at their discretion, include additional information limited to the question and the "off cycle" response. Industry proposed that FDA would also have the option to provide preliminary responses to the additional information at their discretion.

FDA asked questions about instances when the Type 1 meeting would be appropriate. Industry responded that the intent of proposing use of the Type 1 meeting in this context is for sponsors to

have a follow-up discussion that they otherwise would have been able to have with FDA, had the agency been able to answer the question during the meeting review cycle.

FDA said they would follow up on this proposal in a future meeting.

Next Steps

The goal for the next meeting on April 28th will be to discuss Industry's modernizing BLA review, enhancing review efficiency, and regulatory science proposals, and FDA's regulatory science proposal.