Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 16, 2026 | 9:30 am – 11:30 am

Virtual Format

MEETING PURPOSE

To discuss FDA's response to Industry's supplements proposals, FDA's Pediatric Research Equity Act (PREA) counterproposal, and Industry's Investigational New Drug (IND) Protocols proposal.

PARTICIPANTS

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

MEETING SUMMARY

FDA responded to Industry's supplements proposal and Industry asked clarifying questions. Next, FDA presented a counter to Industry's PREA proposal and Industry asked clarifying questions. Industry then presented their IND Protocols proposal.

Supplements Proposal Discussion

FDA provided a response to Industry's proposal to communicate agreement or non-agreement with applicant's CMC supplement classification within a designated timeframe, noting that CBE-0 and CBE-30 Chemistry, Manufacturing, and Controls (CMC) supplement classification issues appear to be rare events. FDA said that Industry's proposal would introduce a process that would impact other user fee programs. In turn, FDA said they do not support advancing this aspect of Industry's proposal for further negotiation. Industry said they would provide a response in a future meeting.

FDA then presented a comparison of Industry's and FDA's proposed supplement categories and timelines, and shared data on the volume of supplement submissions. FDA noted alignment between the proposed 4-month review clock for Type 1 supplements and some of Industry's proposed 4-month review scenarios. FDA stated that the proposed Type 2 and Type 3 supplements categories require additional discussion. FDA reiterated that their proposal aligns the proposed timelines with the workload associated with the data submitted and discipline involvement, while Industry's proposal appears to be primarily structured on the removal of clinical efficacy data and alignment with 351(a) supplement review timelines. FDA reiterated that their proposal aims to provide clarity and consistency regarding the subsets of supplements that the Agency knows are resource intensive. FDA also reiterated that their proposal would result in the elimination of Category A and that relevant considerations for this supplement category would be captured in guidance.

Industry shared they did not understand why the proposed Type 3 supplement category would require a 10-month review clock and requested clarity on the factors contributing to greater complexity in 351(k) versus 351(a) supplement review. Additionally, Industry asserted that this type of proposed change, and the data submitted to support the supplement is comparable under the Generic Drug User Fee Act (GDUFA) and requires a 6-month review clock. Industry also requested clarity on how the Agency would manage supplements that currently fall under Category A, noting they are concerned there wouldn't be a specified timeline in the absence of updated guidance or an established supplement category.

Regarding the 351(a) comparison, FDA noted that 351(a) sponsors can introduce a new strength, dosage form, route of administration, or presentation (SDRP) without providing comparisons to another company's product. However, for 351(k)s, sponsors must make comparisons to the reference product which increases the burden on the Agency due to the data and types of analyses that need to be reviewed. FDA said the complexity in reviewing biosimilar supplements is in assuring the proposed SDRP meets all of the different aspects of the statute. Regarding the GDUFA comparison, FDA said that the GDUFA and BsUFA programs have different resources and noted that GDUFA resources cannot be used to complete BsUFA work. With respect to the elimination of Category A, FDA said they would provide a response in a future meeting.

Industry requested FDA provide a rationale for the proposed 10-month clock for Type 3 supplements and an estimate for the resources that would be required to decrease the proposed 10-month clock for Type 3 supplements. FDA said they would provide a response in a future meeting.

FDA Counterproposal for Pediatric Research Equity Act (PREA) Proposal

In response to Industry's PREA and iPSP proposal, FDA proposed publishing a streamlined, biosimilar-specific initial pediatric study plan (iPSP) template for public comment. Following the public comment period, the Agency said they would commit to finalizing the template within a designated period. FDA noted that this proposal would be mutually beneficial and reduce administrative burden on Industry and the Agency, and eliminate delays caused by the content of the iPSP. FDA said they would also be willing to make reference to the publication of pediatric study plan guidance for biosimilar products in the commitment letter.

Industry acknowledged that a streamlined template would drive meaningful change but noted that they have had experiences when the Agency did not meet the statutory iPSP review timeline. Industry said they are unsure if the streamlined template will completely address this pain point.

FDA requested Industry to provide data supporting their position on iPSP review delays. Industry said they would provide a response in a future meeting.

Industry Investigational New Drug (IND) Protocols

Industry presented the details of their IND protocols proposal, noting their position that there is no clear or consistent process for sponsors to receive FDA feedback when substantive issues arise outside of the Biosimilar Biological Product Development (BPD) process. Industry said that not having feedback from the Agency on study design elements can result in inefficient study conduct and protocols that are misaligned with global clinical trial applications (CTAs). In turn, Industry proposed the FDA commit to communication timelines during protocol and protocol amendment review, including communications on whether and when FDA expects to provide comments.

FDA requested clarity on the types of protocols this proposal aims to address and whether this proposal aims to address a biosimilar-specific issue. FDA also requested clarity on whether Industry considered Type 2A meetings an appropriate vehicle for submitting revised protocols for review. FDA noted that most of the clinical protocols for biosimilar programs are fairly streamlined and requested data from Industry about how frequently the Agency's feedback results in process changes and revised protocols.

Industry clarified that their proposal encompasses clinical protocols, including pharmacokinetic (PK) studies and comparative efficacy studies (CES). Regarding Type 2A meetings, Industry said the Agency has traditionally not accepted revised protocol submissions under that meeting type.

Industry acknowledged that they raised the same proposal during Prescription Drug User Fee Act VIII negotiations, noting that they believe this proposal also has relevance to the biosimilar program. Regarding the data request, Industry said they would provide a response in a future meeting.

FDA said they would provide a response to this proposal in a future meeting.

Next Steps

The goal for the next meeting on April 21st is to discuss FDA's data fidelity, provisional determinations, and imminent action proposals, and Industry's exclusivity determinations, labeling, and REMS proposals. Industry will also provide a response to FDA's PREA counterproposal.