



# Biosimilar User Fee Act (BsUFA) Reauthorization

## FDA and Industry Negotiation Meeting

April 30, 2026 | 9:30 am – 11:30 am

Virtual Format

### MEETING PURPOSE

To continue discussing FDA’s supplements proposal, Industry’s combination products proposal, and Industry’s and FDA’s respective meetings proposals.

### PARTICIPANTS

#### FDA

<i>First Last</i>	<i>Center Acronym</i>
Sunday Kelly	CBER
Andrew Kish	CDER
Emanuela Lacana	CDER
Emily Ewing	CDER
Irene Chan	CDER
Joel Welch	CDER
Kimberly Taylor	CDER
Kristopher Hoover	CDER
Larry Lee	CDER
Mustafa Unlu	CDER
Nikolay Nikolov	CDER
Nina Brahme	CDER
Paul Phillips	CDER
Sarah Yim	CDER
Stacey Ricci	CDER
Thamar Bailey	CDER
Joshua Ostrer	OCC
Marianne Terrot	OCC

#### INDUSTRY

<i>First Last</i>	<i>Trade (Company)</i>
Alisha Sud	AAM
Giuseppe Randazzo	AAM
Jessica Greenbaum	AAM (Sandoz)
Cory Wohlbach	AAM (Teva Pharmaceuticals)
Lina AlJuburi	BIO (Sanofi)
Bee Reed	Biosimilars Forum
Hillel Cohen	Biosimilars Forum
Juliana Reed	Biosimilars Forum
Andrew Zacher	Biosimilars Forum (Amneal)
Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Kristy Lupejkis	PhRMA
Ryan Kaat	PhRMA
Sean Hilscher	PhRMA
Leah Christl	PhRMA (Amgen)

### MEETING SUMMARY

FDA responded to Industry questions about their supplements proposals and presented a response to Industry’s combination product proposal. Industry indicated tentative agreement

with the substance of FDA's combination products counterproposal. FDA and Industry also discussed follow-up questions regarding their respective meeting management proposals.

### **Follow-Up Discussion on Supplements**

At the negotiation meeting on April 16, Industry requested clarification on how FDA would manage supplements that would have been submitted under Category A under BsUFA III within the Agency's supplement proposal. During the meeting on April 30, FDA reiterated that the Agency plans to issue guidance to clarify the BsUFA supplement categories. FDA shared that until the Agency issues such guidance, supplements that would have fallen under the former Category A would be handled as labeling supplements that do not correspond to a specific BsUFA category and that FDA would follow the corresponding timeline and processes for that supplement.

Industry emphasized their need for predictable categories and timelines and expressed concern that the regulations may not be clear enough to ensure predictability. Industry inquired about whether FDA could commit to a timeline for issuing guidance on supplement categories, if clarification on supplement categories would not be appropriate in the commitment letter. Industry also inquired about how unbranded labeling supplements would be considered under FDA's proposal.

FDA stated that policy interpretation is not appropriate for the commitment letter but noted that FDA strives to provide clarity and predictability. FDA agreed to consider whether the Agency could commit to timelines for publishing guidance. FDA also agreed to consider an appropriate avenue through which to provide clarity on unbranded labeling.

### **Human Factors Considerations for Supplements and Combination Products**

FDA responded to concerns that Industry voiced on April 9<sup>th</sup> about FDA's proposal for longer review timelines for supplements including human factor (HF) studies. FDA noted that the Agency revised their supplements proposal to remove the extended timelines for supplements that include new HF data. FDA also responded to feedback from Industry about review of HF study protocols for combination products. FDA agreed to broaden the scope of Type 2b meetings to include specific questions on any HF study protocol, as opposed to only HF validation study protocols. FDA further agreed to broaden the review goal to include any HF study protocol not submitted under a Type 2b meeting request. FDA also proposed to publish draft guidance on an alternative approach to comparative use human factors studies (CUHFs). FDA shared that these agreements would require additional resources.

Industry noted that they appreciate FDA's consideration of their proposals. Industry inquired about the scope of questions appropriate for meetings about HF studies, whether the proposed guidance would overlap with anticipated BsUFA III guidance, and the rationale for FDA's resource estimate.

FDA indicated that the scope of questions appropriate for meetings depends on multiple factors, including whether FDA will have already reviewed certain data and information. FDA also noted that it would not be practical or beneficial for FDA or industry to meet with sponsors after every formative study as iterating on product design can be a fast-moving process and not every design change made in response to formative studies warrant discussion with FDA. FDA also stated that the proposed guidance would provide new information and therefore is not intended to overlap with other BsUFA guidance. With respect to FDA's resource request, FDA stated that the Agency estimated resources based on workload, the reduction in timeline for review, and the type of staff needed for the work.

Industry indicated that they agree with the concepts FDA presented but cannot yet agree to any resource requests. FDA indicated that agreement was contingent on resources. FDA agreed to begin drafting commitment letter language.

### **FDA Meeting Management Counterproposal**

FDA responded to Industry's proposal to improve FDA-Sponsor meetings, presented on April 14<sup>th</sup>. First, FDA acknowledged Industry's interest in streamlining background packages for Type 2a meetings and noted that existing guidance provides sponsors with the flexibility to submit a streamlined background package. FDA suggested that the Agency can clarify this process via revised guidance. Second, FDA acknowledged Industry's concern that the criteria for follow-up opportunities following a formal meeting are unclear. FDA proposed to include the additional follow-up processes that are specified in the PDUFA formal meetings guidance in the BsUFA formal meetings guidance. Third, FDA acknowledged that the current process for requesting clarification using the follow-up opportunity does not apply if sponsors seek clarification about FDA feedback when it is provided outside of the normal review cycle ("off-cycle" response). FDA proposed expanding the follow-up opportunity process to include these cases. Fourth, Industry requested Type 1 meetings as an additional follow-up opportunity after receiving an off-cycle response. FDA noted that if the follow up clarification requires discussion or includes a revised proposal, sponsors should submit a request for a Type 2a meeting to provide adequate time for FDA review.

Industry asked clarifying questions about how FDA's proposals could be reflected in the commitment letter. Industry also inquired about cases in which the expanded follow-up opportunity would apply and cases in which sponsors would need to request a Type 2a meeting. FDA responded to these questions, and Industry agreed to consider FDA's proposals.

### **FDA Meeting Management Proposal Clarification**

Following the discussion of Industry's proposal, Industry asked follow-up questions about FDA's meetings proposal, including a statement on April 14<sup>th</sup> that Biosimilar Initial Advisory (BIA)

meeting requests often extend beyond the intended meeting scope. Industry inquired about what FDA considers “general advice” and how FDA determines whether a request falls under the BIA or Type 2b meeting scope. Industry noted that they have trouble understanding what types of questions would be considered feasibility questions.

FDA shared that feasibility questions should relate to whether it is possible for a product to meet the criteria for approval as a biosimilar, and FDA noted that companies can receive more detailed advice under a Type 2b meeting. FDA acknowledged that there should be more clarity around the scope of the Type 2b meeting. Industry said they would provide example questions that they believe would be appropriate for a BIA meeting, and FDA agreed to review these questions. FDA intends to draft language describing revised criteria for BIA and Type 2b meetings, for discussion with Industry.

### **Next Steps**

The goals for the next meeting on May 5<sup>th</sup> will be to discuss FDA’s facility life cycle proposal and Industry’s inspections proposals, and to follow up on proposals related to provisional determinations and exclusivity determinations.