

Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 7, 2026 | 9:30 am – 11:30 am

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss FDA’s proposal on imminent action, FDA’s response to Industry’s enhancing review efficiency and modernizing Biologics License Application (BLA) review proposals, and FDA’s regulatory science proposal.

PARTICIPANTS

FDA

Sunday Kelly	CBER
Andrew Kish	CDER
Emanuela Lacana	CDER
Joel Welch	CDER
Joshua Barton	CDER
Kimberly Taylor	CDER
Kristopher Hoover	CDER
Larry Lee	CDER
Mustafa Unlu	CDER
Nana Adjeiwaa-Manu	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

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Jessica Greenbaum	AAM (Sandoz)
Cory Wohlbach	AAM (Teva Pharmaceuticals)
Derek Scholes	BIO
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 and Industry discussed the Agency’s proposal to introduce an imminent action (IA) process into the BsUFA IV program. FDA suggested conducting a third-party assessment to better understand the issues Industry had raised regarding timely feedback during drug development

and application review. FDA and Industry discussed the draft commitment letter language for FDA's regulatory science proposal.

FDA Imminent Action (IA) Proposal

FDA responded to Industry's questions from the April 21st meeting about the Agency's IA proposal, which would allow the Agency to work past the goal date for a Biologics License Application (BLA) or supplement by 60 days if, in FDA's judgement, it is reasonably likely to support an approval under specified circumstances. Industry's questions focused on (1) examples that could fall under the FDA's provision to take IA when resolving one or more remaining small issues from one or more disciplines and (2) how IA would be used in situations when there are multiple applications under review that could potentially qualify for first interchangeable exclusivity (FIE).

FDA provided hypothetical examples of the small issues provision, including supplemental information in support of a release or stability specification for the Chemistry, Manufacturing, and Controls (CMC) aspect of the action package and a simple stability update to support desired shelf life. FDA emphasized that these examples involved limited, targeted information gaps or documentation, narrow enough not to constitute a major amendment but nonetheless needed to complete review. When this information is received later in the review cycle, it requires additional time to make updates to the reviews, action letter, and complete review.

In response to Industry's second question, FDA said that currently when exclusivity may be at stake, the Agency does everything possible to make the goal date and treat similarly situated applicants alike, which would not change if IA were introduced into the BsUFA program. FDA also noted that they did not expect to invoke IA in circumstances where multiple applications under review could potentially qualify for FIE and invoking IA could mean changing the existing FIE landscape.

Industry asked questions about the parameters under which the small issues provision would apply. FDA and Industry acknowledged the intent would be to rarely invoke this provision of IA. However, Industry expressed concern about the possibility that this provision may more routinely be invoked to provide additional review time if IA were introduced into the BsUFA program.

FDA and Industry agreed that both sides would propose potential guardrails and guiding principles to more clearly define the scope and application of the small issues provision.

FDA Enhancing Review Efficiency and Modernizing BLA Review Counterproposal

FDA proposed an independent third-party assessment to better understand the issues Industry raised in their proposals to address timely feedback during drug development and application review. FDA said that the Agency is unable to substantiate the issues Industry raised during

BsUFA IV negotiation and therefore does not agree with shortening or introducing new review timelines for Investigational New Drug (IND) protocols and initial pediatric study plans (iPSPs) or introducing new performance goals and timelines for labeling comments and Late-Cycle Meetings (LCMs). FDA stated it was open to contracting an independent third-party to assess the completeness, consistency, and timing of key review process milestones, communications, and materials exchanged between FDA and sponsors during IND and BLA review.

Industry asked clarifying questions about FDA's feedback on Industry's proposals and the process for conducting the third-party assessment. With respect to FDA's feedback on Industry's IND protocols proposal, Industry asked if FDA would be willing to consider prioritizing the review of protocols for Comparative Efficacy Studies (CES), similar to what was negotiated for pivotal protocol review under Prescription Drug User Fee Act (PDUFA). For the third-party assessment, Industry asked about how much detail would be in the commitment letter, the role Industry would have in the data collection and reporting process, and whether the Agency plans to wait until the end of the assessment to address the assessment findings. Lastly, Industry suggested including IA in the third-party assessment.

In response, FDA said that it was best practice to include the goals and objectives of the third-party assessment, rather than a list of metrics, in the draft commitment letter. Regarding Industry's role in data collection and reporting, FDA stated that it would publish a Statement of Work for public comment, Industry would be interviewed as part of the assessment in addition to internal FDA interviews, and that there would be an interim report and public meeting at the midpoint of the assessment. FDA also said the assessment's interim and final reports would be public and that the Agency would take action to address assessment findings as they arise throughout BsUFA IV.

FDA agreed to draft commitment letter language for the third-party assessment and Industry agreed to draft commitment letter language around prioritizing review of CES protocols.

Approach to Draft Regulatory Science Commitment Letter Language

FDA proposed revisions to Industry's draft commitment letter language for FDA's regulatory science proposal.

Industry responded to FDA's proposed revisions. FDA and Industry both agreed to revise the draft commitment letter language and discuss it at a future meeting.

Next Steps

The goal for the next meeting on May 12th is to discuss Industry's Inter-Center Consultative Review (ICCR), modernizing BLA review, and exclusivity determinations proposals, and FDA's data fidelity proposal.