

Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 5, 2026 | 9:30 am – 3:00 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss FDA’s facility life cycle proposal and Industry’s inspections proposals, and to follow up on proposals related to regulatory science, provisional determination, and exclusivity determination.

PARTICIPANTS

FDA		INDUSTRY	
Sunday Kelly	CBER	Alisha Sud	AAM
Andrew Kish	CDER	Giuseppe Randazzo	AAM
Emanuela Lacana	CDER	Scott Kuzner	AAM
Josh Barton	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
Mahesh Ramanadham	CDER	Hillel Cohen	Biosimilars Forum
Mustafa Unlu	CDER	Juliana Reed	Biosimilars Forum
Nikolay Nikolov	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
		Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Nina Brahme	CDER	Kristy Lupejkis	PhRMA
Paul Phillips	CDER	Ryan Kaat	PhRMA
Sarah Yim	CDER	Sean Hilscher	PhRMA
Stacey Ricci	CDER	Leah Christl	PhRMA (Amgen)
Thamar Bailey	CDER		
Joshua Ostrer	OCC		
Marianne Terrot	OCC		

MEETING SUMMARY

FDA presented an update on the status of ongoing negotiations, noting proposal areas where Industry and FDA appear to be aligned. FDA then followed up on their provisional determinations proposal before presenting a counterproposal to Industry's exclusivity determinations proposal. Next, FDA and Industry exchanged draft commitment letter language on sunseting the regulatory science program. FDA and Industry then presented their facility inspections related proposals and exchanged clarifying questions.

BsUFA IV Negotiations Progress Check

FDA presented the status of all of the ongoing proposals that were initially presented during the April 7th meeting. FDA and Industry reaffirmed their alignment on the previously discussed supplements and combination product proposals and agreed to begin drafting commitment letter language for the respective areas.

FDA Provisional Determinations (PD) Proposal

During the April 21st meeting, Industry requested clarity on how FDA would address amendments submitted while a 351(k) application has a PD status. In response, during the May 5th meeting, FDA proposed modeling the process for submitting amendments during PD status on the generics process for submitting amendments while an application has tentative approval status, referencing the guidance, *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under Generic Drug User Fee Act (GDUFA)*.

Industry requested clarity on associated timelines for amendment review and whether the proposed PD process would require resources. Relatedly, Industry raised concerns about defining respective timelines for amendments as part of this process, noting that the GDUFA timelines may not align with the needs of the biosimilar program. Industry reiterated a concern regarding FDA's original PD proposal, stating sponsors may experience logistical challenges submitting requests for final approval within the proposed window if the Agency has not posted the relevant expiry date(s) for reference product exclusivity (RPE) or first interchangeable exclusivity (FIE). FDA responded that they were still considering resource implications for this counterproposal.

Regarding the timing of requests for final approval, FDA acknowledged Industry's stated concern and reiterated that their proposal aims to increase predictability. FDA said if sponsors submitted requests outside of the specified window, the Agency would still have an aspirational goal to complete the review by exclusivity expiration. FDA said they would follow up on this proposal in a future meeting.

FDA Exclusivity Determinations Counterproposal

During the April 21st meeting, Industry presented a proposal to (1) establish goal dates for reference product exclusivity (RPE) determinations within a designated period following licensure and (2) establish a phased goal for FDA to evaluate RPE eligibility for all of the currently approved 351(a) biologics by the end of BsUFA IV. In response, during the May 5th meeting, FDA said they were willing to commit to publishing a limited number of RPE determinations each year that would begin with a limited number and increase once during BsUFA IV. These would be selected at FDA's discretion. FDA said they would also be willing to open a public docket to solicit stakeholder input on which determinations would be most useful. Following the close of the docket, FDA said the Agency would exercise discretion in determining which exclusivity determinations to address. FDA said selected determinations would be limited to scenarios in which application of the statute is relatively straightforward and FDA has made an internal decision on how to interpret and apply the statutory language. FDA said their proposal to publish a limited number of RPE determinations does not require additional resources.

Industry sought additional clarity on what factors FDA would consider in its selection and how these selections would be responsive to Industry's development needs. Industry said submitting feedback on exclusivity determinations through a public docket could risk the disclosure of sensitive information. Industry requested clarity on the rationale behind FDA's proposed annual number of exclusivity determinations, and whether the Agency would publish the exclusivity determinations it plans to address each year and the process by which such determinations were selected. Industry also asked whether additional resources would allow the Agency to commit to a greater number of annual determinations.

FDA advised anonymous submissions or submissions from other parties on behalf of biosimilar developers as options to address Industry's disclosure concern. FDA said they expect to be able to increase the number of determinations over time due to gained experience. FDA said they conducted an internal feasibility assessment to inform the proposed number of annual exclusivity determinations, noting that the Agency's commitment to systematically work through determinations is the critical aspect of their counterproposal. FDA said the Agency does not see value in publishing the list of exclusivity determinations it intends to publish since the determinations would shortly thereafter be available to the public. FDA said the Agency would not have the resources to publish details on the selection process for each selected determination. In response to Industry's questions about developing a selection process, FDA said the Agency does not believe additional resources would be helpful, noting that the rate limiting steps in making exclusivity determinations involves legal and policy related matters that resources would not resolve.

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

Approach to Draft Regulatory Science Commitment Letter Language

FDA and Industry exchanged proposed commitment letter language to sunset the BsUFA Regulatory Science Pilot program. FDA and Industry agreed they were conceptually aligned on

the proposal, but noted that additional language modifications were necessary to clarify the process regarding agency-led biosimilar research initiatives to ensure transparency and accountability.

FDA said they would propose revised language in a future meeting.

FDA IND Protocols Response

FDA responded to Industry's question on previously shared IND protocol timelines data. FDA clarified that the data that was shared includes response times to both hold and non-hold comments as they pertain to initial protocols.

Industry reiterated its interest in understanding timeline performance for follow-up comments submitted after initial comments. In response, FDA said parsing out the data would require manual review that would not be possible during BsUFA IV negotiations. FDA said the Agency cannot commit to performance timelines as stated in Industry's IND protocol proposal without further investigating the data. In turn, FDA said they would be willing to assess IND protocol response timelines as part of the third-party assessment counterproposal the Agency mentioned previously.

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

Facility Inspections Proposals

Industry presented the details of their inspections communications proposal, noting that timely and predictable facility inspections and FDA engagement are essential to achieving first-cycle approvals and enhancing patient access. In turn, Industry proposed FDA communicate the Agency's intent to conduct a Pre-License Inspection (PLI) and/or Remote Regulatory Assessment (RRA) no later than the Day 74 Letter for original Biologics License Applications (BLAs) and no later than the 30-day acknowledgement letter for supplemental applications. Industry said FDA would still reserve the right to conduct unannounced inspections. Industry also proposed establishing a post-PLI or post-RRA meeting and holding the late-cycle meeting after the Agency completed the PLI(s) and/or RRA(s).

Industry then presented the details of their second inspections proposal, noting that the stated aim of their proposal is to increase the consistency and quality of FDA/sponsor interactions regarding inspections. In turn, Industry proposed FDA (1) expand the Biosimilar Biological Product Development (BPD) Type 4 meeting scope to allow site inspection discussion, (2) review facility issues using a risk-based framework, and (3) publicly communicate criteria used to determine which facilities require inspection and risk-based assessment findings in inspected facilities.

In response, FDA noted that a recently published compliance program (7346.832M) addresses Industry's proposal regarding public communication of the risk-based approaches used to

determine which facilities require a PLI. Regarding Industry's proposed risk-based framework, FDA cautioned that this proposal may create a misperception that the standard of approval can be adjusted. FDA also indicated that FDA has been applying a risk-based framework for the facility evaluation including PLIs. Industry clarified that their framework subproposal does not intend to suggest a different approval standard, but rather acknowledge there are components in making risk-based determinations, including the profile of the intended patient population.

Next, FDA presented the details of their inspections proposal, noting that FDA and Industry have a shared goal of reducing the number of complete response letters issued due to facility issues. FDA presented complete response data on 351(k) and 351(a) BLAs, noting the pervasiveness of CR deficiencies caused by facility issues. FDA also presented data on inspections timing, facility sites, and facility deficiencies. FDA data indicated that the majority of PLIs were conducted 60 days before the user fee goal date, and that, in certain instances, the facility deficiencies resulting in CRs were significant enough that they could not be resolved within the review cycle. In turn, FDA proposed an approach to facility readiness that included proactive engagement opportunities for applicants and facilities with the agency. FDA said the Agency raised a similar proposal during Prescription Drug User Fee Act (PDUFA) negotiations.

Industry requested clarity on operational aspects of FDA's proposal, including what information would be provided to FDA at the presubmission meeting and the scope of such meetings, whether the proposed presubmission meeting is required, how any goal date extensions would operate, and how presubmission meetings would work when multiple facilities or parties are involved. Industry also raised concerns that the presubmission meeting could replicate the Pre-Submission Facility Correspondence program under GDUFA, which Industry believes, while well-intentioned, has proven burdensome and has not achieved its objectives. Industry also requested clarity on the time period of the inspections timing data presented, whether the presubmission meeting is separate from a BPD meeting, and how FDA's proposed post-action meetings differs from the post-action letter (PAL) meeting.

FDA said that while presubmission meetings would be voluntary, sponsors who opt out of early engagement may risk repeating the facility-related application challenges previously described. FDA said it would be the applicant's decision to include third parties in presubmission meetings, noting that it would be helpful to have them present, but it is not required. FDA explained that the presubmission meeting and the Pre-Submission Facility Correspondence program under GDUFA are not the same, and said that the Agency would issue guidance to address process considerations for operationalizing their proposal.

FDA said they would follow up on these proposals in a future meeting.

Next Steps

The goal for the next meeting on May 7th will be to discuss FDA's proposal on imminent action, FDA's response to Industry's enhancing review efficiency and modernizing BLAs review proposals, and FDA's regulatory science proposal.