



Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

May 19, 2026 | 9:30 am - 3:00 pm

Virtual Format

MEETING PURPOSE

To discuss FDA’s facility lifecycle proposal and Industry’s inspections proposal, FDA’s supplements proposals, Industry’s Pediatric Research Equity Act (PREA) proposal, and FDA’s draft language for the third-party assessment.

PARTICIPANTS

FDA

Sunday Kelly	CDER
Andrew Kish	CDER
Derek Smith	CDER
Emanuela Lacana	CDER
Irene Chan	CDER
Joel Welch	CDER
Joshua Barton	CDER
Kimberly Taylor	CDER
Kristopher Hoover	CDER
Larry Lee	CDER
Laurel Goldberg	CDER
Mahesh Ramanadham	CDER
Mustafa Unlu	CDER
Nikolay Nikolov	CDER
Nina Brahme	CDER
Paul Phillips	CDER
Sarah Ikenberry	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 Tomsy	Biosimilars Forum (Biocon Biologics)
Kristy Lupejkis	PhRMA
Ryan Kaat	PhRMA
Sean Hilscher	PhRMA
Leah Christl	PhRMA (Amgen)

MEETING SUMMARY

FDA and Industry aligned on regulatory science and IND protocols draft commitment letter language. FDA followed up on the Agency's and Industry's facility inspections proposals. FDA and Industry discussed draft commitment letter language regarding PREA, a third-party assessment, and supplements. Industry presented an exclusivity determinations counterproposal. Then, FDA presented the status of ongoing negotiations.

Approach to Draft Regulatory Science Commitment Letter Language

FDA presented revised draft regulatory science commitment letter language. FDA and Industry agreed they are aligned on the draft language.

Facility Inspections Proposals

During the May 5th meeting, Industry and FDA presented their respective facilities-related proposals. During the meeting, Industry sought clarification on several points, including the time period of the historical data that had been presented by FDA for timing of inspections, the timing for Post Action Letters (PALs), and additional detail on the resources needed to support FDA's proposal. Following the meeting, Industry also shared a list of questions regarding FDA's inspections proposal.

During the May 19th meeting, FDA responded to Industry's list of questions, which sought clarity on the operationalization of the proposed presubmission meetings. FDA clarified that the presubmission meeting scope includes manufacturing facilities and comparative analytical assessment testing facilities, and that the meeting would provide an opportunity for the Agency to provide feedback that may mitigate or eliminate manufacturing or compliance issues prior to application submission. FDA reiterated that the presubmission meeting is voluntary and that opting out will not impact the Agency's review; however, the Agency noted that the meeting is a critical feature of their proposal.

Regarding the timing of PALs, the Agency said it aims to send the letter two weeks following the issuance of a complete response letter. FDA then confirmed that the presented inspections timing data encompassed FY2018 through FY2025. Regarding resources, FDA said the Agency's resource estimate was based on historical data for biosimilar originals, resubmissions, and supplements that required a facility evaluation and potential pre-licensure inspection.

Industry asked clarifying questions about the methodology used to calculate the resource estimate. Industry also shared concerns regarding the capacity of investigators conducting inspections, noting that FDA's proposal will create additional work and could slow investigations. Industry acknowledged that if FDA's proposal worked as intended it could also expedite the process. In response, FDA shared that the Office of Pharmaceutical Quality conducts most of the inspections rather than investigators within FDA's Office of Inspections and Investigations. In

addition, FDA said that in the Agency's view the proposed presubmission meetings would support efficient and effective inspections and acknowledged that the proposed post pre-licensure inspection (PLI) meeting might result in additional work; however, the Agency noted these meetings would be supported by hiring additional resources.

FDA then presented a crosswalk comparing the Agency and Industry's inspections proposals, noting areas of overlap and areas where FDA's proposal includes additional elements. FDA also identified aspects of Industry's proposal that, in the Agency's view, would result in a policy change, which is out of scope for negotiations. Given the proposed presubmission meetings and existing day 60 communication, FDA inquired whether Industry continues to see value in their inspections proposal, which would require the FDA to communicate its intent to conduct a PLI and/or Risk-Based Record 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 asked clarifying questions, including whether the post-PLI meeting would occur within 10 months of a submission, whether the Agency would indicate when sponsors should request a post-PLI meeting, and what the timeline of the proposed third-party assessment would be, which would evaluate the impact of FDA's proposal. In response, FDA said the Agency would provide more information on the timing of the post-PLI meeting in a future meeting and confirmed sponsors could also initiate a post-PLI meeting request unprompted by the Agency. FDA said the Agency would issue guidance to describe operational elements of the proposal. Regarding the assessment, FDA said the Agency intends to hold a public workshop mid-way through BsUFA IV to share assessment findings.

Industry shared they are conceptually aligned on FDA's inspections proposal and FDA agreed to draft commitment letter language.

Approach to Draft Investigational New Drug (IND) Protocols Commitment Letter Language

Industry presented draft IND protocols commitment letter language. FDA proposed minor revisions, which Industry accepted. FDA and Industry agreed they are aligned on the revised IND protocols language.

Approach to Draft Pediatric Research Equity Act (PREA) Commitment Letter Language

FDA presented draft PREA commitment letter language. Industry asked clarifying questions and proposed minor revisions. Industry said they would propose revised language in a future meeting.

Approach to Draft Third-Party Assessment Commitment Letter Language

FDA presented draft commitment letter language to contract a third-party to assess and better understand the issues Industry raised in their proposals to address timely feedback during drug development and application review (i.e., Industry’s “Enhance Review Efficiency” and “Modernizing BLA Review” proposals). Industry requested clarity on whether the Agency plans to act on the assessment findings as they are reported throughout BsUFA IV. FDA confirmed the Agency intends to act on assessment findings as appropriate.

Industry said they are conceptually aligned on the draft language and said they would follow up in a future meeting.

Approach to Draft Supplements Commitment Letter Language

FDA presented draft supplement commitment letter language. Industry asked clarifying questions and proposed minor revisions. Industry requested clarity on terminology included in the draft language, noting that several specific terms may be confusing. Industry also requested the Agency to consider including language from the BsUFA III commitment letter to ensure supplement submissions seeking licensure for an additional indication that do not include data sets other than analytical in vitro data can still receive a 4-month clock.

In response, FDA said the in vitro data language was intentionally not included in the draft language because there were not many circumstances where the inclusion of that language was relevant to incoming submissions. FDA said they would reconsider the inclusion of the identified BsUFA III commitment letter language and consider edits to the language to clarify the previously mentioned terminology.

Industry Exclusivity Determinations Counterproposal

During the May 12th meeting, Industry responded to FDA’s exclusivity determinations counterproposal, noting that the proposal does not address their challenges. Industry said reference product exclusivity (RPE) is a critical component for pipeline planning and long-term portfolio management and that the limited number of RPE determinations FDA proposed is not sufficient.

During the May 19th meeting, Industry presented a counterproposal, which aims to establish (1) a process for prospective biosimilar applicants to request RPE determinations and (2) a performance goal. Under Industry’s proposal, the Agency would be required to update the Purple Book with the RPE expiration date within 90 days of receipt of a request. FDA asked whether there were any limits on the number of requests that a prospective biosimilar applicant could submit. Industry responded that there would be a certification requirement confirming prospective biosimilar applicants are considering biosimilar development related to the RPE determination request, but otherwise there would be no restrictions on the number of requests.

FDA said that the proposed 90-day timeline and the absence of a limit on the number of requests would not be feasible even with additional resources. FDA also noted that Industry had differing views on the scope of the proposal and whether only putative biosimilar sponsors should be able to submit such requests. FDA said making RPE determinations involves complex legal and policy issues, which are out of scope for BsUFA IV negotiations and challenging to address via a user fee agreement. FDA said the Agency was willing to take back Industry's feedback and propose a revised counterproposal; however, the proposal would need to include a limit on the number of RPE determinations. FDA acknowledged that Industry and the Agency may be nearing an impasse on the proposal. FDA shared that the Agency has been working on a proposed rulemaking to modernize biologics regulations and to implement the Biologics Price Competition and Innovation (BPCI) Act, which includes content on the exclusivity provisions. FDA said this proposed rule should provide more clarity on how the Agency approaches RPE once published.

Industry acknowledged FDA's feasibility concerns and said they would follow up on this proposal in a future meeting.

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 draft regulatory science and IND protocols commitment letter language. FDA then identified which party was responsible for following up next on each outstanding proposal.

Next Steps

The goal for the next meeting on May 21st will be to discuss Industry's exclusivity determinations proposal, Industry's imminent action counterproposal, FDA's revised provisional determinations proposal, FDA's response to Industry's modernizing BLA review proposal, and Industry's feedback on FDA's draft Pediatric Research Equity Act (PREA) commitment letter language.