Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 7, 2026 | 9:30 am -3:00 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To agree on reauthorization ground rules and introduce proposals.

PARTICIPANTS

FDA		INDUSTRY	
Sonday Kelly	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)
Josh Barton	CDER	Derek Scholes	BIO
Kimberly Taylor	CDER	Lina AlJuburi	BIO (Sanofi)
Kristopher Hoover	CDER	Bee Reed	Biosimilars Forum
Larry Lee	CDER	Juliana Reed	Biosimilars Forum
Laurel Goldberg	CDER	Andrew Zacher	Biosimilars Forum (Amneal)
Mustafa Unlu	CDER	Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Nikolay Nikolov	CDER	Kristy Lupejkis	PhRMA
Sarah Ikenberry	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

The meeting was focused on establishing shared expectations for the negotiations process and a shared understanding of current state of the BsUFA program. During the meeting, FDA and Industry presented their high-level proposals and shared initial clarifying questions about each

side's proposals. After FDA presented their proposals, Industry asked clarifying questions. Industry then presented their proposals and FDA asked clarifying questions.

Expectations and Ground Rules

FDA shared best practices for efficient and effective negotiations and reviewed the ground rules governing BsUFA IV negotiations. FDA and Industry agreed to ratify the ground rules with no additional edits.

BsUFA Program Overview

FDA presented trends in BsUFA workload in terms of submission volume and performance against BsUFA III goals. FDA highlighted that biosimilar development is increasing; both biosimilar development program enrollment and biosimilar application submissions have steadily increased over the lifespan of the BsUFA program. FDA presented original supplement filings data, noting that a few of the supplement categories introduced during BsUFA III have had zero filings. FDA also noted a steep increase in the number of manufacturing supplements filed over the last few years. FDA shared that both historically and currently, the BsUFA program frequently meets most of its meeting management and review goals.

FDA also shared trends on the percentage of 351(k) applications reviewed by the Center for Drug Evaluation and Research (CDER) that received a first-cycle complete response. The percentage of 351(k) filings that receive a complete response has varied since the inception of the program. FDA shared that the leading cause of 351(k) complete responses is facility inspection deficiencies.

FDA reviewed staffing and hiring data for the CDER and the Center for Biologics Evaluation and Research and Industry inquired about the status of ongoing hiring efforts.

FDA Proposal Presentation

FDA presented summaries of their key proposal topics. FDA's programmatic proposal interest areas include:

- Inspections: FDA proposed a facility life cycle management approach to enable alignment on expectations for inspections and structured forums for proactive discussion and resolution of facility-related deficiencies.
- Data Fidelity: FDA proposed extending review timelines to resolve data fidelity issues. FDA asserted that data fidelity concerns are currently rare in biosimilar reviews, but expressed interest in establishing a clear, prospective process to manage such issues should they occur in the future and could be important as the portfolio continues to grow in size. Industry emphasized the rarity of data fidelity issues in the biosimilars space and

further raised that data fidelity is not unique to biosimilars and can impact all marketing applications (NDAs, BLAs, and ANDAs).

- Imminent Action: FDA proposed introducing flexibility to extend goals dates under certain circumstances where approval may be possible within the same review cycle.
- Provisional Determinations (PDs): FDA proposed establishing a timeline framework to enable a consistent and predictable process for requesting FDA to take action on 351(k)s with PDs upon exclusivity expiry.
- Meeting Management: FDA proposed modifying the Biosimilar Initial Advisory (BIA) and Type 2b meeting type descriptions to allow Industry to request written response only (WRO) for all BsUFA meeting types.
- Supplements: FDA proposed streamlining 351(k) supplement types and timelines.
- Regulatory Science: FDA proposed ending the formal Biosimilar Regulatory Science Pilot Program and utilizing pre-existing regulatory science options if needed.

FDA's financial proposal interest areas include:

- Fee Structure: FDA proposed modernizing the BsUFA fee structure to remove the clinical data differential.
- Small Business Waiver: FDA proposed limiting the small business waiver to only US-based companies.
- Transparency: FDA proposed repurposing the annual Public Financial Meeting to become an annual technical meeting.
- Clarity: FDA proposed making minor updates to statutory language for relevance.

After FDA's presentation, Industry asked clarifying questions to better understand the proposals FDA had presented.

Industry Proposal Presentation

Industry presented summaries of their key proposal topics. Industry's programmatic proposal interest areas include:

- Combination Products: Industry proposed amending the Biosimilar Biologic Product Development (BPD) meeting process to promote early engagement and updating the commitment letter language to reflect current practice and terminology.
- Exclusivity Determinations: Industry proposed establishing a process and timeline to increase transparency around Reference Product Exclusivity (RPE) determinations.

- Pediatric Research Equity Act: Industry proposed streamlining the initial pediatric study plan (iPSP) process, establishing predictable timelines for FDA review and agreement on iPSPs, and issuing a guidance on pediatric study plans.
- Inspections: Industry proposed establishing predictable inspection timelines and post-inspection engagement opportunities. Industry also proposed establishing timelines for final establishment inspection reports (EIRs).
- Meeting Management: Industry proposed modernizing the BPD meeting framework and establishing a process to ensure timely dialogue when FDA cannot answer questions within goal dates.
- Regulatory Science: Industry proposed modernizing the regulatory science framework.
- 351(k) BLA Review Process: Industry proposed modernizing the review process to enhance efficiencies and reflect current biosimilar development paradigms.
- Supplements: Industry proposed streamlining supplement categories and improving the predictability of chemistry, manufacturing, and controls supplement classification determinations.

Industry's financial proposal interest areas include:

- Fees: Industry proposed amending the statute to clarify the fee for 351(k) BLAs without comparative efficacy studies. Industry also proposed eliminating the BPD fee.
- Program Revenue Industry proposed simplifying the user fee setting process by (1) capping the inflation adjustment, (2) removing the capacity planning adjustment, (3) eliminating the Strategic Retention and Hiring adjustment, (4) limiting the addition of Full-Time Employees (FTEs), and (5) decreasing the carryover balance ceiling.
- Spending Trigger: Industry proposed reducing the spending trigger.

After Industry's presentation, FDA asked clarifying questions to better understand the proposals Industry had presented.

Next Steps

The goal for the next meeting on April 9th will be to discuss Industry and FDA's respective supplements proposals and agree on a proposal presentation schedule.