Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Finance Subgroup

May 21, 2026 | 1:00 pm - 3:00 pm

Virtual Format

MEETING PURPOSE

To continue in-depth discussions on BsUFA IV finance proposals, including follow-up on the Operating Reserve Tracking, Reserving, and Reporting (OR TRR) concept, operating reserve carryover balance, the application and biosimilar product development (BPD) fee structure counterproposal from Industry, and technical meeting language.

PARTICIPANTS

FDA		INDUSTRY	
Josh Barton	CDER	Lina AlJuburi	BIO (Sanofi)
Kristopher Hoover	CDER	Leah Christl	PhRMA (Amgen)
Rebecca Kemp	CBER	Jessica Greenbaum	AAM (Sandoz)
Andrew Kish	CDER	Sean Hilscher	PhRMA
Joshua Ostrer	OCC	Ryan Kaat	PhRMA
Sarah Yim	CDER	Scott Kuzner	AAM
		Kristy Lupejkis	PhRMA
		Giuseppe Randazzo	AAM
		Bee Reed	Biosimilars Forum
		Juliana Reed	Biosimilars Forum
		Derek Scholes	BIO
		Scott Tomsky	Biosimilars Forum (Biocon Biologics)

MEETING SUMMARY

The meeting opened with Industry requesting additional clarification on the full-time equivalent (FTE) accounting methodology. FDA walked through the FTE resource ledger and provided a detailed explanation of how BsUFA-funded staffing losses were calculated, and how those figures relate to the number of FTEs that FDA has indicated the program can potentially support for new negotiated BsUFA IV initiatives by reallocating existing programmatic resources. Industry requested OR TRR be included in BsUFA; FDA agreed in principle to include OR TRR.

FDA countered Industry's proposal to reduce the operating reserve maximum. FDA countered with reducing the carryover ceiling from 21 weeks to 18 weeks, with phased reductions to support fee stability; FDA stated they would be unable to lower the maximum to less than 18 weeks.

Industry proposed a three-tiered application fee structure; (1) a quarter fee for additional BLAs for the same drug substance submitted simultaneously; (2) a half fee for additional BLAs for the same drug substance not submitted simultaneously; and (3) full fee for all other applications. FDA countered this by proposing to not charge an application fee for additional BLAs for the same drug substance submitted simultaneously to further incentivize simultaneous submission, when possible, to enable review efficiencies within the FDA.

OR TRR and Enhanced Reporting

Industry reiterated their strong interest in OR TRR for BsUFA, emphasizing the need for parity with other user fee programs and the desire for a dedicated mechanism to track restaffing for positions that support BsUFA work.

FDA reiterated its position that OR TRR adds administrative burden to the agency while not adding meaningful value to BsUFA given the scale of the program. FDA noted that approximately 9 FTEs were lost to non-Reduction-in-Force (RIF) causes between the start and end of FY25. FDA also noted that by the time BsUFA IV begins, those positions are expected to be restaffed. FDA explained that if positions are not added to payroll, the financial system would reflect a downward adjustment to the operating reserve, providing a built-in accountability mechanism. Industry asked clarifying questions about FDA's payroll and resource calculations underpinning the proposed OR TRR model. Industry also asked about the agency's plans for restaffing in advance of BsUFA IV, including how, in the absence of OR TRR, BsUFA funds could be reserved for payroll and not directed to other operating expenses. FDA acknowledged Industry's strong interest in OR TRR and confirmed that it is amenable to including the OR TRR for BsUFA. FDA committed to working through implementation details at the next meeting.

Operating Reserve

Industry clarified their priority regarding the operating reserve is to reduce the carryover balance maximum. Industry expressed a desire to see the carryover reduced, consistent with the program's maturation and anticipated growth. FDA proposed reducing the operating reserve maximum from 21 weeks to 18 weeks, structured to phase in reductions to minimize fee fluctuations. FDA indicated that 18 weeks is a firm floor and that it would not be able to engage with lowering beyond 18 weeks. FDA also noted that if agreement is reached to lower the operating reserve maximum to 18 weeks, the Agency would agree to discontinue the Strategic

Hiring and Retention Adjustment (SHARA). Industry responded that they would discuss internally and provide feedback on the FDA counterproposal.

Fee Structure Counter from Industry

Industry presented their counterproposal to FDA's previously proposed fee structure compromise. Industry acknowledged FDA's goal of encouraging simultaneous submission of subsequent BLAs for the same drug substance, but expressed concern that a fee increase for non-simultaneous submissions could be viewed as punitive. Industry highlighted that split submissions are often driven by factors outside an applicant's control, such as changes to the reference product, pending litigation, or reimbursement considerations. Industry proposed a three-tiered application fee structure; (1) a quarter fee for additional BLAs for the same drug substance submitted simultaneously; (2) a half fee for additional BLAs for the same drug substance not submitted simultaneously; and (3) full fee for all other applications.

FDA countered this by proposing to not charge an application fee for additional BLAs for the same drug substance submitted on the same day to further incentivize simultaneous submission. FDA also confirmed its willingness to eliminate the BPD fee as part of this counter proposal package. FDA noted that target revenue would not be impacted, and that overall fee levels are expected to decrease as the number of fee payers grows. Industry indicated they would take the proposal back for internal review and provide a response.

Technical Meeting Language

FDA noted they had previously circulated draft language on technical staff meetings for Industry review. Industry indicated they had no initial questions and expressed conceptual alignment with the draft. Industry asked whether language could be added to reflect an interactive process in which Industry could provide input into meeting agendas. FDA indicated a preference not to deviate from the language used in other user fee reauthorizations, in the interest of consistency across programs. FDA confirmed, however, that the intention would be to work collaboratively with regulated Industry to establish agendas for these technical staff meetings, and that this collaborative approach will be reflected in practice.

Next Steps

The goals for the next meeting are to discuss FDA’s ideas on how the OR TRR could be applied to BsUFA and for Industry to provide follow up on FDA’s operating reserve maximum and fee structure counterproposals.