

Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Finance Subgroup

April 30, 2026 | 2:30 pm-4:30 pm

Virtual Format

MEETING PURPOSE

To begin in-depth discussions on FDA and Industry proposals.

PARTICIPANTS

FDA

Josh Barton	CDER
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INDUSTRY

Lina AlJuburi	BIO (Sanofi)
Leah Christl	PhRMA (Amgen)
Jessica Greenbaum	AAM (Sandoz)
Sean Hilscher	PhRMA
Ryan Kaat	PhRMA
Scott Kuzner	AAM
Kristy Lupejkis	PhRMA
Giuseppe Randazzo	AAM
Bee Reed	Biosimilars Forum
Juliana Reed	Biosimilars Forum
Alisha Sud	AAM
	Biosimilars Forum (Biocon
Scott Tomskey	Biologics)

MEETING SUMMARY

FDA presented information on the BsUFA spending trigger. Industry presented their proposal to reduce the operating reserve carryover ceiling. FDA reviewed the Agency’s proposals to update the small business waiver to limit eligibility to US-based entities (America First) and to repurpose the annual financial meeting with a technical meeting. Industry provided additional details on their proposal to strengthen hiring and retention commitments and increase transparency.

Spending Trigger Details

FDA provided a historical overview of the BsUFA spending trigger, which defines the amount of budget authority funds that must be obligated to the BsUFA program to allow the collection and spending of user fee funds. FDA asserted that decreases to the allowable threshold are a risk to the continuation of the BsUFA program. FDA highlighted historical examples of how the 15% threshold allowed the program to continue operating without threatening the legal repercussions of violating the compliance threshold. FDA also detailed several historical instances where a lower compliance threshold would have resulted in missing the spending trigger. FDA also noted that the President's budget for FDA in Fiscal Year (FY) 2027 prioritizes budget authority specifically to protect user fee agreement spending triggers. Industry asked questions regarding what factors contributed to FDA missing the trigger in the referenced historical instances. Industry also asked why the Agency was not considering harmonizing the BsUFA spending trigger with other programs given the Agency's stated support for standardization across medical product user fee programs in other areas. FDA responded that both the compliance threshold and the trigger amount would need to be harmonized and that changing the compliance threshold without lowering the trigger amount would add significant risk to the program.

Revenue Framework Proposals

Industry presented their proposal to lower the operating reserve ceiling. Industry stated that the current operating reserve is large, with funds that are not being put to use, and Industry wants to ensure appropriate financing as the program continues to mature. Industry proposed reducing the BsUFA operating reserve cap and aligning it with the Prescription Drug User Fee Act (PDUFA) program. Industry stated their proposal provides greater stability and minimizes the exchange between FDA and Industry through operating reserve adjustments. Industry also stated the importance of ensuring that funds are directed effectively to support biosimilars review and the BsUFA program. Industry also asserted that the BsUFA program will be twenty years old at the end of the BsUFA IV cycle, and is a mature program that now has consistency in funding from application fees and program fees, thereby obviating the need for a 21-week operating reserve cap. Industry also flagged that FDA had previously stated that the operating reserve cannot be used to support hiring additional staff as it is a balance at one-point in time and therefore not available to support long-term liabilities, like payroll. FDA asserted that standardizing the BsUFA operating reserve cap with larger user fee programs like PDUFA or Generic Drug User Fee Amendments (GDUFA) may introduce additional risk that would not necessarily apply to the larger user fee programs if multiple events occurred simultaneously. For example, if BsUFA had a significant under-collection and there was also a lapse of appropriations, there could be significantly more risk to the BsUFA program having to halt operations. FDA highlighted that, from its perspective, if the Agency were to lower the carryover cap, the impact would likely be a one-year reduction of fees and a long-term increase in risk to the program. Industry asked

clarifying questions about FDA's responses to the proposal. Industry introduced the idea of exploring a potential flexible or conditional-based approach to the carryover ceiling. FDA and Industry agreed to further discuss the operating reserve in a future meeting.

Other Proposals

FDA presented its proposal to add an additional requirement for a sponsor to be US-based (in addition to other established criteria) to be eligible for the small business waiver. FDA stated this proposal would promote American small businesses and American biosimilar development and is consistent with proposals raised during PDUFA and Medical Device User Fee Act (MDUFA) negotiations.

FDA offered a proposal to repurpose the annual public financial meeting into an annual technical staff meeting, which would provide for discussion on topics related to fee-setting and program finances. FDA maintained this proposal would increase transparency and provide an opportunity to discuss financial topics, with the opportunity to collaborate with Industry on the agenda and topics in advance of each meeting. The Agency noted this would also maintain consistency with repurposing discussions in the PDUFA and GDUFA negotiations. Both FDA and Industry agreed that transparency was a priority and that meeting minutes from these technical meetings would be posted publicly.

Industry presented their proposal to strengthen hiring and retention commitments and increase transparency. Industry indicated their interest in having an accountability mechanism similar to the operating reserve tracking, reserving, and reporting (OR TRR) concept envisioned in recent PDUFA and GDUFA negotiations with the objective of ensuring an appropriate level of fee funds are reserved for hiring and retaining FDA staff. Industry also expressed a desire to implement enhanced financial reporting akin to what was agreed upon in PDUFA and GDUFA negotiations as well as additional reporting on the carryover balance. The subgroup agreed to discuss OR TRR and its applicability to the BsUFA program in a future meeting.

Next Steps

The goals for the next meeting are to discuss the fee structure proposals (Industry's application fee proposal, FDA's application fee proposal, and Industry's biosimilar biological product development (BPD) fee proposal). This will include an overview of fee setting calculations and methodology accompanied by an analysis of how each proposal would impact fee amounts.