

Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Finance Subgroup

April 14, 2026 | 3:30 pm-4:30 pm

Virtual Format

MEETING PURPOSE

To identify common themes shared by FDA and Industry for BsUFA IV, provide an overview of the BsUFA program, and align on a schedule for in-depth discussions on the BsUFA finance proposals.

PARTICIPANTS

FDA

Josh Barton	CDER
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Rebecca Kemp	CBER
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Sarah Yim	CDER

INDUSTRY

Lina AlJuburi	BIO (Sanofi)
Leah Christl	PhRMA (Amgen)
Jessica Greenbaum	AAM (Sandoz)
Ryan Kaat	PhRMA
Kristy Lupejkis	PhRMA
Giuseppe Randazzo	AAM
Juliana Reed	Biosimilars Forum
Derek Scholes	BIO
Scott Tomsky	Biosimilars Forum (Biocon Biologics)

MEETING SUMMARY

FDA and Industry agreed on the themes of maintaining the predictability, sustainability, stability, and transparency for the BsUFA program. FDA provided historical information on the BsUFA program and asserted that workload has grown significantly; the target revenue after adjusting for inflation is relatively flat; and, due to an increasing number of fees being paid, fees are lower than they were in FY 2018. The subgroup discussed how best to approach the proposals brought forth by FDA and Industry.

Common Themes – Kickoff and Proposals

FDA highlighted the common themes seen in BsUFA finance proposals and heard in the BsUFA negotiations kickoff meeting: predictability, sustainability, stability, and transparency. FDA

stated the intent to utilize these themes for finance discussions and set BsUFA IV up for success. Industry indicated that they were aligned with these themes.

FDA's BsUFA Program Overview

FDA gave a brief overview of the Agency's perspective on the BsUFA program, providing data on workload, target revenue, and fee amounts. FDA highlighted that workload, as measured by submission volume, has increased between 76% and 700% across all categories since FY 2018, with most submission types at least doubling. FDA believes that this indicates a healthy, growing program benefitting the American public.

FDA presented data on the target revenue demonstrating that from the start of BsUFA II in FY 2018 to FY 2026, the target revenue, after adjusting for inflation using the Consumer Price Index, has only grown 5.7%.

FDA observed that while the workload of the program has been rapidly increasing and the target revenue is mostly flat after adjusting for inflation, the application, program, and BPD fees are lower in FY 2026 than they were in FY 2018, reflecting the increasing number of fees being paid. It was also noted that for FY24 and FY26, FDA had taken downward operating reserve adjustments, as the carryover exceeded the limit in place for the year. FDA also noted there was no downward adjustment in FY 2025, however, and all the fees were still lower than in FY 2018, showing that the downward trend in fees is independent of any operating reserve adjustment.

FDA asserted that this growth in workload and decline in fee amounts suggest a growing sector and a well-designed financial framework for the BsUFA program.

BsUFA Proposal Inventory

FDA presented a summary of the FDA and Industry finance-related proposals introduced at the FDA-Industry negotiation meeting on 4/7.¹ FDA suggested grouping the finance proposals by revenue framework, fee structure, and a third 'other' category for proposals unrelated to the revenue or fee structure groups. The grouping would be intended to help plan efficient and effective in-depth discussions of interconnected proposals.

Industry expressed support for the BsUFA program overall and emphasized its interest in maintaining a stable, transparent, and efficient program that is appropriately resourced for the review of biosimilars.

FDA stated it would be unable to engage on Industry's proposals to eliminate the capacity planning adjustment (CPA), cap the inflation adjustment, or lower the statutory spending trigger to match the PDUFA program.

¹ For the FDA and Industry finance proposals introduced, reference the 4/7/26 meeting minutes.

Next Steps

The goal for the next meeting on 4/30 is to begin in-depth substantive discussions on a set of the finance proposals. The group agreed to align on an agenda and which proposals to discuss at the next meeting in advance.