



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

February 19, 2026, 10:00am – 11:30pm

Hybrid Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To continue discussions to reauthorize GDUFA related to finance.

PARTICIPANTS

FDA		Industry	
Kathleen Davies	CDER	Giuseppe Randazzo	AAM
Kimberly Taylor	CDER	Scott Kuzner	AAM
Tasha Ray	CDER	Jess Greenbaum	AAM (Sandoz)
Alison Lyndaker	CDER	Kiran Krishnan	AAM (Apotex)
Jonathan Collins	CDER	Gil Roth	PBOA
Ashley Boam	CDER	Joel Carpenter	BPTF
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

FDA began by following up on previously discussed questions regarding under-collection issues during GDUFA III. FDA explained that in FY 2020-2024 GDUFA obligations exceeded collections in all years (although one year was close to even). FY 2025 saw a drop in spending, with \$50M added to the operating reserve. However, had FDA spent to the FY 2025 plan, given that the program also under collected for FY 2025, it would have ended the year with just under 6 weeks in the operating reserve. FDA noted that reserves of that level would have presented a serious risk to the GDUFA program during the recent lapse in appropriations. FDA stated that leadership has expressed a strong commitment to hiring and fully staffing programs and that when this occurs, FDA may need to take an upward operating adjustment to fully support the program if the under-collection issue has not been addressed. FDA noted that moving the program fee liability date alone would be helpful but would not fully address the under-collection issue.

FDA clarified that in FY25, actual spending was approximately \$580 million, while the plan for a fully staffed program, based on the 2024 update to the five-year plan, was approximately \$640 million and had FDA spent according to plan, they would have spent \$13 million more than was collected. Given the under-spending and the funds added to the carryover in FY 2025, Industry questioned the characterization of a problem for this year and subsequent years.

Industry provided a presentation on the generic market. Industry described the overall value of generics, which represent about 90% of prescriptions by volume but a shrinking share of drug spending, underscoring the role of generics in improving patient access and supporting a resilient supply chain. The generics industry operates on extremely thin margins and, in recent years, is facing stagnant and even deflated prices and rapid price erosion, challenges with getting insurance companies to cover generic drugs, and longer time to market and fewer launches. Industry further explained that approved ANDAs do not necessarily translate into marketed products and large generic manufacturers often lose money on certain ANDAs. In other words, a broad portfolio does not mean broad profitability, with many products maintained despite thin or negative margins because they serve essential patient needs or are necessary to support broader contracting relationships. Industry emphasized that, given these challenges, the generic market is very fragile, with companies considering leaving the market. FDA acknowledged that much of what industry presented is not within FDA's regulatory control but appreciated the context. Industry concluded that their view is that the GDUFA financial framework must be constructed differently from PDUFA. Industry stressed its view that abrupt, large changes and increases in fees, for some companies would adversely impact the market, exacerbating industry challenges and increasing the risk of market exit, which, correspondingly would lead to more supply disruptions and drug shortages. Additionally, these market dynamics are wholly distinct from PDUFA for which it makes sense that product revenues would support an annual program fee tied to the number of marketed products.

Industry presented two options for financial models for GDUFA IV. The first option included accepting FDA's proposals to change the program fee liability date and increase the foreign facility fee differential (without ongoing adjustment for inflation), which was previously tentatively agreed to, and exploring maintaining the current user fee structure and a process for FTE transparency and hiring accountability to be discussed with FDA. The second option included the foregoing elements and further proposed an allocation adjustment trigger if under-collection jeopardizes the GDUFA program.

FDA requested clarification that industry was expressing non-agreement to any of the alternative options for the program fee structure and allocation percentages FDA presented on February 11th. Industry confirmed they want to keep the existing program fee structure with the three program fee tiers, but had tentatively agreed to increasing the foreign facility fee differential (without ongoing adjustment for inflation) and would consider moving the program fee liability date.

FDA reiterated that moving the program fee liability date will only partially address the under-collection problem. To address industry's concerns about the state of the generics market, FDA referenced scenarios previously presented (see minutes from February 11th), including a 5-tier program fee option and a per-ANDA program fee option with a lower cap with the allocations updated to 43% to the program fee and 26% to the ANDA submission

fee. FDA stated that approximately 85% of companies would see the same or lower program fee liability under those options and expressed difficulty understanding why the current structure is the best model based on what industry presented.

Industry explained that the current structure is their preference because market dynamics can differ depending on portfolio size and abrupt changes create shock, with some options FDA provided resulting in a 50% increase in program fees for certain companies. Industry acknowledged that lower application fees could offset this under FDA's proposals but noted it is not a guarantee and also explained FDA's proposal would represent a significant increase in fixed costs for some companies. Industry noted that the large tier contributes 61% to program fees, and when ANDA application fees are factored in, it's approximately 52%.

FDA stated they would still like to better understand industry's perspective on proportionality. FDA noted that while they understand concerns around abrupt changes in fees, the companies that would pay higher program fees under FDA's proposal are those with significant revenue and have larger portfolios contributing a larger share to the program workload – including supplements, which do not require a fee. FDA reiterated a need to understand industry's perspective on how to make the fee structure optimal, pointing out that they were seeing under-collections every year, which demonstrates the current structure is not optimal. FDA again emphasized the need to set the program up for continued success, noting that with a fully staffed program, there will be risks to the operating reserve and increased likelihood of an upward operating reserve adjustment that would raise fees for all industry players.

Industry expressed concerns that given current FDA dynamics, specifically the current FTE deficit and underspending, major structural changes are not warranted in this GDUFA cycle. Additionally, given that GDUFA fees are intended to pay for FTEs, a substantial shift in the financial structure would be difficult to justify without significant program enhancements. . FDA noted they are negotiating program enhancements and that historically, from their perspective, those would have required an increase target revenue (and therefore fees) to cover the additional FTEs needed. In this cycle FDA is trying to manage any negotiated enhancements with current resources. Industry underscored that FDA is also getting enhancements.

FDA asked industry to share more details about their fee allocation change trigger proposal. Industry stated they are open to discussion. FDA asked if the percentage change presented is the maximum industry is willing to consider. Industry stated they will consider this and report back.

Industry expressed concern regarding whether user fees are being spent on FTE hiring as intended and noted it needs more transparency beyond what is provided by OPM. FDA asked for clarification on what industry envisioned this would look like, noting that CDER and

CBER net hiring data is posted on FDA's website quarterly. Industry noted that the program has experienced a net decrease in staff on board and that access to more detailed GDUFA-specific hiring data would be helpful. Industry suggested that the FDA-industry quarterly implementation meetings could be a venue for this information to be shared.