



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

February 11, 2026, 2:30pm – 4:00pm

Virtual Meeting

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	Gil Roth	PBOA
Jonathan Collins	CDER	Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Ashley Boam	CDER	Joel Carpenter	BPTF
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

FDA presented additional options related to the program fee structure and fee allocation percentages. Industry expressed appreciation for FDA's modeling but raised concerns that the program fee options still place disproportionate burden on the largest industry participants. Industry also questioned whether the provided options mitigate the risk of companies moving tiers. FDA acknowledged that risk will continue with any tiered structure but noted that changing the structure reduces fee increases between tiers. FDA shared that the per-ANDA model would most effectively reduce this risk (as well as increasing revenue predictability), though acknowledged movement of ANDAs between firms above and below the cap would be possible. FDA confirmed the per-ANDA model is their preference, acknowledging they are open to a lower cap.

FDA explained their approach to measuring proportionality, noting that 50% of supplements submitted in GDUFA III thus far came from companies impacted by program fee increases under their proposals and that the latest options presented would result in those companies paying a similar proportion of the program fee revenue. Industry noted difficulty using supplements as a proportionality measure when supplements require varying levels of work. FDA expressed openness to considering other data driven ways to think about proportionality if Industry brings them. Industry also questioned the reasons for all tiers other than largest seeing fees decreased. FDA explained the proposed structure was intended to smooth the transition between tiers and reflect growth in the number of approved ANDAs and size of portfolios since the current structure was implemented. FDA

also suggested that, from their perspective, the current structure could also be viewed as unfair given the significant difference in fee burden on a per ANDA basis.

Industry explained that, from their perspective, fees for the largest tier should not increase significantly in the absence of FTE increases, particularly given the fragile nature of the generic industry, where products increasingly generate less revenue. Industry added that when FDA is under spending, the largest industry participants should not pay more to support FTEs that FDA does not currently have. Additionally, Industry stated that the approach taken for new drugs is not translatable to generics, given very different market dynamics. FDA pointed out it is negotiating program enhancements within existing resources, which will provide value for industry even without adding new FTEs, which would otherwise increase target revenue and fees for all players. FDA explained that if it cannot spend GDUFA fees, such that the operating reserve exceeds the upper threshold, Operating Reserve Adjustments (ORA) in fee setting will result in lower fees for all participants the following fiscal year. FDA noted that the Agency is committed to hiring review and inspection staff and that their goal in proposing fee structure updates is to set the program up for ongoing success after restaffing to the levels it had committed to under GDUFA III. Industry responded that given the current staffing levels, an overhaul of the fee structure is not warranted at this time; instead, fee restructuring could occur later when there is more confidence the program is fully restaffed. FDA countered that without any changes, revenue issues from GDUFA III are expected to continue, creating risk for FDA's ability to provide program enhancements sought by industry. While acknowledging potential downward ORA, Industry noted there was too much uncertainty about whether they would materialize. FDA indicated it could consider a mechanism to provide assurance that fee funding that was intended to support payroll would be put towards the operating reserve if it can't be spent on staff, provided industry agrees to some changes to the fee structure.

FDA asked what industry has explored in terms of solving these issues to help find mutually beneficial solutions.

Industry indicated they are working with FDA on fee liability date changes and have tentatively agreed to the increased foreign fee differential without an annual inflation adjustment. Industry stated that they are exploring a "safety net approach," in which certain adjustments could be implemented if, once FDA is fully restaffed, under-collections risked threatening the program. FDA asked for clarification on the safety net concept. Industry suggested potential allocation shifts triggered by hiring with industry more open to larger changes if money is being spent.

FDA noted this would create uncertainty and complexity. FDA suggested that the existing mechanism (the ORA) provides an appropriate mechanism for managing any underspending, particularly if combined with a requirement to reserve unused FTE funding be reserved for hiring within the operating reserve.

Industry asked how much moving the fee liability date could positively impact revenue predictability. FDA agreed it would help but not solve the problem entirely and indicated that some movement on the other revenue protection proposals would be necessary as well from their perspective.

Industry expressed concern about lowering the ANDA fee and its potential impact on the quality of applications. FDA noted its position is that even at a 20% ANDA allocation percentage, the ANDA submission fee would still be a sufficient amount to deter unserious applications.

Closing/Next Steps

FDA confirmed that industry has all of the data needed to develop a position with respect to FDA's finance proposals. Industry confirmed it did, other than FTE cost amounts that would be needed to evaluate total cost if FDA proposes new FTE for any enhancements, which it has not done to date. FDA is working to provide that information to industry.

Industry confirmed they can return with a response to FDA next week but cannot confirm anything without ratifier approval.