Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
February 4, 2026, 2:00pm – 3:15pm
In-Person Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To continue discussions to reauthorize GDUFA IV 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)
Martha Nguyen	CDER	Joel Carpenter	BPTF
Ashley Boam	CDER		
Angela Granum	OC		
Gisa Perez	OC		

MEETING SUMMARY

Industry asked clarifying questions regarding number of FTEs onboard.

Industry asked what the hiring plan looks like for 2026 and into GDUFA IV, indicating concern that their current user fees are funding FTEs that are not on board and raising uncertainty over what GDUFA allowable activities their user fees will be funding in the future. FDA noted it is committed to hiring review and inspections staff and mentioned recent press about 400 hiring actions in progress. FDA highlighted the recently published FY25 GDUFA financial report, which provides information on the program's financials in the most recent fiscal year and indicates that FDA's under-spending of GDUFA fees outpaced under-collection for FY25, with a net carryover increase of over $50M for FY25. In response to industry questions regarding what would happen to the funding for FTEs that are not onboard, FDA explained how the operating reserve adjustment would likely reduce future GDUFA target fee revenue to account for unspent carryover beyond the specified statutory threshold. FDA indicated that it viewed the operating reserve adjustment as providing a mechanism that positions the agency to effectively manage the GDUFA program's finances in the current situation.

Industry asked if the upper threshold of the operating reserve adjustment could be lowered. FDA noted that the upper GDUFA threshold is already lower than most other programs and gave the example of PDUFA's threshold of 14 weeks.

Regarding the fee allocation percentages, industry indicated that they feel it is important for there to be an ANDA fee to reduce the occurrence of low-quality submissions and ensure a reasonable workload for FDA. FDA agrees that there should be a fee associated with an ANDA submission and indicated it does not believe the proposed changes to the allocation percentages would push the ANDA fee below an appropriate level given the submission volumes.

Industry indicated concern about financial impact of companies in arrears because the cost is shifted to companies that do pay. FDA suggested the total amount of arrears, and therefore its impact on fee revenue, is higher than it might otherwise be because some companies are charged less than others on a per ANDA basis under the current structure, and the companies in arrears tend to have higher per ANDA fee liability.

FDA asked if a program fee structure based on marketed ANDAs instead of approved ANDAs would be more feasible. Industry indicated this would be challenging from a predictability perspective for Industry due to market considerations and volatility that impact ANDA marketing status. FDA indicated it could effectively manage the operational requirements of such a program fee structure.

FDA and Industry discussed FDA's proposal to move the program fee liability date. FDA answered questions Industry posed regarding implementation and how the proposal would impact program fee liability for regular business practices of company acquisition and ANDA transfer.

FDA asked if it would be helpful to provide suggestions for different tiers or caps using the per-ANDA model. Industry said this would be helpful and suggested discussing it further in a small group next week.

FDA and Industry agreed that they would like to have proposals to share with their respective ratifiers by the end of February.