Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
January 21 2026, 12:45pm – 1:30pm
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
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

FDA began by indicating that their goal for this time is to continue to talk through finance and answer any questions industry has so far on FDA's response to their finance related data call.

Industry explained their view that any given fee payer should not be disproportionately burdened. Industry also conveyed that they understand that FDA's proposals are FTE resource neutral. Industry indicated that when they consider changes to fees, they need to understand what those changes in fees would support (*e.g.*, program enhancements, FTEs).

Industry also indicated that the data suggest revenues collected from facility fees consistently exceed the target revenue allocation for those fees and offered to share their tracking data on this. FDA acknowledged that facility fee revenue collected in recent years has slightly exceeded what is expected for the target revenue from this fee category, given that fee-setting involves estimates of paying facilities, and suggested that changing the liability date for facilities similar to the proposal for program fees could be considered to help address this issue. FDA explained that changing the liability date could help address both potential under and over collection because fees would be calculated based on the actual number of entities that will be liable for the fee each year, as opposed to estimates.

Industry requested prior years of the GDUFA Program Fee Parent Company Details List file that is posted online annually, as the current version only covers the current fiscal year, as

well as additional years of anonymized data on program fee tiers and ANDA fee payment data from previous years as it is not available online. FDA agreed to provide this.

Industry asked whether FDA had considered changes to tiers instead of a per-ANDA fee model. FDA indicated they are open to considering this, particularly if paired with the change to the program fee liability date to mitigate the impact of tier movement on revenue predictability.

FDA indicated that it is getting challenging to respond to other proposals without a good understanding of industry's overall position on finances. Likewise, industry expressed the challenge of positioning their financial considerations without fully understanding any potential enhancements such as agreed upon operational improvements to the program. That said, Industry agreed to provide initial counterproposals on 1/28. Industry conveyed that it looked forward to receiving the additional finance-related data.