



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

December 17, 2025, 10:00am – 2:00pm

In-Person Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To continue discussions to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Kristin Davis	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
Martha Nguyen	CDER
Susan Rosencrance	CDER
Ashley Boam	CDER
Bhagwant Rege	CDER
Rebecca Dowd	OII
Ivy Sweeney	OII
Angela Granum	OC
Gisa Perez	OC
Josh Brown	OC
Mingham Ji	OC

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Aparna Dagar	AAM (Fresenius – Kabi)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Joel Carpenter	BPTF
Elizabeth White	BPTF (Evonik)

MEETING SUMMARY

User Fee Invoice Timing

Industry presented a proposal requesting FDA make user fee cover sheets available by August 1st of each year to allow more time for companies to process a payment prior to the October 1st due date for annual GDUFA fees, noting that business processes often require 60 days from an invoice for a payment to be made.

FDA asked clarifying questions regarding the current process to better understand how challenges are currently addressed.

FDA indicated they could not make cover sheets available by August 1st due to time necessary to prepare coversheets for the upcoming fiscal year following publication of the fee setting Federal Register Notice, which is statutorily required by August 1st. FDA countered with a proposal acknowledging challenges and offering to make GDUFA

coversheets available by August 15 (or the following business day), two weeks earlier than current practice.

Industry asked clarifying questions. and FDA and Industry will continue to discuss.

No agreements were made at this time.

Update Allocation Percentages of GDUFA Fees for ANDA Submissions

FDA proposed reducing the statutory allocation of ANDA filing fees toward total GDUFA target revenue to improve revenue stability and increase predictability. FDA explained that declining ANDA submission volumes (and inherent variability in long term forecasts), have contributed to under-collection of target revenue and large year-over-year ANDA filing fee increases. FDA indicated no preference on how the potential allocation change would be distributed amongst other GDUFA fee types.

FDA also provided the option of allowing revenue percentages allocated to each fee type to float after the first year of GDUFA IV to reduce year-over-year volatility in fees. FDA explained that in this scenario, the allocation percentages would float with the goal of equalizing the rate of increase across types of fees.

Industry indicated an understanding of the need to increase predictability of fee obligations, though had questions about how FDA's proposal would achieve that objective. Industry asked clarifying questions regarding how FDA estimates the number of submissions, whether there are discretionary changes made to estimates, and how the floating allocation would work in practice. FDA explained the process for modeling submissions through resource capacity planning, indicated that the predictive models are selected based on their performance compared to the baseline, and confirmed there are no discretionary changes made to estimates.

No agreements were made at this time.

Per ANDA Program Fee

FDA proposed a change in the current tiered program fee structure to a per ANDA program fee model with a cap on the number of ANDAs charged per sponsor to address under-collection driven by movement across tiers and firms in arrears. FDA's position is that this structure would reduce the impact of transfers of ownership on fee collections because this change in the fee structure would reduce the program fee for a portion of the ANDA holders, with a cap included to mitigate the magnitude of any potential fee increases. A portion of companies, however, would face an increase in program fees. FDA explained that the current tiered structure creates incentives that contribute to under-collections, such as transfers of ownership designed to avoid fee liability (though FDA acknowledged there are legitimate business reasons to transfer ANDAs which also impact collections) and a significant per ANDA fee burden for small companies that are more likely to be in arrears.

Industry asked clarifying questions regarding transfers of ownership and FDA's enforcement of penalties for companies in arrears. Industry expressed concern regarding whether any subset of companies would see an increase in fees and raised concerns of unintended consequences, such as companies requesting withdrawal of approved applications which could potentially introduce a drug shortage risk. FDA highlighted aspects of the proposal that could help address these concerns.

No agreements were made at this time.

Move Program Fee Liability Date

FDA proposed modifying the date used to determine the approved ANDA portfolio for program fee purposes (i.e., to establish fee liability and each company's program fee amount for the upcoming fiscal year) to April 1st, so that the date is prior to fee setting, instead of the current October 1st date, which occurs after fee setting. FDA also proposed adding clarifying language that for ANDA transfers to be considered when establishing GDUFA program fee liability, they must be submitted to FDA by April 1st of the preceding fiscal year. FDA indicated that this would enhance FDA's ability to accurately determine fee rates and minimize risk of under-collection due to transfers of ANDA ownership between fee setting and the program fee liability date (i.e., the fee due date) that was also a driver of FDA's per ANDA program fee proposal.

Industry indicated that this seems to be a reasonable operational change, though questions remained about implementation. Industry asked clarifying questions regarding the history of the current process and to better understand how this would work in practice.

No agreements were made at this time.

Closing

FDA and industry summarized the proposals presented during this meeting and confirmed that no agreements were made.

Industry indicated they would follow up with a data request to better understand FDA's proposals and to contribute to their response.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, January 7, 2025. The goal of the meeting will be to discuss details of proposals relating to onshoring and continuing discussions on finance.