Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
January 14, 2026, 9:30am – 12:00pm
Virtual Meeting

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

MEETING SUMMARY

Industry requested time with a small group to discuss the finance proposals in more detail, FDA agreed. Ground rules for these meetings were established, including that this and any future similar meetings will be used for more informal discussion purposes and that formal presentations and positions will be taken to the full group for discussion. No agreements will be made at small group meetings.

Overview

Industry began by discussing shared goals for FDA and industry, including maintaining a sustainable GDUFA program, increasing predictability of fees for both FDA and industry, and maintaining patient access to generic drugs.

Industry shared their principles for thinking about GDUFA fees, explaining that they believe ANDAs can vary in terms of public health impact or workload, fee structure should avoid disproportionate burden on any subset of industry, there is a need for balancing revenue and fee obligation predictability with industry's need for predictable processes, changes should avoid unintentional incentives, fee structure should encourage high quality submissions and changes should not undermine patient access.

Further related to incentives, industry expressed that incentives should be tied to public health priorities and should not disproportionately impact any given fee payer. Industry supports the Administration's priority of increasing domestic manufacturing and highlighted

that there may be better incentives to achieve timely domestic manufacturing outside of user fee authority.

Clarifying Questions and Discussion

Industry asked clarifying questions to better understand FDA's fee setting processes, structure, and timelines. The FDA provided additional details around the process and timeline requirements to Industry.

Industry asked to better understand how and why over and under collections occur. FDA explained that for the annual fee categories, FDA generally expects to have a smaller variance in collections, although some variance is unavoidable. For submission-based fees, more variance against the target is common because submissions can be difficult to predict. Industry asked how companies in arrears are handled and how firms in arrears impact companies that are paying fees appropriately. FDA explained the framework for statutory penalties for nonpayment of fees and indicated that fee setting accounts for estimated arrearages.

Industry provided a data call to FDA last week to get a better understanding of how FDA's proposals related to finance would be operationalized. FDA asked clarifying questions to better understand what information would be helpful to industry and provided feedback on which questions FDA was not in a position to answer. FDA indicated that they would provide a spreadsheet that industry can use to model different target revenue allocation scenarios under FDA's proposal.

Industry asked clarifying questions regarding FDA's financial proposals. Related to FDA's proposal to add an inflation adjustment to the foreign facility fee differential, industry expressed concern that continuing to adjust the differential for inflation over time could become cost-prohibitive in terms of fee payor participation in the U.S. market.

Industry also asked clarifying questions to better understand FDA's proposal to reset the base year for certain fee-setting calculations to FY 2025. FDA explained the rationale behind the proposal to reset the base year.

Closing

Industry indicated that this discussion was helpful and requested that additional small group meetings be considered. Industry further conveyed that the requested additional data is necessary to inform its evaluation of FDA's finance proposals. FDA indicated it is working to provide some data as quickly as possible and is expected to provide some initial information within a week.

FDA emphasized that it is difficult to respond to many of industry's proposals before understanding what industry is looking for in terms of its finance-related proposals.