



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

March 26, 2026, 10:00am – 3:00pm

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
Jonathan Collins	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)
Kiran Krishnan	AAM (Apotex)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)

MEETING SUMMARY

Structured Review

Industry asked clarifying questions about the timeline for applying the new enhancement related to missed goal dates. FDA indicated this would begin to apply in GDUFA IV, meaning that applications with missed goal dates in GDUFA III would not receive a new goal date under this enhancement. Industry inquired as to whether the opportunities under the enhancements could be afforded to ANDAs with missed goal dates that remain pending into GDUFA IV. FDA indicated that the agency would be willing to offer such applicants a meeting (consistent with its current practice) if any missed goal date ANDAs from GDUFA III remain pending into GDUFA IV. FDA also indicated it will strive to take action on any such ANDAs as quickly as possible and noted that language could be added to the draft commitment letter to reflect this. Industry indicated they felt that would be valuable. Industry also shared that

they plan to provide edits to the commitment letter language that FDA previously shared, including to add further guardrails around when FDA will extend the goal date under section II(B)(1)(c)(i) of the commitment letter to indicate that FDA will strive to not extend the goal date unless post-mid-cycle IR responses contain new data or testing. FDA noted that these were not the only situations where such a goal date extension could be appropriate, and mentioned that, for example, the timing of the IR response from industry could also warrant a goal date extension to provide adequate time to review the response and take action on the ANDA. Industry acknowledged this and noted they were proposing to add to current proposed language and not replace it. FDA agreed to review language from industry once provided.

Industry indicated they would provide suggested edits at a later date.

Complex Data Issue Commitment Letter (CL) Language

FDA proposed CL language reflecting the agreement regarding complex data issues. Industry asked clarifying questions and indicated that they would provide suggested edits at a later date.

Controlled Correspondence CL language

FDA proposed CL language regarding the agreement that industry will provide pre-assigned ANDA numbers for controlled correspondences and for a new 90-day controlled correspondence category. Industry asked clarifying questions and indicated they would provide suggested edits at a later date.

Early Facility Inspections for US Facilities

Industry asked clarifying questions regarding how this program would work for ANDA applicants listing multiple facilities. FDA clarified that the requestor would be the facility. Industry indicated alignment in principle on this proposal. FDA indicated it would provide commitment letter language for review at a later date.

Post PAI Meetings

Industry asked whether FDA would track post PAI meetings. FDA indicated the agency would track meetings separately by program (e.g., PDUFA and GDUFA meetings would be separately tracked). Industry indicated alignment with this proposal. FDA indicated it would provide commitment letter language for review at a later date.

Finance

FDA presented a counterproposal for a full finance package for GDUFA IV. FDA summarized previous tentative agreements including moving the program fee liability to May 1 and excluding facilities with a first reference in a new ANDA approval after May 1 from the upcoming FY facility fee, updating the foreign facility fee differential from \$15,000 to

\$25,000 (without an inflation adjustment for the differential amount), and making coversheets available August 15 and increasing visibility related to payment timelines on the GDUFA website.

FDA indicated alignment with industry's most recent proposal for a shift in fee allocation percentages to 26% to the ANDA submission fee and 43% to the program fee. FDA reiterated that it needed information on what industry is proposing related to encouraging high quality submissions and fee collections and deploying resources to maximize public health impact in order to effectively respond to those ideas.

FDA also provided a revised proposal for the previously discussed facility fee waiver for a one-time GDUFA ANDA application fee waiver for domestic companies if both the finished dosage form (FDF) manufacturer(s) and the active pharmaceutical ingredient (API) supplier(s) identified in the ANDA are located in the U.S. This waiver would be available for one-time use for firms where neither they nor any affiliate had received the waiver before for any ANDA. Industry asked clarifying questions about how FDA defines a domestic company. FDA indicated it would be domestic companies that are established in the U.S. and do not have any foreign affiliates. Industry asked if a DMF could list both U.S. and non-U.S. facilities and still be considered. FDA indicated that it will look into how the process will work in cases where the DMF lists multiple facilities, including foreign facilities, but a generic applicant referencing that DMF is only referencing the domestic facility. Industry asked about how this would work in the event of a later site transfer of API or FDF manufacturing to a foreign facility. FDA indicated it would take that into consideration when operationalizing the waiver and suggested that the waiver could require that the batches relied on for ANDA approval be manufactured at the domestic FDF facility with API from the domestic facility. Industry also inquired whether conversion of an advanced intermediary to API at a domestic facility could qualify, and FDA indicated it would consider the question further. Industry asked if FDA will track and report on the use of this waiver. FDA indicated that it would. Industry reiterated previous comments that incentives that could most strongly encourage domestic manufacturing are largely outside of FDAs remit.

Regarding industry's request to discuss FTE transparency and hiring accountability, FDA proposed a process for tracking, reserving, and reporting on potential payroll underspending, if any. FDA indicated this is intended to address industry's concern that fees intended to support GDUFA review staff may not support payroll and industry's concern that these funds could be applied to other GDUFA-allowable expenses. FDA also indicated this proposal increases the likelihood of a downward Operating Reserve Adjustment (which would reduce fees) if FDA has not restaffed by the start of GDUFA IV. Industry asked clarifying questions about payroll and shared services, which FDA responded to.

To improve shared understanding of financial topics, FDA also proposed a new annual technical staff meeting, which could take place during a quarterly implementation meeting (QIM) or be held as a standalone meeting, and for which public meeting minutes would be

generated to provide public transparency. FDA proposed that this could replace the existing financial public meeting, as these meetings require significant effort to prepare for and are not highly attended. FDA also noted that this technical staff meeting could provide a better mechanism for industry to gain an understanding of the program's financial status, including staffing, as well as an opportunity for them to ask questions on the financial report and five-year plan. FDA also proposed adding granularity to financial reporting on FDA GDUFA fee spending and additional context of funding shifting to shared services. Industry asked clarifying questions about how time is reported for shared services, and FDA explained that there are models based on consumption of services by the various centers.

FDA also proposed CL language regarding making coversheets available August 15th and increasing the visibility of payment timelines. Industry indicated they would review the language and provide a response or agreement at a later date.

FDA indicated that it would absorb the cost of FTEs for the new negotiated enhancements within the existing overall target revenue levels, including for the post PAI meetings discussed that day.

Additional Industry Topic

Following up on considerations raised during the March 20th finance small group, industry suggested a pilot program to support development and review of products described by industry as "high value generics" which could include enhancements like more meetings, prioritized review, and dedicated review teams. FDA asked industry to clarify where the gaps are regarding products that would be considered "high value" by industry and proposed for inclusion in such a pilot but would not be covered by other enhancements, such as the meetings enhancements, or would not currently be subject to prioritization, and also asked if industry could provide more clarity about what is meant by "high value." Industry indicated that the current priority review works well and that the negotiated meetings enhancement are also a positive step. Industry indicated the proposal was for a pilot priority designation request and if the product meets the criteria there would be benefits/features with faster review timelines, more face-to-face meetings, and dedicated review teams. FDA understood industry's intention and indicated the agency would bring a response to the following meeting.

ANDA Meeting Program CL Language

FDA proposed CL language to reflect the agreements on the changes to meetings. Industry asked clarifying questions and indicated they would provide suggested edits at a later date.

Closing

FDA and industry summarized conversations and confirmed topics for the next meeting.

NEXT MEETING

The next meeting is scheduled for Friday, March 27, 2026. The goal of that meeting will be to complete discussions on finance and all other outstanding topics.