



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

March 18, 2026, 9:30am – 3:00pm

Virtual Meeting

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
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)
Joel Carpenter	BPTF

MEETING SUMMARY

Stakeholder Feedback

FDA shared the following feedback from stakeholders from the March 10th meeting:

- Stakeholders requested clearer understanding of the resource asks (IT, FTEs) from the FDA for each of the proposals under discussion expressing concern that industry is asking for more from FDA without giving them more resources. FDA clarified this is not the case.
- Stakeholders raised concerns about generic drug quality, bioequivalence, contamination, and foreign manufacturing quality; they questioned why bioequivalence testing improvements and inspection enhancements are out of scope for negotiations. Stakeholders requested performance metrics linking program

outcomes to public health impact. Specific metrics include recalls, inspection results, and quality issues. Stakeholders continued to support FDA's data fidelity proposal as a mechanism to address these issues within the user fee framework.

- Stakeholders questioned the new prioritization criteria for applications from manufacturers with US-based operations and expressed concerns about potential public health consequences of prioritizing drugs based on manufacturing location rather than patient needs.
- Stakeholders expressed concerns about the structure and timing of public input opportunities. Stakeholders stated there was a lack of clarity about when and how stakeholder input can influence negotiations and reiterated interest in being included in the negotiations process.
- Stakeholders sought clarification on what topics are within scope for negotiations versus what requires congressional action or falls under FDA's independent scientific authority.

Structured Review

FDA proposed commitment letter language to reflect the agreed-upon aspects of the structured review proposal including language around consults, an option for applicants to choose a single 90-day goal date extension, commitments around missed goal dates, labeling review process enhancements, and breaking out reporting on certain metrics by complex vs. non-complex generics. Industry asked clarifying questions and indicated they would bring proposed revisions to a future meeting.

FDA also presented a response to industry's proposal for changes to FDA's template for Regulatory Project Managers to provide ANDA review status updates. Industry indicated they would have preferred a further breakdown but ultimately agreed to FDA's proposal. FDA provided commitment letter language to reflect this change for review following the meeting.

FDA also asked industry for more information on the further clarity what industry is seeking regarding the use of imminent action under section II(B)(3)(iii) of the current commitment letter. Industry acknowledged this and indicated they would bring a response at a later date.

Forfeiture Determinations

FDA shared that they appreciated the revisions industry made to their proposal to try to address FDA's concerns and the information industry provided about why the issue is important for subsequent applicants in planning for a timely launch post-approval. FDA shared that there is ongoing litigation related to forfeiture of 180-day exclusivity and that given this, the agency is unable to commit to a new program enhancement related to forfeiture at this time.

Industry indicated they understood FDA's concerns and agreed to discontinue pursuing their proposal but asked that FDA keep in mind the information industry had provided about the

benefits an enhancement could have when FDA is in a better position to consider this issue. FDA agreed to keep this in mind.

Data Fidelity

FDA presented an additional counter proposal on data fidelity, in response to industry's counter proposal on February 11, 2026. FDA indicated that a single 90-day extension would not provide adequate time for FDA to determine the potential scope and impact of identified data fidelity issues. Given industry's concern about timely resolution, FDA indicated the agency intends to resolve data fidelity issues within the initial 180-day extension as often as possible and agreed to assign a second goal date of 180 days if the issue is not resolved during the first extension, but proposed to remove applications for which this provision is invoked from the denominator for performance reporting purposes. Regarding addressing other outstanding deficiencies not directly impacted by the data fidelity issue, FDA indicated it would continue to send a DRL as in current practice and continue to send IRs for issues that appear to be unrelated to the data fidelity concerns after the midcycle. FDA cautioned that there is a possibility that an applicant could expend effort to respond to such an IR that may ultimately not resolve the issue or may not have been needed depending on the outcome of the data fidelity investigation. Regarding industry's proposal for a public workshop, FDA agreed to hold a public workshop or webinar to provide additional insight into best practices to avoid data fidelity issues. Regarding concerns about the nature and breadth of the trigger for an extension, FDA agreed to issue a MAPP describing the kinds of specific triggers that could lead to a conclusion that a data fidelity issue has been identified. FDA also indicated that it is open to alternative language to describe the subject of this proposal to address industry's assertion that data fidelity is not an issue unique to generics but applies to all marketing applications.

Industry suggested that aspects of FDA's proposal were similar to the approach being taken for missed goal date ANDAs and suggested the process being proposed for those ANDAs could be leveraged for these issues as well. Industry also asked whether there were any subset of data fidelity issues that could be addressed in a shorter timeframe, especially if the issue is identified early in the review cycle. Industry expressed concerns that a MAPP and workshop focused only on generics could inadvertently create a misperception that this is only an issue in the generics space, which is not the case, as data fidelity issues also occur for other FDA-regulated products.

FDA and industry caucused and FDA suggested the agency could fit aspects of this proposal under the missed goal dates approach, if a provision were made for these applications to not count as misses for performance metrics. Industry suggested they were aligned with this approach. FDA agreed to bring proposed commitment letter language to a later meeting. Industry asked whether FDA would be willing to still communicate identification of an issue prior to the goal date to facilitate transparency and more efficient resolution and FDA agreed to look at aspects of notification before the goal date.

Early Facility Inspection for US Facilities

FDA provided a revised proposal on early facility inspections for US facilities with revised eligibility criteria for consideration of inspection requests including that the facility is a domestic facility and is expanding production for a new generic product that is planned for submission in an original ANDA, ANDA supplement, or DMF, the facility has not had an FDA-classified surveillance inspection in the prior 3 fiscal years, and the facility is not in pOAI or OAI status, and is not in arrears on its GDUFA Facility Fees at the time of the request. FDA also agreed to a performance goal where FDA would complete 90% of granted inspections before the planned application or DMF Submission date, proposed the request be submitted at least 9 months but no more than 24 months before planned ANDA submission, and agreed to issue grant/deny decisions within 30 calendar days of the request in response to industry's previous counterproposal.

Industry asked questions regarding resources required and logistics of this process. FDA indicated their expectation that this would not require additional resources. Industry also asked questions about reporting metrics, and FDA proposed providing such information at future QIMs. Industry indicated they would bring a response at a later date.

Drug Master Files (DMF)

Industry indicated they are generally aligned with FDA's revised proposal on DMF Prior Assessment and that they would like to move forward with the 6-month timeline for complex active pharmaceutical ingredient DMFs (meaning the number of requests FDA would accept in this category would be lowered to 4). Industry provided alternative language regarding DMF IRs and FDA provided another alternative. Industry agreed to FDA's alternative.

Clarification of FDA's Position on Additional FTEs

Because of questions industry asked, FDA took a moment to clarify the agency's position in the context of these GDUFA IV negotiations with respect to agreeing to enhancements that would require additional FTEs. FDA clarified that, while FDA's initial proposals had been scoped to be resource neutral given cost sensitivity concerns highlighted by industry, the agency is not constraining its response to industry proposals to only what would be resource neutral. FDA indicated it is focusing on hiring review and investigator staff and believes that in doing so it can reinvest funding to support staffing needed for some GDUFA IV enhancements, but that is not a limitation on what FDA could agree to. FDA also noted that to the extent the agency had raised concerns about any given proposal, it was on programmatic grounds and not because the agency was not able to agree to proposals that could require additional FTEs. FDA further explained that given the time to train FTEs and that some areas require significant expertise, additional FTEs are not always the solution to

a problem. Industry responded that it had understood FTE increases were off the table and indicated it was helpful to have this clarification on FDA's position.

Facility Inspection and Classification: pOAI Alerts

Industry presented a counter proposal related to pOAI alerts involving a single 90-day extension. Industry reiterated that they are open to a goal date extension in the event of a pOAI alert occurring late in a review cycle under certain conditions. Industry proposed that the goal date be extended 90 days from the time of the pOAI alert (generally the close of the inspection) if FDA notifies the applicant when a pOAI alert is issued, and further proposed that FDA and industry continue to work to resolve any minor deficiencies by the original goal date, that FDA only extend the goal date when it becomes clear that the inspection will not be classified by the original goal date, and if necessary FDA use imminent action if additional time is needed to route the ANDA for approval after an inspection is classified as NAI or VAI.

FDA asked how industry proposed this would work in the event the final classification was OAI (which is the final classification for the clear but modest majority of pOAI alerts), because in this case imminent action could not be used, and the single 90-day extension would not provide adequate time for FDA to take an action (i.e., issue the CRL). Industry indicated they had not considered that possibility and they would bring a response at a later date. FDA agreed that the proposal under which unrelated disciplines would work toward resolving any minor deficiencies by the original goal date was reasonable.

With respect to industry's request to be notified of pOAI alerts, FDA explained its intention was to issue a notification that the goal date is being extended referencing the relevant section of the commitment letter regarding pOAI alerts.

Facility Inspection and Classification: post PAI meetings

FDA presented a proposal for how the process for post PAI meetings could work, in response to industry's inquiry on March 13. FDA indicated that this process would parallel one being discussed in PDUFA negotiations and that if industry would like to proceed, the programs would need to be parallel for operationalization purposes. FDA indicated that the scope of the post PAI meetings would be to discuss inspection findings that could impact approvability; the applicant could be in attendance if there is authorization by the inspected facility; FDA may opt to defer comment on acceptability of the facility's proposed corrective actions and whether they would adequately address issues observed during the inspection bearing on the application's approvability; the goal date may be extended in certain circumstances; and that agreeing to this program enhancement would require resources.

Industry indicated appreciation for this proposal. Industry suggested these meetings could follow the meeting structure being discussed in these negotiations. Industry asked if reporting could be done separately for GDUFA versus PDUFA. FDA indicated they would track

metrics separately for each program. Industry requested more details on timelines and logistics for these meetings. FDA agreed to bring that information to the next meeting.

Standard Information in ANDA Submissions

FDA proposed commitment letter language regarding its proposal to standardize some information in ANDA Submissions. Industry agreed to the language.

Closing

FDA and industry discussed which topics should be on the agenda for the next meeting and indicated they would confirm the following day.

NEXT MEETING

The next negotiation meeting is scheduled for Friday, March 20, 2026. The purpose of that meeting will be to continue discussions on program efficiency and data fidelity.