Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
March 20, 2026, 11:00am – 1:00pm
Virtual Meeting

PURPOSE

To continue discussions to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA		Industry	
Kathleen Davies	CDER	Giuseppe Randazzo	AAM
Kimberly Taylor	CDER	Scott Kuzner	AAM
Tasha Ray	CDER	Andrew Zacher	AAM (Amneal)
Alison Lyndaker	CDER	Kiran Krishnan	AAM (Apotex)
Jonathan Collins	CDER	Nimi Chhina	AAM (Teva)
Kristin Davis	CDER	Jess Greenbaum	AAM (Sandoz)
Rob Lionberger	CDER	Gil Roth	PBOA
Kendra Stewart	CDER	Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Martha Nguyen	CDER	Joel Carpenter	BPTF
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		

MEETING SUMMARY

CGMP Compliance Communication Tools

FDA provided a response to industry's counter proposal on CGMP Compliance communication tools.

Regarding industry's proposal that FDA execute site inspections within 5 years and meet this objective 95% of the time and should an excursion occur, develop a mechanism to escalate the risk ranking to ensure the site would become a top priority, FDA explained that the agency uses a risk-based inspection schedule, based on statutorily-specified risk factors, as required under section 510(h)(3)-(4) of the FD&C Act and strives for coverage of all drug/drug product sites within a 5-year period. FDA noted that changing the statutory risk factors or risk schedule established under section 510(h) is out of scope of negotiations.

Regarding industry's proposal for FDA to exclude foreign Health Authority Inspection reports from the risk matrix assessment, FDA shared that this cannot be excluded because one of the statutory risk factors that FDA must take into account is whether the establishment has been inspected by a foreign government or foreign regulatory agency under a Mutual Recognition Agreement, per section 510(h)(4)(E).

Regarding industry's proposal that FDA provide a mechanism for a manufacturer to notify FDA of a site's expansion or reconfiguration such that the change would be considered in the risk assessment, FDA explained there are existing mechanisms for this.

Regarding industry's proposal to enhance inspection classification letters to include a date range, FDA agreed.

Regarding industry's proposal to require FDA to issue a Form FDA 4003a after each CGMP inquiry and enhance Form FDA 4003a to indicate closure of the inquiry, FDA further clarified that Form FDA 4003a is specific to section 704(a)(4) records requests and under established agency policy (as reflected in the applicable SMG and Form 4003a), it is only used to confirm receipt of records requested under section 704(a)(4). FDA further clarified that other types of RRAs are not covered by this form. FDA also stated that changing Form FDA 4003a is out of scope of GDUFA negotiations, including because Form FDA 4003a is used for section 704(a)(4) requests across FDA programs.

Industry confirmed their understanding of FDA's non-agreement with their proposal outside of the date range addition. FDA shared there is another process that provides similar information to what industry is requesting. Industry requested FDA share that information, and FDA agreed.

Structured Review

FDA asked industry to provide more information about what they are looking for in terms of their request for further clarity on the use of imminent action when there are one or more small issues remaining in an ANDA that in FDA's judgment may be resolved within 60 days after the goal date. Industry explained they were looking for information to help them better understand how FDA determines what qualifies for imminent action under this commitment letter provision, and that illustrative examples (including examples of small issues) would also be helpful. FDA indicated it would commit to developing a MAPP. Industry inquired whether industry input could be considered prior to publication of the MAPP. FDA indicated this was feasible. FDA indicated that it would send industry draft commitment letter language to review.

Facility Inspection and Classification: pOAI Alerts

Industry indicated they understand FDA's need for additional time when a pOAI alert occurs and refined their proposal under which, other disciplines would continue to work towards the original goal date if there is a pOAI alert, and, if the inspection remained unclassified and

there were no outstanding major deficiencies as of the original goal date, FDA could extend the goal date, calculated as 120 days from the pOAI alert. FDA indicated it was aligned that under these circumstances other disciplines would continue to work towards the original goal date and FDA would consider how to operationalize this, including when the goal date would be formally extended. In terms of industry's request for notification when there is a pOAI alert such that the goal date could be extended, FDA indicated that there is a relevant notification that can be sent to the applicant.

Overall FDA and industry agreed on the approach and FDA indicated that it would draft commitment letter language.

Facility Inspection and Classification: Post PAI Inspection Meetings

FDA outlined a process for post PAI inspection meetings and eligibility criteria. Industry asked clarifying questions about how eligibility criteria and meeting grant/deny decisions would work and what communications they would receive related to denials. FDA indicated that it could develop guidance to help industry understand when they are eligible. Industry also asked questions about the length and criteria for potential goal date extensions, and how these would interact with goal date extensions being discussed under structured review. FDA indicated that extensions related to these meetings would be separate from the ones discussed under structured review.

Industry indicated they would bring a response on this topic to the next meeting.

Facility Inspection and Classification: Communication of Intent to Inspect

Regarding industry's proposal that FDA make a timely determination of whether a PAI is needed and if so, notify the applicant, FDA shared that while the agency has internal goals for making a timely determination, the determination is preliminary and can change with more in-depth assessment of the application. FDA indicated that the agency reviewed its processes and based on this review and from FDA's perspective, the internal goals are working well for ensuring PAIs are completed in a timely manner so that ANDA goal dates are met. Industry asked whether FDA is working to conduct timely PAIs when the inspection determination is made early in the cycle. FDA indicated that once it is determined a PAI is needed, this is communicated to OII as quickly as possible, with the aim of having the PAI done around mid-cycle, but also acknowledged that international inspections can take longer to schedule. FDA also expressed concern about the utility of the notification given that preliminary determinations related to PAIs can change. FDA instead recommended that facilities review the compliance program for PAIs, which outlines FDA's risk-based approach to determining whether a PAI is needed, to help assess the likelihood that a PAI will take place for a facility named in an ANDA. FDA also noted that language in the PDUFA commitment letter that industry had flagged that involves notifying an applicant of an inspection is limited to situations where it is necessary to conduct the inspection at a time

when the product identified in the application is being manufactured, and that this is generally only necessary for a large molecule product.

Data Fidelity

Industry proposed to use "complex data issue" as terminology for these issues. Consistent with discussion on March 18, industry proposed using the missed goal date framework from the structured review proposal with certain modifications if a potential complex data issue arises. Industry proposed that applications that FDA identifies as containing a potential complex data issue be excluded from performance goal reporting, and that FDA would separately report the number of impacted ANDAs. Industry also proposed that an ANDA applicant could participate in the missed goal date meeting if the impacted CRO or manufacturing facility provided a letter of authorization. Industry also proposed that FDA develop a MAPP which would describe how FDA identifies potential complex data issues generally and conveys them in public-facing documents. Finally, industry proposed that for facilities that are reclassified from OAI to VAI/NAI status, the procedure under discussion would only be appropriate if the OAI had been based in whole or in part on a complex data issue, as captured in the Form 483 or Warning Letter.

Industry indicated that they were withdrawing the proposal for a public workshop.

FDA shared that it had no concerns with using "complex data issue" for the terminology or with notifying the applicant and agreed with the approach that this process would be invoked if FDA could not issue a CRL by the goal date. FDA also agreed to excluding the impacted ANDAs from performance goal reporting and instead reporting separately the number of impacted ANDAs and agreed that the ANDA applicant could participate in the meeting with a letter of authorization.

Regarding the MAPP, FDA asked clarifying questions and indicated it could be a general MAPP that also addresses the GDUFA-specific processes for complex data issues.

Closing

FDA summarized next steps including that the agency would share commitment letter language related to imminent action within the structured review proposal, industry would respond regarding post PAI meetings, FDA would develop commitment letter language for pOAI alerts, and FDA would develop commitment letter language for complex data issues.

NEXT MEETING

The next meeting is scheduled for Thursday, March 26, 2026. The goal of that meeting will be to continue discussions on program efficiency and data fidelity.