Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
March 13, 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)
Malik Imam	CDER	Joel Carpenter	BPTF
Martha Nguyen	CDER		
Susan Rosencrance	CDER		
Ashley Boam	CDER		
Bhagwant Rege	CDER		
Erin Skoda	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

Industry provided an additional counter proposal in response to FDA's most recent response to industry's proposal on this topic. Industry proposed that for legacy domestic API sites with static product offerings, FDA execute site inspections within 5 years, meet this objective 95% of the time, and develop a mechanism to escalate the risk ranking in the agency's risk-based site selection model to ensure the site would be prioritized for inspection in the event this metric is not met. Industry also proposed FDA exclude foreign Health Authority Inspection reports as a factor in FDA's risk model and for FDA to 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 indicated that the agency expects to be fully caught up inspecting domestic API sites at the end of this fiscal year or shortly thereafter, but that FDA could not commit to a percentage that may conflict with the statutory requirement to follow the risk-based approach. FDA also indicated the agency would not be willing to exclude foreign health authorities inspections from the model.

Industry also proposed FDA always issue a Form FDA 4003a (FDA Records Receipt Confirmation) after each CGMP related records request under section 704(a)(4) of the FD&C Act and enhance Form FDA 4003a to clearly indicate closure of the inquiry. Industry explained that while their members had received Form 4003a's, many of them did not understand what this form was and suggested training could be helpful. FDA inquired about whether industry provides any training for their members on this. Industry agreed there could be opportunity to better communicate with members. Industry also shared that there were times when the form was not received. FDA asked if there were recent examples of this, noting the agency has worked in recent years to consistently provide this form, consistent with the agency's Staff Manual Guide (SMG) on this topic. FDA indicated that industry could refer to this SMG and requested the trade group communicate with their members that the form will be provided. FDA also noted that they would consider industry's feedback on this topic and provide a response at a future meeting.

Facility Inspection and Classification

Industry indicated there were two remaining follow up items on this proposal including a meeting after pre-approval inspections (PAI) and the approach to extensions when pOAI alert occurs during the review cycle.

Industry indicated they would like to discuss a meeting after a PAI and before the final recommendation is made.

With respect to the proposed meeting after a PAI, Industry indicated it would like to continue discussing a meeting after the inspection and before the final recommendation on the application is made. FDA expressed concerns that industry's purpose in seeking this meeting appeared to be to change the agency's mind about a recommendation to withhold approval based on the PAI. FDA noted that when the agency has discussions with a facility after a PAI, the purpose is to get the facility on the right track to remediate the issues observed during the inspection and not to change the agency's mind about the recommendation made at conclusion of the inspection, and that it was important that industry understand this. Industry acknowledged this feedback. FDA also noted that such a meeting could require a review clock extension. Industry indicated they will be ready for further discussion next week.

With respect to the pOAI alert topic, industry suggested they were open to an additional goal date extension for pOAI alerts only in certain circumstances where a single 90-day goal date extension would not provide time for a final classification decision. In this scenario, all other

disciplines would work towards the assigned goal date, and, if the inspection remained unclassified as of the goal date, FDA could extend the goal date for the purpose of classifying the inspection and taking action on the application. FDA indicated this seems reasonable. FDA asked Industry for more details about the length of the extension and how it would be applied. Industry agreed to further consider these points. The agency also agreed to consider the information provided and bring this topic back to a future meeting.

No agreements were made at this time.

DMF Prior Assessment

Industry indicated they were largely aligned with FDA's most recent counterproposal on DMF Prior Assessments. FDA proposed commitment letter language including two options for the outstanding topic of whether FDA could complete DMF prior assessments for complex APIs under the same 6-month timeline as other criteria in exchange for lowering the number of requests that would be considered under this category (to 4), versus maintaining the proposed 9-month timeline with the higher number of requests that would be considered (10 requests). Industry had noted a preference for the 6-month timeline and indicated they would consider this in light of the information FDA provided at the meeting about the impact this would have on lowering the number of prior assessment requests considered. Industry indicated they would get back to FDA to confirm they want to move forward with the 6-month timeline for 4 complex API DMFs by next week.

FDA also proposed commitment letter language to address industry's concern that a DMF prior assessment IR could result in a refuse to receive. Industry indicated they would provide a response by next week.

NEXT MEETING

The next meeting is scheduled for Wednesday, March 18, 2026. The purpose of that meeting will be to continue discussions on increasing program efficiency and data fidelity.