Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
February 11, 2026, 9:30am – 2:30pm
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		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Update Prioritization MAPP

In response to a request from industry in a previous meeting, FDA indicated that it could be feasible to include prior approval supplements that contain a BE study and involve a tech transfer to a new US facility in the exception affording prioritization if 2 of the 3 criteria are met during the first three years of GDUFA IV.

No agreements were made at this time.

Classification of REMS Deficiencies

FDA indicated they do not view the issues industry raised as appropriate for a specific commitment in the GDUFA IV Commitment Letter (CL) because the proposed change to

classification of REMS ETASU amendments conflicts with the definition of a major amendment in applicable GDUFA guidance. FDA also shared that preliminary internal discussions highlighted the significant resources involved across the agency for review of REMS with ETASU modifications, particularly for first generics when establishing a shared system, such that it is generally appropriate for these to be classified as major amendments.

In response to industry's concerns, FDA indicated it could internally evaluate whether there are certain types of REMS ETASU modification submissions by approved application holders that are reviewed in a timeframe that would be consistent with a minor amendment clock, which could inform any future updates to relevant guidance and/or MAPPs. FDA also asked industry to clarify whether the issue industry has identified primarily arises in the context of pending generic applicants who are working with the RLD holder to form a new shared system versus with pending generic applicants who are joining an established shared system, and also requested examples from industry of situations where these issues have occurred (in addition to the one example industry has provided). Industry indicated they would provide a response at a later date.

Industry reemphasized that they viewed this proposal as facilitating first cycle approvals. Industry further stated that they disagree that the CL is not an appropriate venue for this, based on the view that the request is for a timeline change versus a change to amendment classification policy.

FDA indicated interest in finding a solution to industry's challenges and emphasized the need for data demonstrating the occurrence of this issue in order to discuss this further as only one example was previously provided. Industry agreed to provide additional data.

No agreements were made at this time.

Assign ANDA Numbers for Controlled Correspondence

Industry provided a counter proposal to FDA's proposal to require pre-assigned ANDA numbers for controlled correspondence, indicating that they generally support efforts to improve efficiency. Industry stated that if they were to agree to use pre-assigned ANDA numbers for controlled correspondence, industry would like FDA to agree to no longer require prior controlled correspondence documents to be included with subsequent controlled correspondences and to update guidance to reflect the change.

FDA noted that if industry agreed to use pre-assigned ANDA numbers for controlled correspondence, the agency could agree to not require that previous controlled correspondences associated with the same pre-assigned ANDA number be provided in subsequent controls, but highlighted that there would be a transition period where copies of previous controls would still need to be submitted if the previous controls did not have a pre-assigned ANDA number. Industry asked about a feedback mechanism during the transition

period to discuss any non-substantive rejections of their controlled correspondence. FDA indicated that quarterly implementation meetings (QIM) could be an appropriate venue.

Industry also asked for clarity on how this would work for controlled correspondence that may affect multiple products. FDA indicated that it would provide more information on this at a future meeting and would clarify in guidance where multiple products would be appropriate if this proposal is agreed upon.

FDA and industry agreed that next steps are to determine commitment letter language.

Mitigate Certain CRs by Extending Goal Dates for pOAI Alerts

Industry stated that they agree with FDA that changes are necessary to address delays associated with pOAI alerts and issuance of CRLs given that not all facilities ultimately classified as OAI and that they support increased transparency, including a mechanism to inform ANDA applicants that FDA has entered a pOAI alert for a facility referenced in an ANDA. Industry indicated that they prefer to use the single goal date extension under their Structured Review proposal and questioned FDA's need for a 120-day period. FDA noted its view that this is a different circumstance and should be discussed separately. FDA also noted that the 120-day period was intended to provide 90 days for final classification and, should the pOAI be the only remaining issue and be resolved to VAI, an additional 30 days for OGD to complete the necessary steps to approve the application.

Industry also proposed an opportunity for post-inspection meetings for facilities. FDA noted that applicants can attend a meeting between the facility and FDA if they have a letter of authorization from the facility. For surveillance inspections, this can occur in a post-Warning Letter meeting. For a preapproval inspection, there is ongoing engagement with the facility after the inspection; applicants could be involved in meetings between the facility and FDA if the facility provides the appropriate authorization for the applicant to attend. In terms of the industry proposal for a meeting between the close of the surveillance inspection and classification of the inspection, FDA explained that is not within scope of negotiations and would be inconsistent with established processes across product types for surveillance inspections. FDA also shared that manufacturing facilities have opportunities to address inspection observations at the close-out meeting with the investigator and in a written Form FDA 483 response. FDA intends to issue draft guidance on responding to Form FDA 483 observations at the conclusion of a drug CGMP inspection that could mitigate some of industry's concerns. Industry disagreed that post-surveillance inspection meetings were out of scope, noting that GDUFA fees are used to support surveillance inspections. Industry also clarified that its proposal included post-PAI meetings. FDA responded that post-PAI meetings would be within scope and noted that fee coverage of an activity doesn't make its substantive elements subject to negotiation.

FDA and industry agreed that further discussions are needed in this area to come to agreement.

Facility Inspection and Classification

FDA provided a response to industry's four-part proposal relating to facility inspections and ANDA approvals in the case of issuance of Major CRLs for facilities that are ultimately classified as No Action Indicated ("NAI") or Voluntary Action Indicated ("VAI").

Industry's first proposal was for FDA to make early determinations regarding whether a Pre-Approval Inspection (PAI) is needed and for FDA to complete the PAI within a specific timeframe. FDA provided feedback that as proposed, this addresses internal processes which FDA does not typically negotiate but that FDA is open to feedback on potential process improvements. FDA pointed industry to its compliance program 7346.832 on Preapproval Inspections, which outlines a process and timeline for determinations of the necessity of conducing a PAI. FDA noted that while the need for a PAI is generally identified early in the review process and the PAI is completed in advance of the goal date so that action on the application can be taken by the goal date, there are times where the need for a PAI can be identified later in the review process based on the specific information in the application.

Industry disagreed that its proposals were out of scope, clarifying that they were proposing timelines to complete externally facing activities (*i.e.*, communication of intent to inspect and completion of the PAI) rather than internal FDA operations. Industry reiterated that ensuring timely communication of FDA's intent to inspect and timely completion of the PAI is critical to providing applicants with greater transparency and predictability, especially in cases where delayed or evolving inspection decisions can materially affect ANDA approval timelines. Industry also clarified that the communication of the intent to inspect would not be binding on FDA but would provide Industry with useful information for planning purposes for applicants to allocate resources, coordinate with facilities, and anticipate potential impacts on review milestones. FDA clarified whether this was in the original proposal or new. Industry confirmed this was not in the original proposal. No agreement was reached.

Industry's second proposal was for an opportunity to discuss inspection findings and corrective action plans before FDA classifies the inspection or makes a withhold approval determination. This topic was discussed in connection with the Mitigate Certain CRs by Extending Goal Dates for pOAI Alerts proposal.

Industry's third proposal was for mitigating Facility-Based Major CRLs when FDA does not classify an inspection by the action date, including expanding the use of imminent action when there are no remaining deficiencies, and shortening the timeline for review of reclassification requests for facility-based major CRL amendments. FDA indicated a preference for the agency's proposal for pOAI extensions because it would provide a shorter timeline in most situations. FDA indicated non-agreement with the proposal to reclassify amendments because this approach would add undesired logistical complexity for FDA and additional uncertainty for the applicant. Industry asked clarifying questions, including what

percentage of pOAI alerts are ultimately classified as OAI; FDA responded that the majority receive OAI classification.

Industry explained they would like to ensure that other deficiencies continue to be worked on by the original goal date when there is an extension due to a pOAI since a goal date extension could also result in extended timelines for all disciplines. FDA indicated it was open to discussing options further.

Industry's fourth proposal was for a public workshop and pilot program to create an interim probationary or conditional facility inspection classification category as an alternative to an OAI classification for certain facilities. FDA stated that the creation of a new inspection classification category would change well-established agency policy and practice regarding inspectional operations, conflict with the ANDA approval standard by negating the consequences of inspection observations warranting OAI classification, and have impacts beyond GDUFA, and thus is not within the scope of negotiations, so a public meeting on this topic would not be appropriate as a commitment. FDA also shared stakeholder feedback in opposition to any changes to inspection classification categories. Industry clarified that such a system would be consistent with other health authorities, although no specific authorities were specified, but agreed that no further discussion is needed on this proposal.

No agreements were made at this time.

Address Data Fidelity Issues

Industry provided feedback on FDA's proposal to extend goal dates by 180 days in the event of a potential data fidelity issue being identified. Industry stated they agree with the critical importance of ensuring data fidelity in all marketing applications; data fidelity is not a uniquely ANDA problem, and Industry is concerned that only addressing this in GDUFA would perpetuate a false narrative that data fidelity is solely an issue with ANDAs, when it can impact all types of marketing applications. Industry also described oversight mechanisms it has in place to ensure data fidelity for manufacturing sites and Contract Research Organizations (CROs). FDA agreed that data fidelity issues can impact all types of applications.

FDA noted there has been a substantial impact on ANDAs requiring more agency resources. FDA explained that the goal was to reduce agency resources being used for reviewing applications that are not approvable due to a potential data fidelity issue, as this takes away resources from reviewing approvable ANDAs.

Industry agreed that transparency is beneficial when a data fidelity issue arises and that this would support timely resolution. FDA explained what was envisioned in the agency's proposal was having a separate letter that would notify applicants that a potential data fidelity issue had been identified, so the applicants could then reach out to their manufacturing and testing sites to gain more insight.

Industry suggested that the goal date extension mechanism in their Structured Review proposal could be used for this and shared concern that in FDA's proposal the goal date would be considered met after the second notification and would not support timely resolution. FDA indicated the intention was to reach a decision within the first 180-day extension, but that the agency could consider offering a second goal date to provide additional predictability. Industry explained that FDA's proposal could effectively extend the goal date by nearly a year, and earlier communication could more expeditiously resolve any issues.

Industry requested clarity around the scope of the trigger for a goal date extension. FDA indicated that this extension would not be used without cause and that specific types of data fidelity issues that would trigger this extension could be defined.

Industry suggested FDA convene a public workshop to solicit industry input on improving policies and processes for handling data fidelity issues. FDA asked for clarity on how this would be helpful, as the root issue is not with respect to FDA's policies and processes but rather with the policies and processes of facilities/sites with data integrity issues. FDA also asked industry about where they see gaps in light of their own oversight efforts for contracted manufacturing facilities and testing sites. Industry described their efforts, and noted it can be difficult to identify issues, including if recent audits of the site, such as by FDA, did not raise issues. Industry also explained that an applicant only has access to the data generated for its own application, whereas FDA can evaluate all data generated by the manufacturing facility or CRO. Industry suggested that the focus of the workshop could be further discussed and that it would be helpful as it could provide an opportunity to hear from FDA on common failings the agency has observed with respect to data fidelity across all marketing applications to help identify additional practices for industry to monitor.

No agreements were made at this time.

CGMP Compliance Communication Tools

FDA provided a response to industry's two-part CGMP Compliance Communication Tools proposal. Industry's first proposal was for FDA to provide a mechanism for a manufacturer to request a surveillance inspection for a site with a static product offering as FDA has proposed for new sites and expanded sites with new-to-site APIs and FDFs. FDA indicated that this would be out of alignment with the existing statutory risk-based surveillance inspection program. FDA instead offered to update the current inspection classification decision letter, which currently includes the date of inspection and outcome, to also include the profiles/operations covered in the inspection and update the inspection classification database to include this information so that a 3rd party could verify the accuracy of such a letter.

Industry indicated that this does not solve the observation that some domestic API facilities appear to have long periods between inspections. FDA acknowledged that there have been

delays and a backlog due to the pandemic and shared that significant progress has been made with respect to inspections of domestic API facilities. Industry indicated that this information is helpful.

Industry's second proposal was to require FDA to formally close out and provide documentation for all CGMP assessments. FDA indicated that Form FDA 4003a is a closeout document that is generated for RRAs (including 704(a)(4) records requests and remote interactive evaluations) and explained that EIRs are generated for inspections. Industry provided feedback that the Form FDA 4003a has been provided to them but this may not always have been consistent. FDA acknowledged this feedback.

No agreements were made at this time.

NEXT MEETING

The next negotiation meeting is planned for Thursday, February 19, 2026. The goal of the meeting will be to continue discussions on program efficiency, reducing number of review cycles, and finance proposals.