Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
March 4, 2026, 10:00am – 4:00pm
In-Person Meeting | FDA White Oak Campus, Silver Spring, MD

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)
Jonathan Collins	CDER	Kiran Krishnan	AAM (Apotex)
Kristin Davis	CDER	Nimi Chhina	AAM (Teva)
Rob Lionberger	CDER	Jess Greenbaum	AAM (Sandoz)
Kendra Stewart	CDER	Gil Roth	PBOA
Malik Imam	CDER	Joel Carpenter	BPTF
Martha Nguyen	CDER		
Susan Rosencrance	CDER		
Ashley Boam	CDER		
Bhagwant Rege	CDER		
Erin Skoda	CDER		
Partha Roy	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Negotiation Status Review

FDA presented an overview of the status of all proposals, including details of next steps. Industry indicated general agreement but said that they would review separately and indicate any disagreement with status following the meeting.

Maximum Daily Dose (MDD)

FDA presented proposed commitment letter language regarding implementation of a public database for MDD values, indicating that the agency would populate the database with at least 500 values by the end of FY 2028, and by the end of FY 2030, it would assess the resources needed to provide and maintain a full coverage database. FDA also indicated that

it would seek public input on the utility of the database and potential improvements, including how to prioritize values for inclusion. Industry asked questions regarding the public input process, including whether there would be opportunities to provide input on the first 500 values, and how FDA would communicate information about the resources needed to maintain the database. Industry explained that certain MDD values are more challenging to calculate than others (*e.g.*, topicals, weight-based dosing, and MDD values that are informed by clinical practice). Industry further conveyed that the initial 500 values would be more meaningful if they were informed by Industry input and included these types of more challenging MDD values. Industry and FDA discussed potential mechanisms to gather Industry input to inform selection of the initial 500 values. Industry indicated they would bring revised proposed language to a later meeting.

Inactive Ingredient Database (IID)

Industry proposed commitment letter language reflecting previously discussed updates to the inactive ingredient database. FDA shared concerns with some aspects of the proposed language, including the timing of updates and the inclusion of a specific timeframe for providing Maximum Daily Exposure information for all inactive ingredients. FDA and industry caucused and FDA provided revised proposed language. After further discussion, FDA and industry agreed on revised language for the commitment letter regarding updates to the IID.

Structured Review

FDA provided responses to outstanding questions from industry regarding FDA's structured review counter proposal. With respect to Filing IR response timeframes, FDA indicated they would be willing to provide industry 8 calendar days instead of the originally proposed 7 calendar days in response to industry's request to change FDA's proposed 7-calendar day timeline to business days. With respect to industry's request to consider alternatives to guidance to provide information on best ANDA submission practices to facilitate earlier consults, FDA indicated that they were open to framing the commitment letter language to provide for guidance or other appropriate alternative communication(s). FDA also proposed that the agency could provide training to industry around best practices to facilitate earlier consults.

With respect to industry's question about whether a single 90-day goal date extension calculated based on the goal date instead of based on the date of the applicant's response to the IR/DRL would be likely to mitigate some of the risk FDA identified of increased minor CRLs, FDA indicated this could mitigate this risk. For missed goal date ANDAs, FDA indicated the agency is willing to offer applicants an opportunity to meet with the agency if the second goal date applied to the missed goal date ANDAs is also missed.

With respect to industry's request that the agency communicate by the original goal date all issues unrelated to the complex issue causing the missed goal date, FDA indicated that this is generally possible for minor deficiencies. However, FDA indicated that communication by

this date this poses issues for major deficiencies that would generally be communicated in a CRL once the complex issue causing the goal date miss is resolved. Industry explained that earlier visibility into major deficiencies is critical, as it would enable applicants to begin to address those issues while the ANDA remained pending past its goal date. Industry indicated that, overall, FDA's responses were helpful and that they will respond when they bring their counterproposal.

Drug Master Files (DMF)

Industry provided an additional counter proposal regarding the DMF Prior Assessment program. With respect to the qualifying criterion related to the timing of expiration of patents and exclusivities relative to the planned ANDA submission date, industry requested that eligibility be expanded to include submissions for which patents/exclusivities will expire within 24 months of the planned submission date. FDA indicated this would likely be feasible.

Industry proposed changes to the language around how many prior assessment requests FDA would accept under the domestic API and complex API criteria to allow for more requests to be accepted at FDA's discretion. FDA caucused and provided alternative proposed language. Industry indicated general alignment.

Industry proposed alternative timelines to FDA's proposal related to the timeframe for complex APIs submitted in DMFs to be reviewed, requesting that these be reviewed in the same 6-month timeframe as other prior assessments. Industry also requested that IR comments be due 4 months after receipt of the prior assessment request as opposed to FDA's proposal of 1 month prior to the planned ANDA submission date. FDA indicated that the shorter timeframe for complex APIs is not feasible due to resource constraints unless a smaller cap is placed on the total number of submissions that would be accepted under the complex API criterion. Industry indicated they would consider this trade-off. FDA also explained why it's important to link the timing of sending IRs to the timing of the planned ANDA submission rather than to the date the DMF prior assessment request was sent. Industry also expressed concern about the potential for IRs related to a DMF prior assessment to impact the receipt decision for the linked ANDA. FDA indicated that it does not anticipate that these IRs related to the DMF prior assessment would impact the filing of the ANDA. FDA also noted that if there are ongoing concerns among industry about the timing of IRs, the agency is still open to its original proposal in which requests for DMF prior assessment (for non-complex) could generally be submitted five months prior to the planned submission date for the linked ANDA and IRs would be provided at the planned ANDA submission date.

No agreements were made at this time.

Pre-Launch Activities Importation Requests (PLAIR) Process

FDA provided feedback on industry's proposal to conduct a workshop to gather input on the potential benefits of expanding the PLAIR program to increase flexibility to enable more timely launches to the benefit of U.S. patients and to use this information to update the PLAIR guidance or generate new guidance. FDA indicated that the agency is not open to addressing a possible expansion to the PLAIR program or a workshop through negotiations, as this is broader than GDUFA. FDA noted its earlier point that eligibility for this program is outlined in FDA's final guidance (the specific content of which the agency does not negotiate) and that the appropriate channels for submitting questions about or suggested changes to the PLAIR program is via the guidance docket or to the office responsible for PLAIR. Industry noted they consider a workshop to be within scope for negotiations but agreed to withdraw this proposal.

ANDA Meeting Program & Controlled Correspondence

Industry presented topics for discussion in response to FDA's counterproposal on meetings, including a proposal for a timeframe by which the meeting would occur in addition to the timeframe for issuance of the preliminary written response. FDA provided a document that outlined these timeframes as well, and FDA and industry generally aligned on meeting scheduling timeframes and the due date for preliminary written responses. Industry proposed changing the meeting type for 3 specific meetings. FDA indicated that some of these changes were possible but outlined challenges with others. Industry also raised concerns about meeting format preferences, indicating that industry and FDA appear to have different perspectives on when face-to-face meetings (i.e., in-person or videoconference) versus Written Responses Only (WROs) are appropriate, requesting additional guardrails on conversion and a reconsideration opportunity be considered. FDA indicated the agency generally honors applicants' meeting format requests for meeting requests involving complex, novel issues when the meeting package is complete, though the agency needs discretion to manage workload.

Industry raised procedural questions regarding conversions of meeting requests to Controlled Correspondence, including when FDA would make such decisions and what guardrails exist on FDA's discretion.

FDA and industry agreed that there are a few remaining points for discussion, including a characterization of what FDA refers to as "novel" issues in the meeting context. FDA indicated they would provide proposed commitment letter language for topics discussed at this meeting on Friday March 6th.

NEXT MEETING

The next negotiation meeting is planned for Friday, March 6, 2026. The goal of the meeting will be to continue discussions on topics covered during this meeting.