Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
February 4, 2026, 10:00am – 2:00pm
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)
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
Malik Imam	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		

MEETING SUMMARY

Update Prioritization MAPP

FDA presented an alternative aiming to address industry's counter to FDA's proposal to update the prioritization MAPP to be consistent with the ANDA prioritization pilot FDA launched in October 2025. Under FDA's alternative proposal, consistent with Industry's counterproposal, original ANDAs could qualify for a priority review under this new prioritization factor during the first three years of GDUFA IV (i.e., until October 1, 2030) if they met two of the three following criteria: (1) the pivotal bioequivalence (BE) testing was conducted in the U.S. or the ANDA qualifies for a waiver of bioequivalence testing; (2) the finished dosage form (FDF) manufacturer(s) is located in the U.S.; and (3) the active pharmaceutical ingredient (API) supplier(s) is located in the U.S. After October 1, 2030, original ANDAs would need to meet all three criteria to qualify for a priority review. FDA proposed, however, that supplements would need to meet all three criteria to qualify for a priority review under this factor throughout the course of GDUFA IV.

In lieu of including reporting commitments in the Commitment Letter, FDA also proposed that it would provide feedback at the quarterly implementation meetings on the number of requests for prioritization, the number of denied requests and reason for denial, the number of ANDA submissions qualifying for priority review under this proposed prioritization update, information on the basis for qualification for ANDAs meeting only two of the three prioritization factors (*i.e.*, which two qualifying criteria were met), as well as any trends observed over time for ANDAs in this prioritization category (e.g., with respect to average time to approval and first cycle approval percentage) and requested industry also provide feedback at the quarterly implementation meetings on its impact on incentivizing additional manufacturing/BE testing in the U.S.

Industry requested that prior approval supplements that contain a BE study and involve a tech transfer to a new US facility be included in the exception that affords prioritization if 2 of the 3 criteria are met during the first three years of GDUFA IV. FDA indicated that it would consider this.

No agreements were made at this time.

Meetings/Complex Generics

FDA presented a counter proposal that encompasses industry's response to FDA's proposal to streamline meeting timelines and industry's complex generics proposal. FDA began by explaining that FDA's original proposal would constitute a significant revision to the meeting process to make meetings faster and expand meeting opportunities. FDA indicated agreement to industry's proposed Complex Generic Initial Advisory (CGIA) meeting on the 60-day timeline, eliminating contingencies for some meeting types, providing preliminary written responses 5 business days prior to the meeting, and changing the timeline for requesting an enhanced mid-cycle review meeting from 7 to 14 days.

In FDA's initial proposal, a preliminary written response (PWR) would be provided by or before the deadline (e.g., 60/90/120 days), and the meeting would be scheduled 5-10 days afterwards. Industry's counterproposal requested that FDA schedule the meeting by the deadline instead to avoid, for example, a Day 60 meeting becoming a Day 70 meeting. FDA explained its perspective that under its proposal the focus shifts to providing substantive content related to the subject of the meeting request by no later than the deadline and would provide FDA greater flexibility to hold a meeting versus to close things out with a Written Response Only (WRO). FDA emphasized the need to balance timely responses and meeting scheduling logistics with high quality feedback.

For the reasons noted below, FDA indicated non agreement to industry's proposed 3-day goal clarification on meetings; industry's proposal that at a PSUB meeting, industry and FDA could agree on parts of the application that could be submitted 30 days after the receipt of the original application; and industry's proposed internal complex generic product committee. Specifically, FDA indicated that the 3-day goal clarification is not something it is

negotiating as it is already announced as a pilot and is intended to be broadened to other review programs. For the PSUB meeting proposal, FDA indicated that agreeing to the submission of parts of an ANDA after the receipt of the original application would conflict with authority under the FD&C Act regarding ANDA completeness. For the industry proposal of an internal complex generic product committee, FDA indicated that internal agency procedures are a matter of agency discretion that are outside the scope of negotiations. Further, there are already mechanisms that meet the intention of the proposed committee.

Industry asked for clarification as to whether FDA's counter proposal indicated that FDA is not willing to change the dates proposed in its initial proposal FDA confirmed and emphasized that it is focused on ensuring the agency agrees to something achievable and that allows for the agency to provide high quality feedback. Industry also asked clarifying questions regarding the scope of Day 60 Meetings and what would be considered a "follow up" with new questions, including meetings following a response to controlled correspondence.

Industry asked whether the timeline to hold the meeting would be outlined in the commitment letter under FDA's proposal that focuses on the date of the PWR and indicated concern about timelines being extended. FDA indicated that commitment letter language could be considered once there is general agreement on the enhancements being made, and both parties agreed to further discuss and align on the timeline.

Industry noted the importance of predictability in how and when responses will be provided.

No agreements were made at this time.

Controlled Correspondence

FDA provided feedback on industry's controlled correspondence proposal. FDA indicated that administrative corrections are contemplated under FDA guidance but are not a current practice as there is no provision for stopping the clock while such corrections are being made by industry and so utilizing such a procedure is not currently feasible. FDA indicated that this could become feasible if industry agrees that the clock will start on completeness for items that need correction. FDA indicated that information requests (IRs) during substantive review can be made with a clock stop. FDA also mentioned that it has also proposed a mechanism to provide for conversion between controlled correspondence and meetings.

FDA indicated that the agency is willing to consider adding a 90-day tier to controlled correspondence for some specific categories that currently fall under the 120-day tier to align with proposed new meeting timelines. Industry asked whether FDA would be open to discussing the types of controlled correspondence that could be covered by this new tier, and FDA indicated it was amenable to further discussion.

Industry asked whether new Q1/Q2 legislation, IID, and MDD enhancements will reduce the number of controlled correspondences and allow for faster responses and other efficiencies. FDA indicated that while the agency anticipates some reduction in controls as a result, the data does not indicate enough of a reduction to make an impactful change to its control review timelines.

Industry indicated that the challenge with administrative corrections is that the clock restarts after rejections for what applicants view as superficial reasons (*e.g.*, page orientation), delaying receipt of FDA input. Industry suggested discussing options to obviate clock restarts, including quick turnaround IRs. FDA explained that a delay related to industry's resolution of administrative issues would cause downstream delays in the assessment of and response to the controlled correspondences and impact FDA's ability to meet the deadline.

No agreements were made at this time.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, February 11, 2026. The goal of the meeting will be to continue discussions on program efficiency, onshoring, and finance proposals.