



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

March 6, 2026, 11:00am – 12:30pm

Virtual Meeting

PURPOSE

To continue discussions to reauthorize GDUFA.

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Jonathan Collins	CDER
Kristin Davis	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
Martha Nguyen	CDER
Susan Rosencrance	CDER
Ashley Boam	CDER
Angela Granum	OC
Gisa Perez	OC
Josh Brown	OC
Mingham Ji	OC

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Kiran Krishnan	AAM (Apotex)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)

MEETING SUMMARY

Stakeholder Feedback

FDA provided stakeholder feedback from the February 10th Stakeholder meeting.

- Stakeholders support efforts to ensure high quality medications are available and support efforts for consumer access to original manufacturer and supply chain information.
- Stakeholders have sought detailed clarification on industry proposals and their potential impacts on current approval standards and expressed strong opposition to any proposals that would weaken approval standards or reduce FDA's enforcement ability for post-market commitments.
- Stakeholders expressed the importance of public disclosure when FDA identifies quality issues at manufacturing facilities; they emphasized the critical importance of generic drugs to the healthcare system and the need for transparency.

- Stakeholders expressed strong interest in ensuring the generic pathway works effectively due to its significant impact on drug prices and consumer savings; they asked about efforts to improve information access for generic manufacturers and to address patent barriers.
- Stakeholders expressed concern that brand companies making authorized generics might suppress competition.
- Stakeholders strongly supported efforts to provide generic manufacturers with the information and tools needed to bring products to market, emphasizing public health and cost-saving benefits.
- Stakeholders requested information about the budget for managing the generic drug program and where it comes from.

Industry asked whether FDA conveyed to the stakeholders Industry's position that the postmarketing commitment proposal was not intended to and did not change FDA's approval standard. FDA responded that it could provide Industry's position to the stakeholders.

Prioritization MAPP

Industry indicated alignment with the most recent counter proposal. FDA agreed to draft commitment letter language.

Maximum Daily Dose (MDD) Language

Industry proposed modifications to commitment letter language for the MDD enhancement. FDA indicated agreement with the changes.

Forfeiture Determinations

Industry presented a revised proposal for forfeiture determinations following FDA feedback on the original industry proposal. Industry began by reemphasizing the information asymmetry that makes it challenging for subsequent applicants to assess the potential for forfeiture under the failure to obtain tentative approval provision and that the clarity provided by earlier forfeiture determinations can facilitate more timely launches and earlier patient access. In the revised proposal, industry proposed a mechanism by which, in certain specific circumstances, subsequent applicants can request that FDA make a forfeiture determination under the failure to obtain tentative approval provision, and the agency would then make such determinations within 90 days of receipt of the request and post the outcome of the determination on the Paragraph IV Certification List. FDA asked clarifying questions and also noted that the 90-day timeframe would not be feasible. With respect to this proposed timeframe, industry explained that they are seeking to know the outcome of the forfeiture determination 5-6 months prior to the potential earliest lawful approval date for the drug to provide sufficient time to undertake activities necessary for launch. FDA indicated that it would need to discuss the revised proposal internally.

No agreements were made at this time.

Meetings Commitment Letter Language

FDA proposed commitment letter language regarding meeting format, “novel” issues, and Post-CRL Scientific Meetings. Industry asked clarifying questions and agreed to propose alternative language next week.

No agreements were made at this time.

Additional Topics

Industry raised concerns about the recently announced Reviewer Recognition & Excellence Program (RREP) program to provide bonuses to reviewers and asked about implications on the GDUFA program’s financial predictability and operating reserve. FDA indicated awards have always been paid with a mix of user fees and budget authority and that the agency does not expect large impacts on payroll or operating reserve.

NEXT MEETING

The next negotiation meeting is scheduled for Wednesday, March 11, 2026. The purpose of that meeting will be to continue discussions on improving program efficiency and reducing number of ANDA review cycles.