Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
January 7, 2026, 10:00am – 1:00pm
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
Alison Lyndaker	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	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		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Waive Fees for New Domestic Manufacturers

FDA presented a proposal to amend provisions of section 744B of the Federal Food, Drug, and Cosmetic Act to waive annual facility fees for the first three years for companies that break ground in the U.S. to manufacture one or more finished generic drugs or active pharmaceutical ingredients (APIs) domestically. FDA indicated this proposal aims to reduce overreliance on foreign drug manufacturers, which may pose risks to U.S. patient access and national security, e.g., the supply of critical drugs.

Industry asked questions about the definition of breaking ground and how this would be operationalized. FDA explained it is proposing for the fee waiver to apply for the first three years a facility would incur a GDUFA facility fee, which would be after it is first referenced in an approved ANDA. Industry indicated that expanding capacity at existing U.S. facilities, or

retrofitting dormant capacity would be a faster path to increasing domestic manufacturing capacity in the near term as building new facilities takes several years. Industry also provided feedback that since waivers necessitate increasing fees on other facilities to compensate for the loss of revenue, this may subsidize new competition at the expense of existing domestic manufacturers that have already made investments in U.S. manufacturing.

No agreements were made at this time.

Adjust Foreign Fee Differential

FDA presented a proposal to adjust the foreign facility fee differential from $15,000 to $25,000 to account for inflation since the fee was instituted in GDUFA I and adjust the fee for inflation going forward. This would support an increase in unannounced foreign human generic drug inspections and aligns with the Administration's onshoring goals and Executive Order 14293 "Regulatory Relief to Promote Domestic Production of Critical Medicines." FDA noted that the foreign facility fee differential has not been adjusted since the start of GDUFA in FY 2013.

Industry asked questions about outcomes of the ongoing unannounced inspection pilot. FDA indicated that it's too early in the pilot to draw conclusions but that controls are in place for FDA to assess differences in outcomes from announced and unannounced inspections. Industry shared concerns that adjusting this fee for inflation could result in the fee becoming prohibitively costly over time, resulting in companies exiting the U.S. generic drug market.

No agreements were made at this time.

Update Prioritization MAPP to Reflect the ANDA Prioritization Pilot

FDA presented a proposal to update the Prioritization MAPP to add a new prioritization category consistent with the ANDA prioritization pilot to support U.S. generic drug manufacturing and testing that FDA launched in October 2025. Specifically, ANDAs could qualify for a priority review under this proposal if: pivotal bioequivalence testing is conducted in the U.S. or the ANDA qualifies for a waiver of bioequivalence testing; and the finished dosage form manufacturer is located in the U.S.; and the API supplier(s) is located in the U.S.FDA indicated this is intended to incentivize domestic manufacturing and testing to address risks associated with over-reliance on foreign drug manufacturing.

Industry asked questions about the ongoing pilot and indicated that it could provide a greater incentive to manufacture and test products in the U.S. if ANDA submissions could qualify for priority review under the proposal even if they only met a subset of the three criteria.

No agreements were made at this time.

Address Data Fidelity Issues

FDA presented a proposal to modify the commitment letter to provide for FDA to extend the ANDA goal date by 180 days when FDA identifies data fidelity issues related to bioequivalence or bioanalytical data, or associated with a manufacturing facility. This extension would provide time for FDA to evaluate the scope and impact of the data fidelity issues. Under this proposal, FDA would issue a first notification to the applicant that the goal date has been extended when FDA identifies relevant data fidelity issues. FDA indicated that under this proposal, if the impact of the data fidelity issues remains unresolved after 180 days, a second notification letter would be issued to the applicant, and the goal date would be considered met. Under the proposal, with appropriate authorization from the facility or contract research organization (CRO), applicants could also request a meeting with FDA after the issuance of a complete response letter or second notification letter. FDA described the extensive additional work and time required when a potential data fidelity issue is identified and provided examples of findings that could signal data fidelity issues as well as the impact of a data fidelity issue on GDUFA review resources.

Industry agreed with the importance of ensuring data fidelity in marketing applications (whether originator or generic drugs) and asked clarifying questions about how the proposal would address the root causes of data fidelity issues. FDA explained that in addition to saving FDA resources, the proposal could provide incentives to contract with high quality CROs and manufacturers, which would be a step towards addressing the root cause. Industry acknowledged FDA's response but emphasized that Industry already conducts extensive due diligence when selecting CROs and manufacturers.

No agreements were made at this time.

Closing

FDA summarized the proposals presented during this meeting and FDA and industry confirmed that no agreements were made.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, January 14, 2026. The goal of the meeting will be to discuss details of proposals relating to improving program efficiency and continuing discussions on finance.