Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

January 21, 2026, 10:00am – 12:00pm

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
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		
Francis Godwin	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Invoice Timing

Industry presented a response to FDA's counter proposal on invoice timing, where FDA indicated they could not make invoices available August 1st, but could make them available August 15th or the next business day. Industry noted FDA's counter proposal is not in full alignment with industry's original proposal, but indicated it is acceptable provided that FDA ensures language is publicly available highlighting the statutory language that says firms will not be placed on the arrears list until 20 days after the October 1 due date.

FDA indicated agreement to review where language could be added on its GDUFA website.

Update Prioritization MAPP

Industry presented a counterproposal to FDA's proposal to update the prioritization MAPP. FDA's proposal was to update the MAPP to reflect the ongoing pilot that provides for ANDA review prioritization if three conditions are met: (1) pivotal bioequivalence testing is conducted in the U.S. or the ANDA qualifies for a waiver of bioequivalence testing, (2) the finished dosage form (FDF) manufacturer is located in the U.S, and (3) the active pharmaceutical ingredient (API) supplier(s) is located in the U.S. Industry indicated interest in this idea and proposed that ANDAs be eligible for prioritization if they meet any two of the above criteria during FY 2028-2030, while then needing to meet all three criteria to qualify during FY 2031-2032. Industry indicated that this approach would allow time for such activities to move to the US and for industry to be ready when more stringent criteria begin to apply. Industry also proposed that FDA commit to creating a report to assess the impact of the program.

FDA indicated that they might be open to the proposal to allow ANDAs meeting two of the three eligibility criteria to qualify for prioritization during FY 2028-2030 for original ANDA submissions, but that this would be overly burdensome for supplement submissions, given the volume of those submissions and the high number that could qualify if only two of the three criteria had to be met. For this reason, FDA indicated that supplements would need to meet all three criteria to qualify for prioritization, rather than being phased in with only two of the three criteria needing to be met in the first three years of GDUFA IV.

No agreements were made at this time.

US Facility Fee Waiver

Industry indicated that they are not supportive of FDA's proposal to waive annual facility fees for the first three years for companies that break ground in the US to manufacture one or more generic drugs or APIs. Industry indicated that they support incentivizing onshoring of generic drug and API manufacturing but that they believe this proposal would not be an effective incentive because, among other things, it could result in increased fees for existing U.S. facilities in order to make up for the lost revenue, thereby potentially undermining existing domestic manufacturing operations. Industry also suggested that other provisions being discussed in this negotiation would be better suited to achieve the goal of onshoring. .

FDA acknowledged industry's concerns and confirmed that industry did not intend to present a counter to this proposal.

No agreements were made at this time.

Foreign Fee Differential

Industry presented a counter proposal to FDA's proposal to increase the foreign fee differential to $25,000 and adjust for inflation annually. Industry's counter proposal

included a $25,000 fee differential, with no adjustment amount for inflation. Industry indicated the inflation adjustment to this differential risks fees becoming prohibitively costly for a very cost-sensitive industry.

FDA acknowledged industry's counter and did not ask additional questions.

No agreements were made at this time.

Early Facility Inspections for US Facilities

Industry presented a counter proposal to FDA's proposal to allow US facilities without recent inspection history to request a surveillance inspection prior to submission of an ANDA. Industry proposed changing the language describing FDA's proposal from "recent inspection history" to "recent inspection," changes to the timeline to allow for inspections to be completed and classified before submission of an ANDA, a grant/deny decision communication, reporting on the process, and a meeting opportunity when a facility is issued a potential Official Action Indicated (pOAI).

FDA asked clarifying questions to better understand industry's proposal and indicated that many of these changes were likely possible but indicated concern about utility and appropriateness of the meeting opportunity proposed by industry.

No agreements were made at this time.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, January 28, 2026. The goal of the meeting will be to continue discussions on program efficiency and finance proposals.