Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
January 14, 2026, 1:00pm – 3:30pm
Virtual Meeting

PURPOSE

To continue discussions to reauthorize 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		
Natalia Comella	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		
Kim Dettelbach	OC		

MEETING SUMMARY

Forfeiture Determinations and Timelines

Industry presented a proposal for FDA to assess whether a first applicant has forfeited eligibility for 180-day exclusivity under the failure to obtain tentative approval forfeiture provision, by 90 days after the 30-month period provided in statute for the first applicant to obtain tentative approval. Industry also proposed that FDA update its Paragraph IV Certifications List to note the grounds on which forfeiture was assessed and for a process and timeline for making forfeiture determinations publicly available.

FDA asked questions to better understand the intended scope of this proposal in terms of criteria and timeframe, and the problem this would solve. Industry explained that the current forfeiture determination process creates uncertainty as to whether an applicant will be able to receive final approval, complicating and delaying launch preparations and other activities to facilitate market access. As conveyed by Industry, this proposal could improve predictability for both first applicants and subsequent filers, supporting timely access to generics. FDA explained why its policy is to make forfeiture decisions in the context of specific ANDAs that are otherwise eligible for approval, as many factors influence eligibility for exclusivity up to the time an application is ready for approval and thus could render a premature eligibility determination incorrect, and noted the proposal would require a significant increase in resources for these determinations.

No agreements were made at this time.

Pre-Launch Activities Import Requests (PLAIR) Process

Industry presented a proposal for FDA to conduct a public workshop on the PLAIR program to seek input on potential benefits of expanding the program and to consider updating the PLAIR guidance based on the input received, if appropriate. Industry expressed their appreciation for the existing program and current levels of flexibility but would like FDA to explore additional flexibility, particularly related to including Prior Approval Supplements (PAS), the 6-month time period for securing ANDA approval related to the PLAIR request, the timing of quality reviews as they relate to the process, and impacts of relabeling, repackaging, and shipping activities.

FDA asked clarifying questions.

No agreements were made at this time.

Postmarketing Commitments

Industry presented a proposal to revise the commitment letter to include a process for communications related to postmarketing commitments (also referred to by FDA as quality postmarket agreements (QPAs)) and to revise relevant guidance or create new guidance accordingly. As part of the proposal presentation to FDA, Industry provided examples of areas industry suggested could be considered eligible for a QPA under GDUFA.

FDA asked questions, including about the potential for the proposal to weaken the approval standard, the enforceability of the postmarketing commitments as proposed, as well as the potential for the use of such commitments to lead to inequitable treatment of similarly situated applicants. Industry affirmed that the proposal is not seeking to change the approval standard, consistent with how postmarketing commitments are at times used in other product areas FDA also discussed their reasons for differences in approach to postmarketing commitments between the GDUFA program and the PDUFA and BsUFA program, and Industry asked additional questions.

No agreements were made at this time.

Stakeholder Feedback

FDA shared feedback provided at the December 9th stakeholder meeting. The feedback FDA shared included the following:

- Stakeholders want more transparency and public disclosure of inspection results, including for product-specific information to be linked to inspection results in FDA's public dashboard and real-time consumer alerts regarding quality issues.
- Stakeholders view the current stated time frame outlined in FDA's compliance program between inspections and final action letters as potentially too long but acknowledged that FDA can (and often does) take earlier action when necessary.
- Stakeholders desire enhanced tracking and public reporting of inspection completion timelines.
- Stakeholders wanted to better understand what data fidelity issues are.
- Stakeholders are supportive of an effective GDUFA program and want to ensure the program is appropriately resourced but are concerned about the high user fee to budget authority funding ratio.
- Stakeholders requested direct participation in FDA-industry negotiations rather than parallel discussions.

Industry asked clarifying questions regarding what groups attended the stakeholder meetings and provided this feedback. FDA explained and directed industry to the public facing minutes for full attendee lists.

Closing

FDA and industry summarized proposals presented and confirmed that no agreements were made. FDA requested industry provide details on priority level of certain elements of industry proposals to inform FDA's response.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, January 21, 2025. The goal of the meeting will be to continue discussions on onshoring and finance proposals.