Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
November 12, 2025
Virtual Meeting

PURPOSE

To continue negotiations 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		
Rebecca Dowd	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

UFA Standardization

FDA presented two proposals to adjust statutory provisions to standardize certain aspects of fee authority and financial management across user fee programs. Industry asked clarifying questions and indicated they may have additional follow-up questions later. No agreements were made at this time.

Change Filing Language to Clarify Timeframe

FDA presented a proposal to clarify the timeframe listed in the commitment letter related to filing information requests to reflect the actual process used and to align with what was agreed to in GDUFA III negotiations but not fully articulated in the CL. Industry asked clarifying questions. No agreements were made at this time.

Online Database of ANDA and DMF Review Status

Industry presented a proposal to request FDA develop a secure online portal that provides real time ANDA and DMF review status updates to properly authorized parties and discussed the features this portal could potentially have. FDA asked clarifying questions. No agreements were made at this time.

Classification of ANDA amendments addressing REMS Deficiencies

Industry presented a proposal regarding classification and timelines for review of certain amendments to ANDAs regarding Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) including amendments that would not substantively affect the REMS with ETASU requirements. Industry qualified their proposal with circumstances under which certain ANDA amendments would be covered by the proposal, including those that incorporate editorial or grammatical modifications to REMS with ETASU language. FDA asked clarifying questions. No agreements were made at this time.

Closing

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

FDA shared feedback heard during the November 10, 2025, stakeholder meeting including comments from stakeholders regarding the utility of existing performance reporting and what parties are at the table for negotiations. For additional information see minutes from Stakeholder Discussions.[1]

NEXT MEETING

The next negotiation meeting is planned for Wednesday, November 19, 2025. The goal of the meeting will be to discuss details of proposals relating to reducing number of ANDA review cycles and improving program efficiency.

[1] Minutes from stakeholder discussions will be posted at https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032 as they become available.