Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
October 22, 2025, 9:30am-2:00pm
In-Person Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To begin 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		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Welcome and Introductions

Attendees introduced themselves.

Ground Rules

FDA and industry discussed and agreed to ground rules for negotiations to ensure efficiency and consistency. Ground rules included language around meeting conduct, the presentation of negotiation proposals, confirming agreements reached at negotiations, and communication with external parties during ongoing negotiations. Ground rules also cover the timing for presentation of proposal topics for them to be considered during this

negotiation and timing for reaching agreement regarding which proposals are in scope for this negotiation.

Negotiation Process and Scope

FDA presented information on the negotiation's process, and its scope as described in statute.

Perspectives on GDUFA IV

FDA and industry each made opening statements discussing their perspective on successes and challenges in GDUFA III and priorities for GDUFA IV. Industry also raised concerns regarding recent resourcing changes and budgetary constraints that the Agency is facing. Following opening statements, the parties presented their respective proposals for consideration during this negotiation at a high level. Proposals were presented in areas that included the following:

- Revenue: FDA and industry presented proposals regarding the GDUFA fee structure and processes related to fee collection with the goal of ensuring long-term financial stability of the GDUFA-supported generic drugs program, i.e., the agency's human generic drug activities.
- Standardization Across User Fee Programs: FDA presented proposals to adjust statutory provisions to harmonize certain aspects of fee authority and financial management with other user fee programs. Industry did not present any proposals in this area.
- Reduce Number of ANDA Review Cycles: FDA and industry presented proposals to improve processes and provide support to ANDA applicants throughout the application process to minimize the number of review cycles.
- Improve Program Efficiency: FDA and industry presented proposals to improve program efficiency through areas such as streamlining or enhancing communications, providing additional transparency, and standardizing submission format. These efficiency improvements could apply to standard generic drug applications as well as complex generics.
- Data Fidelity: FDA presented a proposal to help address the occurrence of data fidelity issues and enhance transparency around data fidelity issues at manufacturing facilities and Contract Research Organization sites. Industry did not present any proposals in this area.
- Onshoring: FDA presented proposals around creating pathways for incentives for companies that manufacture and/or conduct studies in the US. Industry did not present any proposals in this area. Industry committed to discuss these proposals but noted that more information on elements of these proposals will be needed to determine if these proposals are in scope given the parameters for what is within scope for UFA negotiations.

Closing

FDA and industry verbally summarized next steps and action items, indicating that a planning meeting would occur to align on a schedule for specific proposal details to be presented and discussed going forward. FDA and industry agreed that all proposals presented could be grouped into similar categories and that grouping could be used to plan a schedule of topics to be covered in meetings as well as what might be in or out of scope from the negotiations.

NEXT MEETING

The next negotiation meeting is planned for Thursday, November 6, 2025. The goal of the meeting will be to confirm which proposals are in scope for negotiation and begin detailed discussions of FDA and industry proposals.