



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

November 6, 2025

In-Person Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To continue negotiations to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Jonathan Collins	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
Martha Nguyen	CDER
Susan Rosencrance	CDER
Ashley Boam	CDER
Bhagwant Rege	CDER
Partha Roy	CDER
Rebecca Dowd	OII
Angela Granum	OC
Gisa Perez	OC
Josh Brown	OC
Mingham Ji	OC

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Kiran Krishnan	AAM (Apotex)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Joel Carpenter	BPTF
Claas Gronewold	Darmstadt
Kari Abboud	BASF
Elizabeth White	Evonik

MEETING SUMMARY

Scope Confirmation

Industry presented modifications or additional details for proposals on which FDA had questions regarding scope. Industry also presented one additional proposal on pre-submission facility correspondence after indicating they would like to discuss programs that are not highly used and could potentially be reduced. FDA provided additional feedback on these proposals with respect to scope for the negotiations and FDA and industry agreed that all proposals from both FDA and industry would remain on the table, subject to further discussion about the details of these proposals. Industry agreed to consider FDA feedback with regard to scope when presenting full details on the proposals.

Inactive Ingredient Database (IID)

Industry presented a proposal recommending improvements to the IID. Industry requested changes to the timing of when FDA adds new excipients and other improvements to increase the IID's utility. FDA asked clarifying questions. No agreements were made at this time.

Maximum Daily Dosage (MDD) Posting

Industry presented a proposal requesting FDA to publish MDD values for RLDs (reference listed drugs). FDA asked clarifying questions. No agreements were made at this time.

ANDA Meeting Program Improvements

FDA presented a proposal to streamline the types of meetings available to industry into a structure based on the purpose and timeline needed to schedule and conduct the meeting. FDA suggested that this structure would allow for faster meeting timelines and more efficient meetings. Industry asked clarifying questions and noted their upcoming proposal on Complex Generics will tie into the Agency's meetings proposal. No agreements were made at this time.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, November 12, 2025. The goal of the meeting will be to continue detailed discussions of FDA and industry proposals.