



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

December 4, 2025, 10:00am – 3:00pm

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

PURPOSE

To continue discussions to reauthorize GDFUA (GDUFA IV).

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Jonathan Collins	CDER
Kristin Davis	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
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

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Kiran Krishnan	AAM (Apotex)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Aparna Dagar	AAM (Fresenius Kabi)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Joel Carpenter	BPTF

MEETING SUMMARY

ANDA Process – Structured Review

Industry proposed changes to ANDA review timelines and related processes with the goal of creating more predictable timelines. These included changes to the completeness assessment process, discipline review letter practices, goal date extensions, and labeling review timing. Industry suggested enhancements for imminent actions and ANDAs with missed goal dates (including communication enhancements), and increased transparency throughout the process.

FDA asked clarifying questions.

No agreements were made at this time.

Complex Generics Program

Industry proposed enhancements to FDA-applicant interactions during the development and review of complex generics related to communication, clarity, and consistency of scientific advice and processes to better support complex generics development and review. Building on FDA's proposal to streamline meeting types, industry proposed some modifications to the FDA proposal, including different timelines and inclusion criteria for certain meeting types. Industry also proposed new meeting types including a "faster clarification" opportunity and a complex generic initial advisory meeting.

FDA asked clarifying questions.

No agreements were made at this time.

Controlled Correspondence

Both FDA and industry presented proposals regarding changes to the controlled correspondence program. FDA proposed enhancing the efficiency and consistency of the process by requiring pre-assigned ANDA numbers to be provided when submitting a controlled correspondence.

Industry proposed expanding the allowable types, permitting for amendments to controlled correspondence to correct minor deficiencies, and shortening timelines for controlled correspondence to enhance the speed of responses and reduce administrative delays associated with correcting minor issues.

FDA and industry 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.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, December 10, 2025. The goal of the meeting will be to discuss details of proposals relating to improving program efficiency.