



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

March 27, 2026, 11:00am – 1:00pm

Virtual Meeting

PURPOSE

To continue discussions to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Kristin Davis	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
Susan Rosencrance	CDER
Bhagwant Rege	CDER
Rebecca Dowd	OII
Ivy Sweeney	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

MEETING SUMMARY

Finance

Industry indicated alignment with the fee waiver counterproposal FDA presented at the previous meeting but had some clarifying questions, including about the qualifying criteria, and also about what would happen if an applicant later changed manufacturing facilities to no longer use the ones that qualified them for a waiver. FDA noted that because a company (including its affiliates) could only qualify for the waiver one time, that mitigates some concerns around potential gaming via facility changes and also indicated that the agency is considering language indicating that batches relied on in the qualifying ANDAs need to be produced at the qualifying domestic facilities. In response to questions about which facilities are considered the finished dosage form (FDF) and active pharmaceutical ingredient (API) manufacturing facilities, FDA noted that this is already defined for GDUFA-fee paying purposes and would be used for purposes of the new waiver. Industry asked further clarifying questions about the definition of affiliate. FDA indicated there is no intention to

change the statutory definition and explained existing processes for administering waivers in other user fee programs where affiliates are examined. FDA indicated the language for this would consist of statutory changes, not commitment letter language, and indicated it would draft language and provide it to industry for review.

FDA clarified whether industry was in alignment with replacing the financial public meeting with a technical meeting. Industry indicated alignment.

CGMP Compliance Communication Tools

Industry asked clarifying questions on when remote regulatory assessment reports (RRARs) are provided for records requests. FDA indicated these are generally provided when records requests are conducted in lieu of an inspection (rather than 'in advance' of an inspection). FDA acknowledged the challenge industry is trying to solve and discussed how the proposal for early inspections of US facilities may help. FDA also shared that they are aiming to conduct surveillance inspections at all sites in their inventory within a 5-year cycle. Industry indicated they may ask further clarifying questions outside of negotiations to improve their understanding.

Additional Industry Topic

FDA responded to the discussion initiated by industry the previous day and indicated that FDA would like to continue conversations with industry on any gaps they perceive in terms of products they would consider high value and eligibility for such products for negotiated enhancements like meetings and noted this could be an ongoing topic of conversation at quarterly implementation meetings (QIM). FDA indicated that many of the proposals that had been discussed and aligned on could support the needs outlined by industry. Industry indicated they agree the improvements in the structured review proposal and meetings framework will address some issues and indicated alignment with the approach to continue conversations on any gaps during QIMs.

Commitment Letter Approach

FDA and industry agreed that they will transition to using a secure file sharing platform to finalize the remaining commitment letter language, with this being the last scheduled negotiation meeting.

FDA and industry agreed that for items from GDUFA III being carried over to GDUFA IV that had escalating performance goals over the course of GDUFA III, the FY27 performance goal would be carried forward into the GDUFA IV CL, while other text would be deleted.

FDA and industry discussed a timeline for ratifying the commitment letter.

Closing

FDA and industry summarized outstanding materials to be shared.

FDA and industry indicated they are in tentative agreement, and this will be the last scheduled negotiation meeting.