Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
November 19, 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	Kari Abboud	BPTF (BASF)
Susan Rosencrance	CDER	Elizabeth White	BPTF (Evonik)
Ashley Boam	CDER		
Bhagwant Rege	CDER		
Partha Roy	CDER		
Diana Solana-Sodeinde	CDER		
Francis Godwin	CDER		
Derek Smith	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Inactive Ingredient Database (IID) Examples

To better understand Industry's challenges and proposal, FDA requested to be shown what challenges industry experiences with the IID. Industry provided 3 examples of challenges.

FDA asked clarifying questions. No agreements were made at this time.

Extending Goal Dates When Appropriate After pOAI Alerts to Facilitate First Cycle ANDA Approvals

FDA presented a proposal for a goal date extension of 120 days from the date of a surveillance inspection closure when a potential Official Action Indicated (pOAI) alert affects a facility named in an application, the application does not have other major deficiencies, and the current goal date for the application falls before the 90 day final classification due date for the final Establishment Inspection Report (EIR) classification. FDA outlined that not all inspections resulting in a pOAI alert are finalized as Official Action Indicated ("OAI"). Because of that, FDA said this extension would allow for both time for final EIR classification and, if the final classification is not OAI and there are no other pending review issues impacting approval, for the agency to prepare an approval action instead of sending the applicant a Complete Response Letter (CRL) by the non-extended goal date.

Industry asked clarifying questions. No agreements were made at this time.

Facility Inspection and Classification

Industry presented a four-part proposal relating to facility inspections and ANDA approval in the case of issuance of Major CRLs for facilities that are ultimately classified as No Action Indicated ("NAI") or Voluntary Action Indicated ("VAI"). This included: (1) a proposal for FDA to make early determinations regarding the necessity of and conducting Pre-Approval Inspections; (2) proposal for an opportunity to discuss inspection findings and corrective action plans before FDA classifies the inspection; (3) a proposal for mitigating Facility-Based Major CRLs when FDA does not classify an inspection by the action date, including expanding the use of imminent action when there are no remaining deficiencies, and shortening the timeline for review of reclassification requests for facility-based major CRL amendments; and (4) a proposal for a public workshop and pilot program to create an interim probationary or conditional facility inspection classification category as an alternative to an OAI classification for certain facilities.

FDA provided information on current process and asked clarifying questions.

FDA provided feedback, including concerns about the impact of a proposed new "interim" inspectional classification on programmatic matters beyond those properly subject to these user fee reauthorization negotiations. No agreements were made at this time.

Early Facility Inspection for US Facilities

FDA presented a proposal to allow existing US generic Active Pharmaceutical Ingredient (API) and Finished Dosage Form (FDF) facilities without recent inspection history to request a surveillance inspection in advance of DMF or ANDA submission to potentially reduce the likelihood that a preapproval inspection would be needed after ANDA submission.

Industry asked clarifying questions. No agreements were made at this time.

Closing

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

FDA and industry both indicated forthcoming data requests would be sent to each other requesting data related to the proposals presented.

NEXT MEETING

The next negotiation meeting is planned for Thursday, December 4, 2025. The goal of the meeting will be to discuss details of proposals relating to improving program efficiency.