Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
February 10, 2026
Hybrid Meeting

Participants

FDA		Stakeholders
Mark Ascione	CDER	Michael Abrams – Public Citizen's Health Research Group
Jonathan Collins	CDER	Mike Jones
Kathleen Davies	CDER	Gavin Clingham – Alliance for Patient Access
Rebeccas Dowd	OII	Patricia Kelmar – US Public Interest Research Group (PIRG)
Alison Lyndaker	CDER	Alexander Naum – Generation Patient
Jayani Perera	CDER	Olivia Perry – Alliance for Patient Access
Tasha Ray	CDER	Tess Robertson-Neel – National Center for Health Research
Kimberly Taylor	CDER	Diana Zuckerman – National Center for Health Research
Ivy Sweeney	CDER	

Purpose

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA hold discussions at least monthly with representatives of patient and consumer advocacy groups on their views on the reauthorization of GDUFA and their suggestions for changes to the statutory provisions governing the GDUFA program. These discussions are to take place during the GDUFA reauthorization negotiations between FDA and the generic drug industry.

Welcome and Overview

The FDA outlined the topics for the meeting: follow-up items from previous discussions, drug master file (DMF) assessment and additional enhancements. The next meeting will focus on providing updates on previously discussed topics and provide opportunities for comments on new information from posted meeting minutes.

Stakeholder Comments

Transparency and Public Disclosure of Inspections Follow-up:
FDA provided follow-up related to facilities and inspections/compliance. FDA addressed stakeholder concerns regarding transparency in the generic drug supply chain. FDA reiterated that it is limited by statute regarding what information it can share. The agency shared that they have a legislative proposal in the President's Fiscal Year 2026 Budget to require drug labeling to include the original manufacturer and supply chain information and shared a link to a senate hearing which occurred on January 29th where FDA emphasized their desire for this transparency. Stakeholders asked how they could support these proposals. FDA clarified that these proposals are proceeding through a separate legislative process, rather than through GDUFA negotiations

Post-Marketing Commitments:
Stakeholders requested clarification on FDA's concerns about industry proposals regarding post-marketing commitments, particularly potential impacts on approval standards and enforceability. Stakeholders emphasized strong opposition to any proposals that would weaken approval standards or lower FDA's ability to enforce post-market commitments. FDA explained that the generic drug space differs from innovator products regarding post-marketing requirements. FDA clarified that existing mechanisms address situations where issues arise during review, such as inspection findings, through review clock extensions and other pathways.

DMF Assessment:
Stakeholders asked whether FDA is experiencing issues with the current DMF program requiring resolution or if the focus is on minor improvements. FDA responded that the program has been functioning well, and discussions with industry focus primarily on transparency improvements, coordination during review cycles, and communication optimization. FDA emphasized that discussions are focused on identifying opportunities to enhance transparency and communication between DMF holders and applicant holders.

Additional Enhancements:
Stakeholders expressed strong interest in ensuring the generic pathway works effectively due to its significant impact on drug prices and consumer savings. They asked about efforts to improve information access for generic manufacturers and address patent barriers.
FDA confirmed the agency is working with industry to provide educational opportunities for companies submitting generics, improve review process transparency and communication, and facilitate timely approvals. FDA acknowledged that while patents present challenges, they fall outside of the agency's authority. However, FDA is working to identify and address relevant challenges within the review process.

Stakeholders also asked about resources for generic manufacturers regarding excipients and alternative ingredients. FDA noted that the inactive ingredients database is the subject of a proposal in negotiations, with industry requesting enhancements to improve user-friendliness and provide greater transparency about drug products and drug substance components. Stakeholders strongly supported efforts to provide generic manufacturers with the information and tools needed to bring products to market, emphasizing public health and cost-saving benefits.

Stakeholders raised concerns about patent barriers and suggested enhanced collaboration between FDA and the Patent and Trademark Office. They referenced previous efforts to establish a working group where FDA could share drug expertise with patent examiners and suggested that both PDUFA and GDUFA funds could support this collaborative work.

Stakeholders asked about the evolving landscape of generic drug manufacturing and potential impacts on market competition. Stakeholders raised concerns about public disclosure when FDA identifies quality issues at manufacturing facilities. They emphasized the critical importance of generic drugs to the healthcare system and the need for transparency. FDA referred stakeholders to earlier discussion about legislative proposals aimed at broadening certain of the agency's disclosure authorities relevant to such issues.

Other:
Stakeholders requested information about the budget for managing the generic drug program. FDA committed to consulting with finance staff about what information can be disclosed and offered to provide a more detailed discussion at a future meeting. FDA emphasized that the agency works to manage the generic drug program in a fiscally responsible manner.

Stakeholders requested updates on previously discussed topics and how stakeholder feedback has been incorporated. FDA agreed to provide a high-level summary at the next meeting. Stakeholders also asked about the process and timeline following the final stakeholder meeting. FDA explained the following steps: drafting and ratifying the commitment letter package, agency clearance, posting a Federal Register notice, hosting a public meeting for stakeholder feedback, making any necessary changes, submitting to Congress, and conducting briefings for Congress before reauthorization. Stakeholders can submit written comments or make public statements at the public meeting with advance sign-up.

Stakeholders asked about coordination with other user fee programs. FDA explained that PDUFA, GDUFA, and MDUFA are being negotiated simultaneously with hopes to wrap up in late March/early April. While programs share the same reauthorization deadline and staff are coordinating for efficiency and policy consistency (where appropriate), public meetings will occur at different times because each program has different ratifiers and may finish negotiations at different times.

Stakeholders were encouraged to email questions or comments to the GDUFA Reauthorization inbox between meetings.