Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
January 13, 2026
Hybrid Meeting

Participants

FDA		Stakeholders
Mark Ascione	CDER	Michael Abrams – Public Citizen's Health Research Group
Thamar Bailey	CDER	Gavin Clingham – Alliance for Patient Access
Jonathan Collins	CDER	Brett Howard – US Pharmacopeia
Kathleen Davies	CDER	Mike Jones
Malik Imam	CDER	Patricia Kelmar – US Public Interest Research Group (PIRG)
Rob Lionberger	CDER	Alexander Naum – Generation Patient
Alison Lyndaker	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

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 meetings, review of negotiation meeting minutes, and stakeholder comments on ANDA development and complex generics. FDA noted that due to holiday schedules, updates on facility inspection details were not yet available, and stakeholder feedback had not yet been provided to industry but would be shared during the week of the meeting.

Stakeholder Comments

Follow-Up Items:
Stakeholders sought clarification on industry's proposal for a secure online portal to provide real-time ANDA review status updates. FDA explained this would allow applicants to check application status themselves rather than contacting review division staff. Stakeholders suggested that some status information could be valuable to physicians and patients for treatment planning and requested consideration of public disclosure of certain milestones.

Stakeholders raised concerns about patent barriers that delay generic drug market entry and asked whether proposals to help generic developers overcome patent obstacles have been discussed in negotiations. FDA directed stakeholders to the meeting minutes to learn what has been discussed during negotiations.

Stakeholders raised concerns about generic drugs found to be non-equivalent after market approval, referencing recent media coverage. Questions were raised about FDA resources dedicated to addressing such issues and whether user fees could support enhanced monitoring and public notification. FDA noted that information about specific products had been published on FDA's website prior to media coverage and provided the website where additional details can be found.

Stakeholders requested clarification on FDA's proposal to extend goal dates by 120 days when facilities receive pOAI (potential Official Action Indicated) status near application goal dates. Stakeholders expressed concerns about potential delays with inspections and requested transparency if such changes are implemented. FDA explained this would potentially prevent issuing complete response letters for applications that might otherwise be approvable, allowing time for final facility classification determinations and potentially enabling faster approvals.

Stakeholders expressed concerns about industry's proposal for a public workshop and pilot program to create an interim or conditional facility inspection classification category. Stakeholders characterized the classification as potentially dangerous and a policy decision requiring public comment processes. They emphasized the need for public involvement in any such discussions to ensure patient safety and prevent manipulation by industry of their inspection classifications.

ANDA Development:

Stakeholders inquired about patient and consumer involvement in generic drug development, similar to processes for brand-name drugs. FDA described existing patient listening sessions conducted by the Office of Generic Drugs on topics such as inhalation products and dermatology products, typically organized through outreach to patient advocacy groups. Stakeholders suggested broader participation opportunities for consumer groups with public health expertise beyond disease-specific advocacy, particularly around patient-centered outcomes and research.

Stakeholders requested quantitative information about generic approvals, budgetary data, and the impact of proposed changes to help evaluate GDUFA IV proposals. Stakeholders expressed concern about potential budget cuts and requested concrete information about FDA's current performance, resource constraints, and rationale for proposed changes. FDA acknowledged these concerns and noted efforts are underway to thoughtfully consider what

works well, what needs improvement, and what is reasonably achievable while sustaining a strong program.

Complex Generics:
Stakeholders sought clarification on the definition of complex generics, distinguishing them from biosimilars. FDA explained that complex generics include products with complex active ingredients (such as GLP-1 peptides), drug-device combination products, and/or formulations that are challenging to develop, particularly when patent landscapes prevent exact duplication of brand products. Stakeholders expressed support for complex generic development support.

Stakeholders emphasized the importance of addressing healthcare affordability and identifying therapeutic areas with high public health spending that lack generic alternatives. They requested that FDA identify barriers to generic competition where stakeholder advocacy could be helpful and provide perspective on systemic challenges affecting access to affordable medications.

Other:
Stakeholders requested information about coordination between different user fee reauthorization processes. FDA explained that negotiation leads, program management staff, and review teams coordinate across user fee programs to ensure consistency and harmonization where appropriate.