Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
November 10, 2025
Virtual Meeting

Participants

FDA		Stakeholders
Mark Ascione	CDER	Michael Abrams – Public Citizen's Health Research Group
Jonathan Collins	CDER	Gavin Clingham – Alliance for Patient Access
Kathleen Davies	CDER	Mike Jones
Malik Imam	CDER	Patricia Kelmar – US Public Interest Research Group (PIRG)
Robert Lionberger	CDER	Alexander Naum – Generation Patient
Alison Lyndaker	CDER	Tess Robertson-Neel – National Center for Health Research
Tasha Ray	CDER	Diana Zuckerman – National Center for Health Research
Kimberly Taylor	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

FDA provided clarification on the scope of the monthly meetings. FDA clarified that the agency's intention is to hear from public stakeholders on topics relevant to negotiations, particularly those related to the generic drugs program, while noting limitations on what can be shared about specific negotiation details.

The agency outlined the planned meeting schedule and topics that will be discussed based on stakeholder prioritization: ANDA review and performance reporting for the current meeting, user fee management and fee structure plus facilities and inspections for December, development and complex generics for January, followed by drug master file (DMF) assessment and additional enhancements in February.

The agency also clarified that negotiations are statutorily mandated to occur between FDA and regulated industry, meaning this structure cannot be modified for purposes of conducting the current negotiations.

Stakeholder Comments

ANDA Review:

Stakeholders inquired about alternative equivalent evaluation methods and shared concerns that diverse communities, including young adults and various racial and demographic groups, may not be adequately represented in these alternative approaches. FDA explained that alternative approaches focus on product comparisons rather than clinical study designs with transparency provided through product-specific guidances.

Stakeholders inquired about post-market surveillance capabilities, manufacturing quality issues, and the adequacy of current monitoring systems. They asked about the frequency of quality issues, inspection capabilities, and whether user fees could better support post-market evaluation activities. FDA explained the current pharmacovigilance systems, marketplace testing, and various response mechanisms available when issues are identified.

Stakeholders inquired about how quickly safety information and labeling changes are communicated to consumers and implemented across generic products. FDA explained the current processes for label updates during application review and post-approval periods.

Performance Reporting:

Stakeholders expressed concerns about the current performance reporting framework, arguing it focuses excessively on procedural timing measures rather than meaningful public health outcomes. They requested reporting of public health indicators such as estimated cost savings from new generic drug approvals, metrics related to drug quality and safety, and information about whether the right generics are reaching the market to support healthcare affordability. Stakeholders emphasized that current reports are not satisfying or interpretable to the public who are both taxpayers and beneficiaries of the generic drug program.

Other:

Stakeholders reiterated interest in having joint meetings with industry stakeholders regarding reauthorization of GDUFA rather than separate sessions.

Stakeholders discussed their perspectives on the current appropriations to user fee ratio.