Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
December 9, 2025
Hybrid Meeting

Participants

FDA		Stakeholders
Mark Ascione	CDER	Michael Abrams – Public Citizen's Health Research Group
Jonathan Collins	CDER	Mike Jones
Kathleen Davies	CDER	Patricia Kelmar – US Public Interest Research Group (PIRG)
Rebeccas Dowd	OII	Alexander Naum – Generation Patient
Angela Granum	CDER	
Alison Lyndaker	CDER	
Gisa Perez	CDER	
Tasha Ray	CDER	
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

The FDA outlined the topics for the meeting: user fee management and fee structure, and facilities and inspections. Future topics will include development and complex generics, drug master file (DMF) assessment and additional enhancements.

Stakeholder Comments

Negotiation Minutes Clarification:
Stakeholders sought clarification on the definition of "data fidelity" and proposals to address related concerns. FDA explained this refers to uncertainties around the reliability of data collected by FDA during inspection or assessment by FDA from a facility that produces generic products.

One stakeholder mentioned navigation challenges with FDA's website, noting difficulty locating and distinguishing between different types of meeting minutes. FDA explained the layout of the site. Stakeholders also requested improved clarity of both stakeholder and negotiation meeting minutes to allow them to verify stakeholder input was captured by FDA and relayed to industry.

Facilities and Inspections:
Stakeholders raised concerns regarding transparency and public disclosure of inspection results. They requested more specific information be provided to the public about which products are implicated when facilities receive negative inspection results and suggested real-time alerts for consumers about quality issues.

Stakeholders expressed concerns about the ways FDA currently displays inspection results that could indicate a facility is out of compliance. FDA shared that there is a public inspection dashboard. Some stakeholders reviewed the dashboard during the meeting and explained their desire for the this dashboard to include or link to specific product information that a consumer would purchase or be prescribed.

Questions were raised about the timeframe outlined in FDA's compliance program between inspections and final action letters, with stakeholders suggesting this may be too long for public safety considerations. Stakeholders acknowledged FDA's explanation that action could be and is taken earlier when necessary but requested better tracking and public reporting of inspection completion timelines.

User Fee Management and Fee Structure:
Stakeholders expressed their desire to ensure GDUFA's financial sustainability and repeated their perspectives on the ratio of user fee to budget authority funding.

FDA explained current challenges that contribute to under-collecting fees against target revenue. Stakeholders expressed support for improving FDA's ability to collect intended fee revenue to ensure the agency can fulfill its regulatory duties effectively.

Other:
Stakeholders continue to advocate for direct participation in negotiations rather than parallel discussions.

FDA will consider inviting FDA subject matter experts to future public stakeholder meetings to address specific technical questions related to facilities and inspections.

FDA will continue to share stakeholder feedback with industry negotiators.

FDA encouraged stakeholders to submit additional questions and comments via GDUFAReauthorization@fda.hhs.gov between meetings.