Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
March 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	Patricia Kelmar – US Public Interest Research Group (PIRG)
Angela Granum	CDER	Alexander Naum – Generation Patient
Alison Lyndaker	CDER	Olivia Perry – Generics Access Program
Tasha Ray	CDER	Tess Robertson - Neel
Kimberly Taylor	CDER	Suzanne Robotti – Medshadow

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 outlined the topics for the meeting: Follow-up items from previous GDUFA negotiations meeting minutes and follow-up questions from previous topics. FDA noted that negotiations are scheduled to end at the end of March, and if they continue into April, another stakeholder meeting will be scheduled. Otherwise, this represents the final stakeholder meeting of the current negotiation cycle.

Stakeholder Comments

Budget and Staffing:
Stakeholders requested a clearer understanding of the resource needs for IT and FTEs from the FDA for each of the proposals discussed. Stakeholders expressed concern that industry is asking for more from FDA without providing adequate resources. FDA clarified that the proposals it presented to industry were resource neutral. FDA explained that they are working to address under-collection issues from GDUFA III with their proposals to allow for some enhancements to be made under current funding levels. Discussions regarding any resource needs for industry proposals have not concluded.

Inspection and Quality:

Stakeholders raised concerns about bioequivalence, contamination, and foreign manufacturing quality; they questioned why bioequivalence testing improvements and inspection enhancements being “out of scope” for negotiations. FDA explained that scientific standards and the inspectional paradigm are not and should not be negotiable with industry, but that they are addressing related issues through proposals such as data fidelity and enhanced communication processes during inspections. Stakeholders continued to support FDA’s data fidelity proposal as a mechanism to address these issues within the user fee framework.

Performance Metrics and Transparency:
Stakeholders reiterated their requests for performance metrics that link program outcomes to public health impact. They requested metrics on recalls, inspection results, quality issues and other safety-related data to be more closely coupled with GDUFA performance reporting. FDA acknowledged existing dashboards that track this information and stated they conveyed stakeholder concerns to industry.

Prioritization MAPP:
Stakeholders questioned the proposal for new prioritization criteria for applications from manufacturers with US-based operations. Stakeholder expressed concerns about potential public health consequences of prioritizing drugs based on manufacturing location rather than patient needs. FDA clarified that onshoring is one of multiple prioritization criteria (including drug shortages and high-need patient populations) and was put forward in response to an executive order.

Stakeholder Engagement:
Stakeholders expressed concerns about the structure and timing of public input opportunities. Stakeholders stated there was a lack of clarity about when and how stakeholder input can influence negotiations. Stakeholders asked about the process for proposing pilot programs to FDA and reiterated their interest in being included in the negotiations process. FDA explained the formal mechanisms for stakeholder input, including public meetings before negotiations begin, public dockets, and these monthly stakeholder meetings. FDA reiterated that all proposals were placed on the table on the first day of negotiations and that stakeholder feedback from these meetings is communicated to industry and informs FDA's approach to proposals.

Process and Scope:
Stakeholders sought clarification on what topics are within scope for negotiations versus what requires congressional action or falls under FDA's independent scientific authority. FDA explained that negotiations focus on processes and procedures rather than scientific standards or enforcement authority. Questions were also raised about pilot programs and how stakeholders might propose new initiatives. FDA clarified that pilot programs can be initiated outside of negotiations but may be formalized through the UFA reauthorization process when resources are needed.