Generic Drug User Fee Amendments (GDUFA) Reauthorization

Public Stakeholder Meeting
October 14, 2025
Virtual Meeting

Participants

FDA		Stakeholders
Mark Ascione	CDER	Brett Howard – US Pharmacopeia
Kimberly Taylor	CDER	Gavin Clingham – Alliance for Patient Access
Tasha Ray	CDER	Olivia Perry – Alliance for Patient Access
Kathleen Davies	CDER	Michael Abrams – Public Citizen's Health Research Group
Jonathan Collins	CDER	Mike Jones
		Samantha Sears – National Consumers League
		Alexander Naum – Generation Patient
		Tess Robertson-Neel – National Center for Health Research
		Diana Zuckerman – National Center for Health Research
		Patricia Kelmar – US Public Interest Research Group (PIRG)
		Lisa Apolis

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 background on the GDUFA program, reauthorization negotiations process, and intention of these meetings. The agency outlined the history of GDUFA reauthorizations (GDUFA I through GDUFA III) and explained that negotiations with industry occur every five years, with stakeholder input gathered through initial public meetings, dockets, stakeholder meetings, and final public meetings.

FDA clarified the scope of these monthly meetings, noting that procedural questions, public stakeholder input on meeting topics, and comments on publicly released meeting minutes are within scope, while specific negotiation details, ongoing proposals, and agreements made to date remain out of scope.

Stakeholder Comments

Attendees asked clarifying questions on the scope of these meetings according to the statute. Attendees requested FDA regularly provide clarification on meeting minutes if attendees find them unclear. Stakeholders expressed concerns about transparency and the

need for more context to provide meaningful input. Stakeholders emphasized the importance of performance metrics that evaluate public health impact, including quality measures and benefit-to-cost ratios. There was particular interest in ensuring the public is informed about generic drug quality issues when problems arise.