



Prescription Drug User Fee Act (PDUFA) Reauthorization

Stakeholder Meeting with FDA

May 20, 2026 | 10:00 am - 10:30 am

Virtual Format

MEETING PURPOSE

To confirm the conclusion of FDA-Industry PDUFA negotiations and highlight opportunities for public engagement in the clearance process.

MEETING SUMMARY

The seventh PDUFA VIII Reauthorization Public Stakeholder Consultation Meeting was held on May 20, 2026, bringing together FDA officials and patient and consumer advocacy groups to confirm the conclusion of FDA-Industry negotiations. FDA staff confirmed that the final negotiations meeting had been held, marking the close of negotiations. FDA staff also restated the purpose and accomplishments achieved through this meeting series and reshared an overview of the reauthorization process timeline and opportunities for continued public engagement through formal comment periods and public meetings.

Patient and consumer advocacy groups asked FDA to consider hosting brief meetings to explain technical content to stakeholders when there are public comment opportunities related to PDUFA documents or programs. Participants also asked for clarification on whether FDA would be publishing the recommended statutory changes, in addition to the commitment letter. FDA agreed to take these requests under consideration, as both requests would differ from past practices. Following the comment period, FDA staff thanked public stakeholders for their participation in this series.

Next Steps

FDA staff shared an overview of the reauthorization process timeline and opportunities for continued public engagement, including a public docket and public meeting.

PARTICIPANTS

STAKEHOLDERS

Alexander Naum

Annie Kennedy

Anthony So

Brianna Greeno

Brittany McKelvey

Cara Tenenbaum

Chanel Press

Cynthia Bens

Generation Patient

EveryLife Foundation for Rare Diseases

Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), Johns Hopkins Bloomberg School of Public Health

Breakthrough T1D

LUNGeivity Foundation

National Organization for Rare Diseases (NORD)

Breakthrough T1D

Personalized Medicine Coalition

Emily Anderson	Physicians Committee for Responsible Medicine
George Eastwood	Emily Whitehead Foundation
Ian Kremer	LEAD Coalition
Isabelle Xu	Center for Science in the Public Interest
Jamie Sullivan	EveryLife Foundation for Rare Diseases
Jeff Allen	Friends of Cancer Research
Kathryn "Taylor" Livelli	1Day Sooner
Mark Fleury	American Cancer Society, Cancer Action Network
Mary Hilley	Humane World for Animals
Michael Jones	n/a
Michael T. Abrams	Public Citizen
Michelle Adams	NORD
Patricia Kelmar	U.S. PIRG
Patrick Wildman	Lupus Foundation of America
Rachel Chon	The Cure Starts Now Foundation
Ryan Fischer	Foundation for Angelman Syndrome Therapeutics
Shion Chang	National Health Council
Sophia Phillips	Doctors of America
Tess Robertson-Neel	National Center for Health Research
Therese Ziaks	Yale School of Medicine

FDA

Andrew Kish	CDER
Christine Hunt	OGC
Emily Ewing	CDER
Pamela Acero	CDER
Jason Bunting	CDER
Sau Lee	CDER