Prescription Drug User Fee Act (PDUFA) Reauthorization

Stakeholder Meeting with FDA

March 27, 2026 | 9:00 am - 10:00 am

Virtual Format

MEETING PURPOSE

To gather stakeholder perspectives on PDUFA VIII topics, specifically regarding Chemistry, Manufacturing, & Controls (CMC).

MEETING SUMMARY

The fifth PDUFA VIII Reauthorization Public Consultation Meeting focused on Chemistry, Manufacturing, & Controls facility lifecycle approaches. The session brought together patient and consumer advocacy groups to discuss a proposed program designed to limit preventable manufacturing-related complete response (CR) actions through enhanced transparency and earlier engagement between FDA and industry. The presentation outlined how facility assessments and inspections may identify deficiencies that may not be correctable within user fee timelines, leading to complete response letters and delayed approvals. Stakeholders expressed strong support for the proposed preventive approach while raising questions about data transparency, resource allocation, Active Pharmaceutical Ingredient (API) manufacturer compliance with applicable requirements, and the proposed program's scope across therapeutic areas.

Chemistry, Manufacturing, & Controls

Chemistry, Manufacturing, & Controls encompasses FDA's assessment and inspection of manufacturing establishments to ensure compliance with requirements, application commitments, and data accuracy. As part of drug application review, FDA evaluates whether facilities can manufacture products to preserve identity, strength, quality, purity, potency, stability, and bioavailability. The Agency issues complete response actions when manufacturing establishments fail to meet requirements, and deficiencies are not satisfactorily corrected within the user fee clock timeframe.

FDA's presentation at the meeting outlined the proposed PDUFA VIII CMC Facility Lifecycle program, which aims to decouple or mitigate manufacturing facility risks that could lead to complete response actions through enhanced transparency and engagement. The lifecycle approach focuses on earlier shared understanding of manufacturing facility expectations,

proactive facility readiness for evaluation and inspection, and transparent communication enabling earlier issue identification and resolution.

Stakeholder questions during the discussion period focused on data transparency and resource implications. Multiple participants inquired about data sharing, including percentages of applicants with deficiencies, severity levels, time to resolution, and complete response rates, particularly organized by disease categories. Stakeholders also inquired about whether the proposed program's scope addresses manufacturers of Active Pharmaceutical Ingredient (API) compliance with applicable requirements and supply chain integrity. There was particular concern about foreign manufacturer compliance rates. Participants sought clarification about how the proposed program would accommodate rapidly evolving technologies in rare disease and cell and gene therapy development, and whether earlier engagement timelines would be flexible enough for these specialized areas. FDA generally shared that it plans to share information on program impact to application actions during an envisioned workshop, that the scope of the program intends to cover all drug manufacturers (including API manufacturers) that are relevant to application assessment, and that the early engagement opportunities would apply to all PDUFA products including cell and gene therapy products.

Perspectives on the proposed program shared by stakeholders were overwhelmingly positive, with participants expressing strong support for the prevention-focused approach rather than reactive enforcement. Representatives from multiple organizations praised the shift to preventing problems before they occur, acknowledging that prevention is easier than correction. Participants appreciated the lifecycle evaluation focus and the potential to reduce surprise complete response letters that have impacted their communities. However, concerns emerged regarding resource allocation and potential tradeoffs, with some stakeholders expressing worry about staffing constraints and the need for additional staff to support this proposed program. Those stakeholders expressed a need for transparency about what existing programs might be affected by any shifts in resourcing. FDA confirmed that additional resources would be needed to implement the proposed program and that FDA will maintain existing standards and obligations.

Next Steps

The final PDUFA VIII stakeholder consultation meeting is tentatively scheduled for April 20, 2026, and FDA plans to present an overview of the proposed PDUFA VIII agreement, discuss next steps for reauthorization, and outline avenues for continued public engagement.

PARTICIPANTS

STAKEHOLDERS

Alexander Naum	Generation Patient
Ashleigh Tharp	National Multiple Sclerosis Society
Brianna Greeno	Breakthrough T1D
Cara Tenenbaum	National Organization for Rare Disorders

Chanel Press	Breakthrough T1D
Cynthia Bens	Personalized Medicine Coalition
Diana Zuckerman	National Center for Health Research
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
Janet Krommes	Doctors for America
Jeanne Ireland	The diaTribe Foundation
Jon McCord	Physicians Committee for Responsible Medicine
Kara Berasi	Haystack Project
Kaylin Bower	On a Mission for Multiple Sclerosis LLC
Mark Fleury	American Cancer Society, Cancer Action Network
Mary Hilley	Humane World for Animals
Michael T. Abrams	Public Citizen
Michelle Adams	NORD
Naomi Maxwell	Humane World Action Fund
Patricia Kelmar	U.S. PIRG
Paul Melmeyer	Muscular Dystrophy Association
Rachel Chon	The Cure Starts Now
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
Tod Guidry	LUNGevity Foundation

FDA

Amy Ramanadham	CDER
Andrew Kish	CDER
Christine Hunt	OGC
Danielle Villata	CDER
Emily Ewing	CDER
KaLonna Maull	CDER
Kate Greenwood	OGC
Mahesh Ramanadham	CDER
Pamela Acero	CDER
Jason Bunting	CDER
Sara Abdollahi	CDER
Sau Lee	CDER
Sonday Kelly	CBER