Public Meeting on the Recommendations for Prescription Drug User Fee Act (PDUFA) Reauthorization

September 16, 2026

9:00 – 9:05 am	**Welcome and Introduction** **Nana Adjeiwaa-Manu**, Center for Drug Evaluation and Research (CDER), FDA *Meeting Moderator*
9:05 – 9:10 am	**Opening Remarks** **Grace Graham**, FDA *Deputy Commissioner for Policy, Legislation, and International Affairs*
9:10 – 9:20 am	**PDUFA Background and Overview of Recommendations** **Andrew Kish**, CDER, FDA *Director, Office of Program and Strategic Analysis*
9:20 – 9:45 am	**Pre-Market Review: Proposed Enhancements** **Mary Thanh Hai,** CDER, FDA *Director, Office of New Drugs* **Annetta Beauregard,** Biotechnology Innovation Organization (BIO) *Senior Vice President, Science and Regulatory Affairs* **Kristy Lupejkis**, Pharmaceutical Research and Manufacturers of America (PhRMA) *Vice President and Chief of Staff, Science and Regulatory Advocacy*
9:45 – 10:00 am	**Post-Market Safety: Proposed Enhancements** **Amy Ramanadham,** CDER, FDA

Director, Drug Safety Operations

Annetta Beauregard, BIO
Senior Vice President, Science and Regulatory Affairs

Ryan Kaat, PhRMA
Deputy Vice President, Law

10:00 – 10:10 am **Break**

10:10 – 10:30 am **Chemistry, Manufacturing, and Controls: Proposed Enhancements**

Sau (Larry) Lee, CDER, FDA
Deputy Director of Pharmaceutical Quality

Annetta Beauregard, BIO
Senior Vice President, Science and Regulatory Affairs

Ryan Kaat, PhRMA
Deputy Vice President, Law

10:30 – 10:55 am **Finance: Proposed Enhancements**

Josh Barton, Office of Finance, Budget, and Acquisitions, FDA
Director, Resource Capacity Planning Staff

Steve Berman, BIO
Vice President, Science and Regulatory Affairs Strategy

Kristy Lupejkis, PhRMA
Vice President and Chief of Staff, Science and Regulatory Advocacy

David Spangler, Consumer Healthcare Products Association (CHPA)
Senior Vice President, Legal, Government Affairs & Policy

10:55 – 11:10 am **Other Topics: Proposed Enhancements**

Andrew Kish, CDER, FDA
Director, Office of Program and Strategic Analysis

Steve Berman, BIO
Vice President, Science and Regulatory Affairs Strategy

Kristy Lupejkis, PhRMA
Vice President and Chief of Staff, Science and Regulatory Advocacy

11:10 – 11:25 am **Break**

11:25 – 12:40 pm **Public Stakeholder Perspectives**

Steve Wosahla, Children's Cancer Cause

Marc Yale, International Pemphigus and Pemphigoid Foundation

Tingting Zhang, Hear2Care

Megan Miller, Critical Path Institute

Reshma Ramachandran, Yale Collaboration for Regulatory Rigor, Integrity, and Transparency

Thomas Hwang, Brigham and Women's Hospital; Harvard Medical School

Kara Berasi, Haystack Project

Diana Zuckerman, National Center for Health Research

Jon McCord, Physicians Committee for Responsible Medicine

Jeff Allen, Friends of Cancer Research

Tim Scott, Biocom

Suzanne Robotti, MedShadow Foundation

Jamie Sullivan, The RARE Foundation

Andrew Coats, on behalf of Bruce Carroll for Telix Pharmaceuticals (U.S.)

Ryan Fischer, Foundation for Angelman Syndrome Therapeutics

Mary Hilley, Humane World for Animals

Patricia Kelmar, U.S. PIRG

Taylor Livelli, 1Day Sooner

Alexander Naum, Generation Patient

Erin O'Quinn, Parkinson's Foundation

Michael Abrams, Public Citizen

Kathryn Lowell, NORD

12:40 – 12:45 pm **Closing Remarks**

Andrew Kish, CDER, FDA
Director, Office of Program and Strategic Analysis