



U.S. FOOD & DRUG
ADMINISTRATION

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

September 16, 2026

9:00 – 9:05 am	Welcome and Introduction
9:05 – 9:10 am	Opening Remarks
9:10 – 9:20 am	PDUFA Background and Overview of Recommendations
9:20 – 9:45 am	Pre-Market Review: Proposed Enhancements
9:45 – 10:00 am	Post-Market Safety: Proposed Enhancements
10:00 – 10:10 am	Break
10:10 – 10:30 am	Chemistry, Manufacturing, and Controls: Proposed Enhancements
10:30 – 10:55 am	Finance: Proposed Enhancements
10:55 – 11:10 am	Other Topics: Proposed Enhancements
11:10 – 11:25 am	Break
11:25 – 12:25 pm	Public Stakeholder Perspectives
12:25 – 12:30 pm	Closing Remarks

This is a draft agenda and is subject to change. FDA will post an updated agenda before the public meeting.