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

September 28, 2021

9:00 a.m. **Welcome and Introduction**

Graham Thompson, Center for Drug Evaluation and Research, FDA
Meeting Moderator, Decision Support and Analysis Team

9:05 a.m. **Opening Remarks**

Janet Woodcock, FDA
Acting Commissioner of Food and Drugs

9:10 a.m. **PDUFA Background and Overview**

Andrew Kish, Center for Drug Evaluation and Research, FDA
Director, Office of Program and Strategic Analysis

9:25 a.m. **CBER Review Support Proposed Enhancements**

9:45 a.m. **Pre-Market Review Proposed Enhancements**

10:15 a.m. **Break**

10:25 a.m. **Regulatory Decision Tools Proposed Enhancements**

10:45 a.m. **Post-Market Safety Proposed Enhancements**

11:05 a.m. **Chemistry, Manufacturing, and Controls Proposed Enhancements**

11:30 a.m. **Digital Health and Informatics Proposed Enhancements**

11:50 p.m. **Finance and Hiring Proposed Enhancements**

12:15 p.m. **Lunch**

12:45 p.m. **Public Stakeholder Perspectives**

Michael Abrams, Public Citizen
Senior Health Researcher

Cynthia Bens, Personalized Medicine Coalition
Senior Vice President, Public Policy

Annie Kennedy, EveryLife Foundation for Rare Diseases
Chief of Policy and Advocacy

Ed Neilan, National Organization for Rare Diseases
Chief Medical and Scientific Officer

1:15 p.m. **Public Comments**