Public Meeting on Reauthorization of the Generic Drug User Fee Amendments of 2017 (GDUFA)
July 21, 2020
Agenda

Current as of July 15, 2020

Online Registration **8:00 a.m. – 9:00 a.m.**

Welcome and Opening Remarks **9:00 a.m. – 9:45 a.m.**

Stephen M. Hahn
Commissioner of Food and Drugs, FDA

Sally Choe
Director, OGD, CDER, FDA

Michael Kopcha
Director, Office of Pharmaceutical Quality (OPQ), CDER, FDA

Introduction of the Panel **9:45 a.m. – 9:50 a.m.**

Michael Kopcha
Director, Office of Pharmaceutical Quality (OPQ), CDER, FDA

Overview of GDUFA II **9:50 a.m. – 10:10 a.m.**

Maryll Toufanian
Director, Office of Generic Drug Policy, OGD, CDER, FDA

The Future of Inspections – Role of ORA **10:10 a.m. – 10:25 a.m.**

Elizabeth Miller
Assistant Commissioner for Medical Products and Tobacco Operations

The Future of Pharmaceutical Quality **10:25 a.m. – 10:40 a.m.**

Ashley Boam
Director, Office of Policy for Pharmaceutical Quality, OPQ, CDER, FDA

Break **10:40 a.m. – 11:00 a.m.**

Overview of Pre-ANDA and Complex Generic Activity **11:00 a.m. – 11:30 a.m.**

Rob Lionberger
Director, Office of Research and Standards, OGD, CDER, FDA

Other Federal Agency Presentations **11:30 a.m. – 12:10 p.m.**

Jeffrey Kelman
Center for Medicare and Medicaid Services

Peter Glassman
Department of Veterans Affairs

Christopher Lamer
Indian Health Services

Clarifying Questions from the Panel **12:10 p.m. – 12:15 p.m.**

Trade Association Presentation **12:15 p.m. – 12:25 p.m.**

David Gaugh
Association for Accessible Medicines

Clarifying Questions from the Panel **12:25 p.m. – 12:30 p.m.**

Lunch Break **12:30 p.m. – 1:00 p.m.**

Healthcare Provider Presentations **1:00 p.m. – 1:30 p.m.**

Jillanne Schulte Wall
American Society of Health-System Pharmacists

Anthony Barrueta
Kaiser Permanente

Clarifying Questions from the Panel **1:30 p.m. – 1:35 p.m.**

Stakeholder Presentations **1:35 p.m. – 2:20 p.m.**

Scott Tomsky
Teva Pharmaceuticals

Diane Zuckerman
National Center for Health Research

Priscilla Zawislak
IPEC-Americas

Clarifying Questions from the Panel	**2:20 p.m. – 2:25 p.m.**
Open Comment Period	**2:25 p.m. – 2:55 p.m.**
Closing Remarks	**2:55 p.m. – 3:00 p.m.**

Jacqueline Corrigan-Curay
Director, Office of Medical Policy, CDER, FDA