

# Public Meeting on Reauthorization of the Generic Drug User Fee Amendments of 2017 (GDUFA)

July 21, 2020

## Agenda

<b>Online Registration</b>	<b>8:00 a.m. – 9:00 a.m.</b>
<b>Welcome and Opening Remarks</b>	<b>9:00 a.m. – 9:45 a.m.</b>
<i>Stephen M. Hahn Commissioner of Food and Drugs, FDA</i>	
<i>Sally Choe Director, OGD, CDER, FDA</i>	
<i>Michael Kopcha Director, Office of Pharmaceutical Quality (OPQ), CDER, FDA</i>	
<b>Introduction of the Panel</b>	<b>9:45 a.m. – 9:50 a.m.</b>
<i>Michael Kopcha Director, Office of Pharmaceutical Quality (OPQ), CDER, FDA</i>	
<b>Overview of GDUFA II</b>	<b>9:50 a.m. – 10:10 a.m.</b>
<i>Maryll Toufanian Director, Office of Generic Drug Policy, OGD, CDER, FDA</i>	
<b>The Future of Inspections – Role of ORA</b>	<b>10:10 a.m. – 10:25 a.m.</b>
<i>Elizabeth Miller Assistant Commissioner for Medical Products and Tobacco Operations</i>	
<b>The Future of Pharmaceutical Quality</b>	<b>10:25 a.m. – 10:40 a.m.</b>
<i>Ashley Boam Director, Office of Policy for Pharmaceutical Quality, OPQ, CDER, FDA</i>	
<b>Break</b>	<b>10:40 a.m. – 11:00 a.m.</b>
<b>Overview of Pre-ANDA and Complex Generic Activity</b>	<b>11:00 a.m. – 11:30 a.m.</b>

*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*  
*Centers 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 Barraeta*  
*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 Tomsy*  
*Teva Pharmaceuticals*

*Diana 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.**

*Kristina Gehrki*  
*USAPN (USA Patient Network)*

*Jonathan Furman*  
*USAPN (USA Patient Network)*

*Peiling Cheng*  
*Pharmaceutical Sourcing Partners, Inc.*

**Closing Remarks**

**2:55 p.m. – 3:00 p.m.**

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