

# **GDUFA Reauthorization Stakeholder Meeting**

## **December 15, 2020**

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Virtual Meeting

### **Agenda**

#### **Welcome and Overview**

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

#### **FDA and Stakeholder Introductions**

#### **Summary of Recent Negotiation Sessions**

Jacqueline Corrigan-Curay, MD, JD

#### **Stakeholder Comments**

#### **Stakeholder Presentations**

- "New prior knowledge for Generic and Repurposed Products" - Professor Kenneth Morris
- "Facilitating implementation of advanced manufacturing systems for generic companies" - Professor Fernando Muzzio

#### **Closing**

Carter Beach, JD  
*Deputy Director, Office of Executive Programs, CDER, FDA*

- Next Stakeholder meeting scheduled for January 26, 2021, 12pm – 1pm.