

# **GDUFA Reauthorization Stakeholder Meeting**

## **November 17, 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**

#### **Role of Regulatory Science in Generic Drug Development and Application Assessment**

Lei Zhang, Ph.D.  
*Deputy Director, Office of Research and Standards, OGD, CDER, FDA*

Sau (Larry) Lee, Ph.D.  
*Deputy Director of Science, Office of Pharmaceutical Quality, CDER, FDA*

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

Jacqueline Corrigan-Curay, MD, JD

#### **Stakeholder Comments**

#### **Closing**

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