GDUFA Reauthorization Stakeholder Meeting
January 26, 2021

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

Presentations

1. "Information Technology Improvements to Enhance Regulatory Assessment," Susan Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality

2. "Office of Generic Drugs Reorganization," Tawni Schwemer, Senior Advisor and Acting Associate Director for Regulatory Affairs, Office of Generic Drugs

Summary of Recent Negotiation Sessions

Jacqueline Corrigan-Curay, MD, JD

Stakeholder Comments

Closing

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

- Next Stakeholder meeting scheduled for February 22, 2021, 12pm – 1pm.