

GDUFA Reauthorization Stakeholder Meeting

October 20, 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

Stakeholder Meeting Process and Ground Rules

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

Reauthorization Overview

Maryll Toufanian, JD
Director, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Stakeholder Comments

Summary of Recent Negotiation Sessions

Jacqueline Corrigan-Curay, MD, JD

Next Steps and Closing

Carter Beach, JD