GDUFA Reauthorization Stakeholder Meeting May 25, 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

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 June 30, 2021