

GDUFA Reauthorization Stakeholder Meeting

December 17, 2015

**Food and Drug Administration
10903 New Hampshire Avenue
Building WO 52/72, Room 1100
Silver Spring, MD 20993**

Agenda

Registration

Welcome and Overview

Mary Beth Clarke, RPh
Director, Office of Executive Programs, CDER, FDA

FDA and Stakeholder Introductions

Summary of Recent Negotiation Sessions

Keith Flanagan, JD
Director, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

Closing

Martha Nguyen, JD
Director, Division of Policy Development, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA