

Public Meeting on the Recommendations for Generic Drug User Fee Amendments (GDUFA) Reauthorization

November 16, 2021

Agenda

[\[Zoom Webinar Link*\]](#)

Participants can join the Meeting starting at 8:30 a.m.

- 9:00 - 9:05 a.m.** **Welcome**
Carter Beach
*Deputy Director, Office of Executive Programs, Center for Drug
Evaluation and Research (CDER), FDA*
- 9:05 - 9:15 a.m.** **Opening Remarks**
Jacqueline Corrigan-Curay,
Principal Deputy Director, CDER, FDA
- 9:15 - 9:30 a.m.** **GDUFA II Successes**
Maryll Toufanian
Director, Office of Generic Drug Policy, Office of Generic Drugs, CDER, FDA

GDUFA III Proposals

- 9:30 - 10:15 a.m.** **Advancing Approvals**
- Maximizing Each Review Cycle
 - Improving Regulatory Communication
 - Manufacturing and Facilities
- 10:15 - 10:30 a.m.** **Break**
- 10:30 - 10:45 a.m.** **Enhancing Approval of Complex Generics**

10:45 - 11:00 a.m. Setting a Sound Financial Foundation

11:00 - 11:15 a.m. Industry Perspective

11:15 - 12:00 p.m. Stakeholder Presentations

12:00 – 12:45 p.m. Lunch

12:45 - 1:50 p.m. Public Comment Period

1:50 - 2:00 p.m. Closing Remarks
Sally Choe
Director, Office of Generic Drugs, CDER, FDA

*Zoom Webinar password: GDUFa3!