

**Public Meeting on Reauthorization of the
Generic Drug User Fee Amendments (GDUFA)
July 11, 2025
Agenda**

Welcome	9:00 a.m. – 9:05 a.m.
<i>Mark Ascione Meeting Moderator, Office of Program and Strategic Analysis</i>	
Opening Remarks	9:05 a.m. – 9:15 a.m.
<i>Martin Makary Commissioner of Food and Drugs, FDA</i>	
FDA Presentations	9:15 a.m. – 10:30 a.m.
<i>Ilun Murphy Director, Office of Generic Drugs, CDER, FDA</i>	
<i>Rob Lionberger Director, Office of Research and Standards, OGD, CDER, FDA</i>	
<i>Michael Kopcha Director, Office of Pharmaceutical Quality (OPQ), CDER, FDA</i>	
<i>Ivy Sweeney Deputy Director, Office of Human and Animal Drug Inspectorate, OII, FDA</i>	
Break	10:30 a.m. – 10:50 a.m.
Industry Presentations (15 min each)	10:50 a.m. – 11:15 a.m.
<i>Giuseppe Randazzo Association for Accessible Medicines</i>	
<i>Joel Carpenter Bulk Pharmaceuticals Task Force</i>	
Open Comment Period	11:15 p.m. – 12:35 p.m.

Closing Remarks

12:35 p.m. – 12:40 p.m.

Mark Ascione