



U.S. FOOD & DRUG
ADMINISTRATION

Public Meeting on Recommendations for Generic Drug User Fee Amendments (GDUFA) Reauthorization September 17, 2026

9:00 – 9:05 am	Welcome and Introduction Alison Lyndaker , Office of Finance, Budget, and Acquisitions (OFBA), FDA <i>Meeting Moderator</i>
9:05 – 9:15am	Opening Remarks Kyle Diamantas , FDA <i>Acting Commissioner</i>
9:15am – 9:25am	GDUFA IV Background and Reauthorization Process Kathleen Davies , Center for Drug Evaluation and Research (CDER), FDA <i>Senior Advisor to the Center Director</i>
9:25am – 9:40am	ANDA Assessment Enhancements (Commitment Letter (CL) Section I & II) Kendra Stewart , CDER, FDA <i>Director, Office Regulatory Operations, Office of Generic Drugs (OGD)</i>
9:40am – 9:55am	Application-Related Meetings & Additional Program Enhancements (CL Section III & IV) Rob Lionberger , CDER, FDA <i>Director, Office Research and Standards, OGD</i>
9:55am – 10:05am	DMF Assessment Program & Facilities (CL Section V & VI) Ashley Boam , CDER, FDA <i>Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality (OPQ)</i>



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10:05am – 10:15am **Continued Enhancement of User Fee Resource Management
(CL Section VII & Statutory Recommendations)**

Angela Granum, OFBA, FDA
Division Director

10:15am – 10:30am **Break**

10:30am – 11:05am **Industry Presentations**

Giuseppe Randazzo, Association for Accessible
Medicines (AAM)
Senior Vice President of Sciences and Regulatory Affairs

Gil Roth, Pharma & Biopharma Outsourcing Association
(PBOA)
President

Deborah Attwood, Bulk Pharmaceuticals Task Force
(BPTF)
Member

11:05am – 11:10am **Break**

11:05am – 11:40am **Public Stakeholder Perspectives**

*(Virtual and in-person attendees that requested in advance to provide
remarks and were accepted by FDA will provide comments)*

11:40am – 11:55am **Open Public Comment**

*(Only in-person attendees may make public comments. Virtual
attendees wishing to make a public comment must have pre-
registered for the Public Stakeholder Perspectives section)*

11:55am – 12:00pm **Closing Remarks**

Meeting Moderator