



Public Meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization

July 14, 2025

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| 9:00 – 9:05 am | Welcome and Introduction

Nana Adjeiwaa-Manu, Center for Drug Evaluation and Research, FDA
<i>Meeting Moderator</i> |
| 9:05 – 9:10 am | Opening Remarks

Martin Makary, FDA
<i>FDA Commissioner</i> |
| 9:10 – 9:30 am | PDUFA Background and Reauthorization Process

Andrew Kish, Center for Drug Evaluation and Research, FDA
<i>Director, Office of Program and Strategic Analysis</i> |
| 9:30 – 10:00 am | Regulated Industry Perspectives

Annetta Beauregard, Biotechnology Innovation Organization
<i>Senior Vice President, Science & Regulatory Affairs</i>

Kristy Lupejkis, Pharmaceutical Research and Manufacturers of America
<i>Vice President and Chief of Staff, Science and Regulatory Advocacy</i> |
| 10:00 – 10:15 am | Break |
| 10:15 – 11:30 am | Public Comment |
| 11:30 – 11:35 am | Closing Remarks |