



CDER and You: Keys to Effective Engagement Public Workshop Agenda April 3, 2018

- 8:00 – 9:00 a.m. **Registration**
- 9:00 – 9:10 a.m. **Introductions and Opening Remarks**
John Whyte, M.D., M.P.H.
Director, Professional Affairs and Stakeholder Engagement (PASE)
- 9:10 – 9:25 a.m. **Welcome**
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research (CDER)
- 9:20 – 9:30 a.m. **AUDIENCE RESPONSE QUESTIONS/5 Things You Need to Know About the Drug Approval Process**
Noah Goetzel
ORISE Fellow, PASE
- 9:30 – 9:50 a.m. **Live Demo: FDA.gov/RequestAMeetingOnDrugs**
Christopher Melton
Health Communications Specialist, PASE
Questions and Answers
- 9:50 – 10:15 a.m. **Collecting Patient Experience Data: How You Can Best Help FDA**
Selena Daniels, Pharm.D., M.S.
Team Leader, Clinical Outcome Assessments (COA) Staff, Office of New Drugs (OND)
Questions and Answers
- 10:15 – 10:40 a.m. **Supporting Rare Disease Drug Development: CDER's Rare Diseases Program**
Lucas Kempf, M.D.
Acting Associate Director, Rare Diseases Program, Office of New Drugs (OND)
Questions and Answers
- 10:40 – 10:45 a.m. **AUDIENCE RESPONSE QUESTIONS**
Jamie Bishop
Project Manager, PASE
- 10:45 – 11:00 a.m. **BREAK** – Attendees interested in purchasing lunch should order now at the kiosk in the lobby.
- 11:00 – 11:25 a.m. **Understanding the Needs of CDER Drug Review Divisions**
Elizabeth Hart, M.D.
Medical Officer, Division of Gastroenterology & Inborn Errors Products (DGIEP), OND
Questions and Answers
- 11:25 – 11:30 a.m. **AUDIENCE RESPONSE QUESTIONS**
Portia Seals, J.D.
Health Communications Specialist, PASE
- 11:30 – 11:50 a.m. **What CDER Can and Can't Do**
LCDR Sadhna Khatri, Pharm.D., M.P.H., M.S., M.Ed.
Regulatory Officer, PASE
Questions & Answers
- 11:50 a.m. – 12:00 p.m. **Morning Recap**
John Whyte, M.D., M.P.H.
Director, PASE



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12:00 – 1:00 p.m.	LUNCH
1:00 – 1:30 p.m.	CDER JEOPARDY John Whyte, M.D., M.P.H. Director, PASE
1:30 – 1:50 p.m.	Rocking the Docket John Wright, J.D. Dockets Management Specialist, Division of Dockets Management (DDM), Office of the Commissioner Questions & Answers
1:50 – 2:25 p.m.	Discussion Panel: How to Get Your Voice Heard Moderator Rea Blakey Communications Policy Strategist, Engagement Team Lead, PASE Panelists – Externally-Led PFDDs Pujita Vaidya, M.P.H. Acting Director, Decision Support and Analysis Team (DSAT), Office of Strategic Programs (OSP) FDA Patient Affairs Andrea Furia-Helms, M.P.H. Acting Director, Patient Affairs Staff (PAS), Office of Medical Products and Tobacco (OMPT) Office of Health & Constituent Affairs, Patient Representative Program Salina Miller, M.S., M.B.A. Health Programs Coordinator, Office of Health and Constituent Affairs (OHCA), Office of the Commissioner (OC) CBER Patient Engagement Diane Maloney, J.D. Associate Director for Policy, Center for Biologics Evaluation and Research (CBER) Questions and Answers
2:25 – 2:30 p.m.	AUDIENCE RESPONSE QUESTIONS Chris Melton Health Communications Specialist, PASE
2:30 – 2:55 p.m.	Learn from the Pros Alexandra Kruse Research Coordinator, Platelet Disorder Support Association (PDSA) Phyllis Foxworth Vice President of Advocacy, Depression and Bipolar Support Alliance (DBSA) Questions and Answers
2:55 – 3:00 p.m.	Final Poll Questions and Closing Remarks John Whyte, M.D., M.P.H. Director, PASE