



Roadmap for Engaging with the Center for Drug Evaluation and Research Public Workshop Agenda

May 12, 2017

8:00 - 9:00 am	Registration
9:00 - 9:10 am	Introductions and Opening Remarks John Whyte, MD, MPH Director, Professional Affairs and Stakeholder Engagement (PASE)
9:10 - 9:35 am	Welcome Douglas Throckmorton, MD CDER Deputy Center Director for Regulatory Programs
9:35 - 9:40 am	AUDIENCE RESPONSE QUESTIONS Christopher Melton Health Communications Specialist, Professional Affairs and Stakeholder Engagement (PASE)
9:40 - 10:00 am	“NDA at the FDA” Milena Lolic, MD, MS Medical Officer, Professional Affairs and Stakeholder Engagement (PASE)
10:00 - 10:20 am	“Rocking the Docket” John Wright Dockets Management Specialist, Division of Dockets Management, Office of the Commissioner
10:20 - 10:25 am	Questions and Answers
10:25 - 10:40 am	BREAK - <i>Attendees interested in purchasing lunch should order now at the kiosk in the lobby.</i>
10:40 - 11:00 am	“Measuring How Patients Feel and Function” Michelle Campbell, PhD Social Science Analyst, Drug Development Tools Clinical Outcome Assessments (DDT/COA)
11:00 - 11:05 am	Questions and Answers
11:05 - 11:10 am	AUDIENCE RESPONSE QUESTIONS Mary P Ghods, RPh Pharmacist, Professional Affairs and Stakeholder Engagement (PASE)
11:10 - 11:30 am	“Supporting Rare Disease Drug Development: CDER’s Rare Diseases Program” Larry Bauer Regulatory Scientist, Office of New Drugs, Rare Diseases
11:30 - 11:35 am	Question and Answers



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- 11:35 - 11:40 am **AUDIENCE RESPONSE QUESTIONS**
Noah Goetzl
ORISE Fellow, Professional Affairs and Stakeholder Engagement (PASE)
- 11:40 - 12:15 pm **“How to Get Your Voice Heard” Panel Discussion**
- Moderator**
Rea Blakey
Communications Policy Strategist & Engagement Team Lead, Professional Affairs and Stakeholder Engagement (PASE)
- Panelists**
Andrea Furia-Helms, MPH
Health Programs Coordinator, Office of Health and Constituent Affairs (OHCA)
- Christopher Melton
Health Communications Specialist, Professional Affairs and Stakeholder Engagement (PASE)
- Pujita Vaidya, MPH
Acting Director, Decision Support and Analysis Team, Office of Strategic Programs (OSP)
- Lynne P. Yao, MD
Director, Division of Pediatric and Maternal Health
- 12:15 - 12:25 pm **Questions & Answers**
- 12:25 - 12:30 pm **Morning Recap**
- 12:30 - 1:30 pm **LUNCH**
- 1:30 - 2:00 pm **FDA JEOPARDY**
John Whyte, MD, MPH
Director, Professional Affairs and Stakeholder Engagement (PASE)



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- 2:00 - 2:15 pm **“Knowing the Moment It Happens: CDER’s Social Media Program”**
- Kim Chiu, PharmD
Social Media Lead, Division of Drug Information
- Raj Patel, PharmD
Social Media, Division of Drug Information
- 2:15 - 2:20 pm **Questions and Answers**
- 2:20 - 2:25 pm **AUDIENCE RESPONSE QUESTIONS**
- Shawn Brooks
Health Communication Specialist, Professional Affairs and Stakeholder Engagement (PASE)
- 2:25 - 2:45 pm **“Learn from the Pros”**
- Cynthia Bens
Vice President of Public Policy, Alliance for Aging Research
- Jane Larkindale, D. Phil
Vice President of Research Development, Friedreich's Ataxia Research Alliance
- 2:45 - 2:50 pm **Questions and Answers**
- 2:50 - 3:00 pm **Final Poll Questions and Words of Wisdom**
- John Whyte, MD, MPH
Director, Professional Affairs and Stakeholder Engagement (PASE)