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

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