Purpose: The purpose of Oncology Center of Excellence (OCE) Listening Session is for stakeholders to provide recommendations to the Agency regarding FDA’s OCE, the first Inter-Center Institutes within the Agency for a major disease area. Specifically, the Agency solicits comments regarding what stakeholders desire of the OCE in terms of structure, function, regulatory purview, and activity.

AGENDA

8:30 AM Registration
9:00 AM Welcome and Opening Remarks – Richard Pazdur, MD
9:10 AM Introduction to the Oncology Center of Excellence (OCE) – Tamy Kim, PharmD
9:15 AM Center for Drug Evaluation and Research (CDER) – Amy McKee, MD
9:20 AM Center for Biologics Evaluation and Research (CBER) – Ke Liu, MD, PhD
9:25 AM Center for Devices and Radiological Health (CDRH) – Steven Nagel, MD, FACS
9:30 AM Patient Focused Drug Development – Paul Kluetz, MD
9:35 AM Big Data – Sean Khozin, MD, MPH
9:40 AM Public Oral Presentations

10:00 AM BREAK

10:15 AM Public Oral Presentations
10:40 AM Open Discussion
11:50 AM Closing Remarks – Richard Pazdur, MD

12:00 PM ADJOURN