



Oncology Center of Excellence (OCE) Listening Session

March 15, 2018

FDA Federal Research Center

Great Room, Building 31

10903 New Hampshire Avenue, Silver Spring, Maryland 20993

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