



Public Meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization



August 15, 2016

8:00 – 9:00 am	Registration
9:00 – 9:05 am	Welcome Pujita Vaidya , Center for Drug Evaluation and Research, FDA <i>Office of Strategic Programs</i>
9:05 – 9:15 am	Opening Remarks Janet Woodcock , Center for Drug Evaluation and Research, FDA <i>Director</i>
9:15 – 9:30 am	PDUFA Background and Reauthorization Process Theresa Mullin , Center for Drug Evaluation and Research, FDA <i>Director, Office of Strategic Programs</i>
9:30 – 10:20 am	Panel 1 – Pre-Market Review and Post-Market Safety
10:20 – 10:35 am	Break
10:35 – 11:25 am	Panel 2 – Regulatory Decision Tools
11:25 – 12:25 pm	Lunch
12:25 – 1:15 pm	Panel 3 – Administrative Enhancements: Hiring, IT, and Financial
1:15 – 2:00 pm	Open Public Comment