Interim Assessment of the Program for Enhanced Review Transparency and Communication in PDUFA V

Public Meeting

May 20, 2015

9:30 – 10:00 am	**Registration**
10:00 – 10:05 am	**Welcome** Theresa Mullin *Director, Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA*
10:05 – 11:35 am	**Presentation of the Interim Assessment** Valerie Overton *Vice President, Eastern Research Group, Inc.*
11:35 – 11:45 am	**FDA Perspective** Patrick Frey *Director, Office of Program and Strategic Analysis, CDER, FDA*
11:45 – 12:15 pm	**Industry Perspective** Andrew Emmett *Managing Director, Science and Regulatory Affairs, BIO* Paul Huckle *Chief Regulatory Officer and Senior Vice President, GlaxoSmithKline* Scott Korn *Vice President, Global Regulatory Affairs, Merck*
12:15 – 1:00 pm	**Q&A and Public Comment**