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

Public Meeting

March 27, 2017

9:30—10:00 am **Registration**

10:00—10:05 am **Welcome**

Azada Hafiz, FDA/CDER/Office of Strategic Programs
Program Manager, Office of Program and Strategic Analysis

10:05—10:50 am **Presentation of the Final Assessment**

Valerie Overton, Eastern Research Group
Vice President

10:50—11:30 am **FDA Perspective**

Patrick Frey, FDA/CDER/Office of New Drugs
Chief of Staff

Ellis Unger, FDA/CDER/Office of New Drugs
Director, Office of Drug Evaluation I

James Smith, FDA/CDER/Office of New Drugs
Deputy Director, Division of Metabolism and Endocrinology Products

Robert Iser, FDA/CDER/Office of Pharmaceutical Quality
Director, Office of Process and Facilities

Christopher Joneckis, FDA/CBER
Associate Director for Review Management

11:30—11:50 am **Industry Perspective**

Lucy Vereshchagina, PhRMA
Deputy Vice President, Science and Regulatory Advocacy

Robert Metcalf, Eli Lilly and Company
Vice President, MDU Diabetes and Clinical Transformation

Tahira Khan, Genentech
Associate Program Director, Clinical Regulatory Affairs

11:50 am—12:20 pm **Q&A and Public Comment**