Public Meeting for Reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA II)

October 21, 2016

8:00 – 9:00	**Registration**
9:00 – 9:05	**Welcome** Mary Beth Clarke, Center for Drug Evaluation and Research, FDA Office of Executive Programs
9:05 – 9:15	**Opening Remarks** Kathleen Uhl, Center for Drug Evaluation and Research, FDA Office of Generic Drugs
9:15 – 9:30	**GDUFA Background and Reauthorization Process** Keith Flanagan, Center for Drug Evaluation and Research, FDA Office of Generic Drugs
9:30 – 9:45	**Landscape of the Generic Drug Industry & Small Business Perspective** Rob Berlin, Office of the Commissioner, FDA
9:45 – 10:30	**Panel 1 – Proposed Pre-Market Review: Goals & Pre-ANDA**
10:30 – 10:45	**Break**
10:45 – 11:30	**Panel 2 – Proposed New Fee Structure**
11:30 – 12:30	**Lunch**
12:30 – 1:15	**Panel 3 – Facilities & Reporting**
1:15 – 2:15	**Open Public Comment**
2:15 – 2:20	**Closing Remarks**