The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access

July 18, 2017

8:00 – 9:00 **Registration**

9:00 – 9:10 **Welcome**

Keith Flanagan, Office of Generic Drugs, Center for Drug Evaluation and Research (CDER), FDA

9:10 – 9:35 **Opening Remarks**

Scott Gottlieb, Office of the Commissioner, FDA

Janet Woodcock, Office of the Center Director, CDER, FDA

9:35 – 9:45 **Introduction of the Panelists**

Keith Flanagan, Office of Generic Drugs, CDER, FDA

Panelists

- *Anna Abram*, Office of the Commissioner, FDA
- *Elizabeth Dickinson*, Office of the Chief Counsel, Office of the Commissioner, FDA
- *Keith Flanagan*, Office of Generic Drugs, CDER, FDA
- *Markus Meier*, Bureau of Competition, Federal Trade Commission
- *Grail Sipes*, Office of Regulatory Policy, CDER, FDA
- *Peter Stein*, Office of New Drugs, CDER, FDA
- *Maryll Toufanian*, Office of Generic Drugs, CDER, FDA
- *Kathleen Uhl*, Office of Generic Drugs, CDER, FDA

9:45 – 11:00 **Public Presentations: The Academic/Researcher Perspective**

11:00 – 11:10 **Morning Break**

11:10 – 12:00 **Public Presentations: The Payer/Provider Perspective**

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12:00 – 1:00 **Lunch**

1:00 – 2:40 **Public Presentations: The Pharmaceutical Product Development Perspective**

2:40 – 2:50 **Afternoon Break**

2:50 – 4:50 **Public Presentations: The Patient/Consumer Perspective**

4:50 – 5:00 **Closing Remarks**

Keith Flanagan, Office of Generic Drugs, CDER, FDA

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