

Generic Drug User Fee Amendments of 2012
Public Hearing on Policy Development – Request for Comments
Part 15 Public Hearing
September 17, 2014
College Park Marriot Hotel and Conference Center
3501 University Blvd, East
Hyattsville, MD 20783

Agenda

- 9:00 – 9:10 a.m. Opening Remarks
Keith Flanagan, JD
Office of Generic Drug Policy, Office of Generic Drugs,
Center for Drug Evaluation and Research (CDER)
- 9:10 – 9:20 a.m.
Overview: GDUFA Implementation: Draft Guidance Documents
Martha Nguyen, JD
Office of Generic Drug Policy, Office of Generic Drugs, CDER
- Audience Presentations:**
- 9:20 – 9:35 a.m.
Priscilla Zawislak
Global Regulatory Affairs Manager
International Pharmaceutical Excipients Council (IPEC)
- 9:35 – 9:45 a.m. Questions from Panel
- 9:45 – 10:00 a.m.
Steven Pressman
Executive Vice President
PureTek
- 10:00 – 10:10 a.m. Questions from Panel
- 10:10 – 10:25 a.m.
David Gaugh, RPh
Senior Vice President for Sciences and Regulatory Affairs
Generic Pharmaceutical Association (GPhA)
- 10:25 – 10:35 a.m. Questions from Panel

10:35 – 10:50 a.m.

Break

10:50 – 11:05 a.m.

Marcie McClintic Coates, JD, MBA
Vice President and Head of Global Regulatory Affairs
Mylan Inc.

11:05 – 11:15 a.m.

Questions from Panel

11:15 – 11:30 a.m.

Robert Vincent
Director, US Generics Regulatory Affairs
Teva Pharmaceuticals USA

11:30 – 11:40 a.m.

Questions from Panel

11:40 – 11:55 a.m.

Keith Webber, PhD
Head of Regulatory Review, Regulatory Affairs
Perrigo Company

11:55 – 12:05 p.m.

Questions from Panel

12:05 – 1:05 p.m.

Lunch

1:05 – 1:15 p.m.

Overview: GDUFA Implementation Related to Generic Drug Exclusivity and First Generics
Maryll Toufanian, JD
Office of Generic Drug Policy, Office of Generic Drugs, CDER

1:15 – 1:30 p.m.

Robert Vincent
Director, US Generics Regulatory Affairs
Teva Pharmaceuticals USA

1:30-1:40 p.m.

Questions from Panel

1:40 – 1:55 p.m.

Marcie McClintic Coates, JD, MBA

Vice President and Head of Global Regulatory Affairs

Mylan Inc.

1:55 – 2:05 p.m.

Questions from Panel

2:05 – 2:20 p.m.

David Gaugh, RPh

Senior Vice President for Sciences and Regulatory Affairs

Generic Pharmaceutical Association (GPhA)

2:20 – 2:30 p.m.

Questions from Panel

2:35 – 2:50 p.m.

Break

2:50 – 4:50 p.m.

Open Comment Session

4:50 – 5:00 p.m.

Closing Remarks

Keith Flanagan, JD

Office of Generic Drug Policy, Office of Generic Drugs, CDER