

**FDA-Industry GDUFA Reauthorization Meeting**  
**June 14, 2016, 10:00 am – 4:00 pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 22, Room 1417**

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**Purpose**

To discuss financial considerations and resource needs for GDUFA II.

**Participants**

FDA

Donald Beers  
Robert Berlin  
Mary Beth Clarke  
Keith Flanagan  
Melanie Keller  
Robert Lionberger  
Ann Marie Montemurro  
Donal Parks  
Rachel Richter  
Edward Sherwood  
Martin Shimer

OC/OCC  
OC/OPPLA  
CDER  
CDER  
CDER  
CDER  
ORA  
CDER  
OC/OO  
CDER  
CDER

Industry

John DiLoreto  
David Gaugh  
Kiran Krishnan  
Marcie McClintic Coates  
Alan Nicholls  
Laura Parks  
Gil Roth  
Cornell Stamoran  
Rich Stec  
Scott Tomsy

BPTF  
GPhA  
GPhA (Apotex)  
GPhA (Mylan)  
BPTF  
PBOA (Patheon)  
PBOA  
PBOA (Catalent)  
GPhA (Perrigo)  
GPhA (Teva)

FDA Supporting Staff

Carter Beach, Heather Brown, Matt Defina, Deborah Elliott, Derek Griffing, Kevin Laser, Gisa Perez, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

Industry Supporting Staff

Mark Hendrickson (GPhA), Lisa Tan (GPhA)

**Discussion**

FDA and Industry continued discussions from earlier negotiation meetings on financial issues relevant to GDUFA. FDA clarified key features of the fiscal year 2015 GDUFA Financial Report, and provided further details on GDUFA I spending and hiring activities. FDA and Industry also discussed resource needs and the factors that may affect resource projections in GDUFA II.

**Next Meeting**

The date of the next negotiation meeting is planned for Tuesday, June 28, 2016.