FDA-Industry GDUFA Reauthorization Meeting
April 27, 2016, 10:00 am – 1:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss financial considerations for GDUFA II.

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	Kiran Krishnan	GPhA (Apotex)
Ashley Boam	CDER	Marcie McClintic Coates	GPhA (Mylan)
Mary Beth Clarke	CDER	Alan Nicholls	BPTF
Keith Flanagan	CDER	Laura Parks	PBOA (Patheon)
Michael Jones	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Kevin Laser	CDER	Gil Roth	PBOA
Robert Lionberger	CDER	Cornell Stamoran	PBOA (Catalent)
Ann Marie Montemurro	ORA	Terri Stewart	GPhA (Teva)
Donal Parks	CDER	Tom Thorpe	PBOA (Afton Scientific)
Edward Sherwood	CDER		

FDA Supporting Staff
Carter Beach, Heather Brown, Matt Defina, Deborah Elliott, Derek Griffing, Martha Nguyen, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

Industry Supporting Staff
Lisa Tan (GPhA), Mark Hendrickson (GPhA)

Discussion
FDA and Industry discussed a number of financial issues relevant to GDUFA II. FDA explained key points in the fiscal year 2015 financial report and clarified aspects of the Federal budget as it applies to the generic drug review process.

Next Meeting
The next negotiation meeting is planned for Thursday, April 28, 2016.