FDA-Industry GDUFA Reauthorization Meeting
February 3, 2016, 10:00 am – 12:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To explore strategies for streamlining the negotiation process and to lay the foundation for upcoming discussions on financial issues.

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Ashley Boam	CDER	Kiran Krishnan	GPhA (Apotex)
Mary Beth Clarke	CDER	Marcie McClintic Coates	GPhA (Mylan)
Keith Flanagan	CDER	Alan Nicholls	BPTF
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	Elizabeth Stampa	EFCG (Medichem)
Donal Parks	CDER	Tom Thorpe	PBOA (Afton Scientific)
Edward Sherwood	CDER	Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Deborah Elliott, Derek Griffing, Michael Neuenschwander, Martha Nguyen, Gisa Perez, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

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

Discussion
FDA and Industry discussed strategies to accelerate the sharing of information and streamline the negotiation process. Meeting participants also discussed the generic drug program's workload and the rate of generic drug submissions under GDUFA I. Further, FDA and Industry discussed a number of financial issues.

Next Meeting
The next negotiation meeting is planned for Wednesday, February 17, 2016.