FDA-Industry GDUFA Reauthorization Meeting
January 6, 2016, 10:00 am – 1:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss topics pertaining to small businesses in the generic drug industry.

Participants

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	Laura Parks	PBOA (Patheon)
Kirk Kerr	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Robert Lionberger	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA (Catalent)
Edward Sherwood	CDER	Tom Thorpe	PBOA (Afton Scientific)
		Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Derek Griffing, Thomas Henry, Martha Nguyen, Donal Parks, Gisa Perez, Katie Stronati, Trang Tran, Lucie Yang

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

Discussion
The small business working group provided an update on their deliberations in response to Congress' request for consideration of relief of generic drug user fee facility fees for small businesses. The small business working group discussed the generic drug industry landscape and the small business criteria used in other FDA user fee programs. FDA and Industry agreed that these discussions should be continued in future negotiation meetings.

Next Meeting
The next negotiation meeting is planned for Wednesday, January 20, 2016.