FDA-Industry GDUFA Reauthorization Meeting
July 6, 2016, 9:45 am – 4:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1219

Purpose
To discuss issues pertaining to Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs).

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	Molly Rapp	GPhA (Fresenius-Kabi)
Robert Lionberger	CDER	Gil Roth	PBOA
Edward Sherwood	CDER	Rich Stec	GPhA (Perrigo)
Martin Shimer	CDER	Terri Stewart	GPhA (Teva)
		Tom Thorpe	PBOA (Afton Scientific)
		Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Matt Defina, Derek Griffing, Martha Nguyen, Gisa Perez, Lucie Yang

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

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on issues pertaining to ANDAs and DMFs. Topics included review goals, ANDA/DMF review program enhancements, facility evaluations, resource management enhancements, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence).

Next Meeting
The next negotiation meeting is planned for Thursday, July 7, 2016.