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

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

Participants

FDA		Industry	
Donald Beers	OC/OCC	David Gaugh	GPhA
Robert Berlin	OC/OPPLA	John DiLoreto	BPTF
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)
Robert Lionberger	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Ann Marie Montemurro	ORA	Gil Roth	PBOA
Edward Sherwood	CDER	Cornell Stamoran	PBOA (Catalent)
Martin Shimer	CDER	Tom Thorpe	PBOA (Afton Scientific)
David Skanchy	CDER	Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Matt Defina, Derek Griffing, Katie Stronati, Trang Tran, Lucie Yang

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

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on the ANDA review process and DMF/API issues. Topics surrounding DMF/API issues included: risk-based inspection parity, DMF review issues, and communications. FDA and Industry also discussed review timelines for GDUFA II submissions and communication and transparency enhancements.

Next Meeting
The next meeting is planned for Thursday, March 31, 2016.