FDA-Industry GDUFA Reauthorization Meeting
March 16, 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 Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs)

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
Brian Hasselbalch	CDER	Laura Parks	PBOA (Patheon)
Michael Jones	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Robert Lionberger	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA (Catalent)
Edward Sherwood	CDER	Scott Tomsky	GPhA (Teva)
Martin Shimer	CDER		
David Skanchy	CDER		

FDA Supporting Staff
Carter Beach, Derek Griffing, Michael Neuenschwander, Martha Nguyen, Tawni Schwemer, 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 in two groups based on the topics to be covered. One group's topics included review timelines for GDUFA II submissions, complex generic drug products, the pre-ANDA process, controlled correspondence, transparency, and communication. The other group's topics included DMF review, inspection parity, communications, and active pharmaceutical ingredient (API)/finished dosage form (FDF) characterizations.

Next Meeting
The next negotiation meeting is planned for Wednesday, March 30, 2016.