FDA-Industry GDUFA Reauthorization Meeting
February 17, 2016, 10:00 am – 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss the Abbreviated New Drug Application (ANDA) review process and issues related to Drug Master Files (DMFs).

Participants

FDA		Industry	
Donald Beers	OC/OCC	David Gaugh	GPhA
Robert Berlin	OC/OPPLA	Kiran Krishnan	GPhA (Apotex)
Ashley Boam	CDER	Marcie McClintic Coates	GPhA (Mylan)
Mary Beth Clarke	CDER	Alan Nicholls	BPTF
Karen Corallo	CDER	Laura Parks	PBOA (Patheon)
Keith Flanagan	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Brian Hasselbalch	CDER	Gil Roth	PBOA
Michael Jones	CDER	Cornell Stamoran	PBOA (Catalent)
Robert Lionberger	CDER	Scott Tomsky	GPhA (Teva)
Ann Marie Montemurro	ORA	Keith Webber	GPhA (Perrigo)
Martha Nguyen	CDER		
Edward Sherwood	CDER		
Martin Shimer	CDER		
David Skanchy	CDER		
Russell Wesdyk	CDER		

FDA Supporting Staff
Carter Beach, Heather Brown, Derek Griffing, Katie Stronati, 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. The negotiators split into two groups based on the topics to be covered. One group's topics included review timelines for GDUFA II submissions, complex generic drug products, regulatory science, controlled correspondence, transparency, and communication. The other group's topics included facility evaluation, inspection parity, and DMF issues.

Next Meeting
The next negotiation meeting is planned for Thursday, March 3, 2016.