FDA-Industry GDUFA Reauthorization Meeting
March 31, 2016, 9:00 am – 2:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1206

Purpose:
To discuss the Abbreviated New Drug Applications (ANDAs) review process.

Participants

FDA		Industry	
Donald Beers	OC/OCC	Kiran Krishnan	GPhA (Apotex)
Robert Berlin	OC/OPPLA	Marcie McClintic Coates	GPhA (Mylan)
Mary Beth Clarke	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Keith Flanagan	CDER	Gil Roth	PBOA
Michael Jones	CDER	Scott Tomsky	GPhA (Teva)
Robert Lionberger	CDER	Keith Webber	GPhA (Perrigo)
Ann Marie Montemurro	ORA		
Edward Sherwood	CDER		
Martin Shimer	CDER		

FDA Supporting Staff
Carter Beach, Matt Defina, Katie Stronati, Lucie Yang

Industry Supporting Staff
Lisa Tan (GPhA)

Discussion
FDA and Industry continued discussions from earlier negotiation sessions on the ANDA review process. Topics included: review timeframes for GDUFA II submissions and communication and transparency.

Next Meeting
The next negotiation meeting is planned for Tuesday, April 5, 2016.