FDA-Industry GDUFA Reauthorization Meeting
April 14, 2016, 9:00 am – 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1305

Purpose
To discuss the pre-Abbreviated New Drug Application (pre-ANDA) process.

Participants

FDA		Industry	
Donald Beers	OCC	Steve Giuli	GPhA[1] (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[2]
Michael Jones	CDER	Terri Stewart	GPhA (Teva)
Sean Kassim	CDER	Lisa Tan	GPhA
Robert Lionberger	CDER	Keith Webber	GPhA (Perrigo)
Ann Marie Montemurro	ORA		
Edward Sherwood	CDER		
Martin Shimer	CDER		

FDA Supporting Staff
Carter Beach, Matt Defina, Derek Griffing, Martha Nguyen, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on priority ANDA review and a pre-ANDA process. FDA explained how inspections of bioavailability studies affect the ANDA approval process. Other topics included controlled correspondence, product-specific guidance, and pre-ANDA meetings.

Next Meeting
The next negotiation meeting is planned for Wednesday, April 20, 2016.

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[1] Generic Pharmaceutical Association (GPhA)
[2] Pharma and Biopharma Outsourcing Association (PBOA)