FDA-Industry GDUFA Reauthorization Meeting
April 28, 2016 9:00 am – 3:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 4100

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

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	Marcie McClintic Coates	GPhA (Mylan)
Ashley Boam	CDER	Alan Nicholls	BPTF
Mary Beth Clarke	CDER	Laura Parks	PBOA (Patheon)
Keith Flanagan	CDER	Molly Rapp	GPhA (Frensius-Kabi)
Brian Hasselbalch	CDER	Gil Roth	PBOA
Michael Jones	CDER	Cornell Stamoran	PBOA (Catalent)
Robert Lionberger	CDER	Terri Stewart	GPhA (Teva)
Ann Marie Montemurro	ORA		
Edward Sherwood	CDER		
Martin Shimer	CDER		

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

Industry Supporting Staff
Lisa Tan (GPhA)

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on issues pertaining to ANDAs and DMFs. Topics included review goals for priority submissions, review-related communications, facility evaluations, risk-based inspection parity, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence).

Next Meeting
The next negotiation meeting is planned for Thursday, May 12, 2016.