FDA-Industry GDUFA Reauthorization Meeting
July 12, 2016, 10:00 am – 6:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1219

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	Kiran Krishnan	GPhA (Apotex)
Mary Beth Clarke	CDER	Marcie McClintic Coates	GPhA (Mylan)
Keith Flanagan	CDER	Alan Nicholls	BPTF
Michael Jones	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Robert Lionberger	CDER	Gil Roth	PBOA
Edward Sherwood	CDER	Cornell Stamoran	PBOA (Catalent)
Martin Shimer	CDER	Rich Stec	GPhA (Perrigo)
		Terri Stewart	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Heather Brown, Derek Griffing, Martha Nguyen, Tawni Schwemer, Trang Tran, Lucie Yang

Industry Supporting Staff
Mark Hendrickson (GPhA)

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on issues pertaining to ANDAs and DMFs. Topics included review goals, ANDA/DMF review program enhancements, generic drug program reporting, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence).

Next Meeting
The next negotiation meeting is planned for Wednesday, July 13, 2016.