FDA-Industry GDUFA Reauthorization Meeting
June 28, 2016, 10:00 am – 5:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1315

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

Participants

FDA		Industry	
Robert Berlin	OC/OPPLA	John DiLoreto	BPTF
Keith Flanagan	CDER	David Gaugh	GPhA
Brian Hasselbalch	CDER	Kiran Krishnan	GPhA (Apotex)
Michael Jones	CDER	Marcie McClintic Coates	GPhA (Mylan)
Robert Lionberger	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA
Jennifer Schwartz	OC/OCC	Rich Stec	GPhA (Perrigo)
Edward Sherwood	CDER	Scott Tomsky	GPhA (Teva)
Martin Shimer	CDER	Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Matt Defina, Derek Griffing, Martha Nguyen, Gisa Perez, Tawni Schwemer, Katie Stronati, 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, review-related communications, facility evaluations, generic drug program reporting, regulatory science, 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 6, 2016.