FDA-Industry GDUFA Reauthorization Meeting
July 13, 2016, 9:00 am – 4:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1219

Purpose
To discuss facility evaluations and other 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	Steve Giuli	GPhA (Apotex)
Mary Beth Clarke	CDER	Roger LaForce	EFCG
Alonza Cruse	ORA	Marcie McClintic Coates	GPhA (Mylan)
Keith Flanagan	CDER	Molly Rapp	GPhA (Fresenius-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	Keith Webber	GPhA (Perrigo)
Edward Sherwood	CDER		

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

Industry Supporting Staff
Mark Hendrickson (GPhA), Lisa Tan (GPhA)

Discussion
FDA and Industry continued discussions from the July 12 negotiation meeting on issues pertaining to ANDAs, DMFs, and facility evaluations. Topics included regulatory science, facility evaluations, resource management enhancements, generic drug program reporting, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence). FDA and Industry also discussed resource needs and user fee concepts for GDUFA II.

Next Meeting
The next negotiation meeting is planned for Monday, July 25, 2016.