FDA-Industry GDUFA Reauthorization Meeting
July 25, 2016, 9:30 am – 12:00 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	John DiLoreto	BPTF
Ashley Boam	CDER	David Gaugh	GPhA
Mary Beth Clarke	CDER	Alan Nicholls	BPTF
Keith Flanagan	CDER	Gil Roth	PBOA
Ann Marie Montemurro	ORA	Cornell Stamoran	PBOA (Catalent)
Edward Sherwood	CDER		

FDA Supporting Staff
Carter Beach, Heather Brown, Derek Griffing, Dianoda Lewis, Victor Ng, Katie Stronati, Trang Tran

Industry Supporting Staff
Mark Hendrickson (GPhA), Lisa Tan (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, facility evaluations, resource management enhancements, generic drug program reporting, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence). At the conclusion of the discussion, FDA and Industry tentatively agreed on the final wording of the GDUFA II Commitment Letter.

Next Meeting
The date of the next negotiation meeting is under discussion.