FDA-Industry GDUFA Reauthorization Meeting
April 5, 2016, 10:00 am – 12:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss review goals pertaining to Abbreviated New Drug Applications (ANDAs).

Participants

FDA		Industry	
Donald Beers	OC/OCC	Kiran Krishnan	GPhA (Apotex)
Mary Beth Clarke	CDER	Marcie McClintic Coates	GPhA (Mylan)
Keith Flanagan	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Michael Jones	CDER	Gil Roth	PBOA
Robert Lionberger	CDER	Lisa Tan	GPhA
Ann Marie Montemurro	ORA	Scott Tomsky	GPhA (Teva)
Edward Sherwood	CDER		
Martin Shimer	CDER		

FDA Supporting Staff
Nick Alexander (OC/OL), Carter Beach, Matt Defina, Martha Nguyen, Tawni Schwemer, Dave Skanchy, Trang Tran, Lucie Yang

Discussion
FDA and Industry continued discussions from earlier negotiation meetings on ANDA review goals. Topics discussed included generic drug program performance reporting, review goals for standard vs. priority original applications, and review goals for standard vs. priority prior approval supplements (PASs).

Next Meeting
The next negotiation meeting is planned for Wednesday, April 6, 2016.