FDA-Industry GDUFA Reauthorization Meeting
May 12, 2016, 9:30 am – 2:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1305

Purpose
To discuss issues pertaining to Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs), and financial considerations for GDUFA II.

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Mary Beth Clarke	CDER	Steve Giuli	GPhA (Apotex)
Keith Flanagan	CDER	Marcie McClintic Coates	GPhA (Mylan)
Kirk Kerr	CDER	Alan Nicholls	BPTF
Robert Lionberger	CDER	Laura Parks	PBOA (Patheon)
Donal Parks	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Edward Sherwood	CDER	Gil Roth	PBOA
Martin Shimer	CDER	Cornell Stamoran	PBOA (Catalent)
		Tom Thorpe	PBOA (Afton Scientific)
		Scott Tomsky	GPhA (Teva)
		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
Lisa Tan (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, and a pre-ANDA process (pre-ANDA meetings, product-specific guidance, and controlled correspondence). FDA and Industry discussed resource needs, user fee concepts, and fee structure considerations for GDUFA II.

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