FDA-Industry GDUFA Reauthorization Meeting
January 20, 2016, 10:00 am – 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose

To discuss review timeframes for Abbreviated New Drug Applications (ANDAs), elements of the pre-ANDA process, facility evaluations, and issues concerning Drug Master Files (DMF).

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Ashley Boam	CDER	Marcie McClintic Coates	GPhA (Mylan)
Mary Beth Clarke	CDER	Alan Nicholls	BPTF
Karen Corallo	CDER	Laura Parks	PBOA (Patheon)
Keith Flanagan	CDER	Cristina Planellas	EFCG (Medichem)
Brian Hasselbalch	CDER	Molly Rapp	GPhA (Fresenius-Kabi)
Michael Jones	CDER	Gil Roth	PBOA
Robert Lionberger	CDER	Scott Tomsky	GPhA (Teva)
Ann Marie Montemurro	ORA	Keith Webber	GPhA (Perrigo)
Edward Sherwood	CDER		
David Skanchy	CDER		
Russell Wesdyk	CDER		

FDA Supporting Staff

Carter Beach, Heather Brown, Derek Griffing, Michael Neuenschwander, Martha Nguyen, Donal Parks, Tawni Schwemer, Katie Stronati, Trang Tran

Industry Supporting Staff

Mark Hendrickson (GPhA), Lisa Tan (GPhA)

Discussion

FDA and Industry continued discussions from earlier negotiation sessions on the ANDA review timeframe and review goal metrics. Topics included: transparency, pre-ANDA processes, controlled correspondence, first generics, and regulatory science. FDA and Industry also discussed the current FDA facility evaluation model and DMF scientific review and completeness assessments. FDA and Industry agreed that both sides are generally aligned on major principles for GDUFA II.

Next Meeting

The next negotiation meeting is planned for Wednesday, February 3, 2016.