FDA-Industry GDUFA Reauthorization Meeting
October 7, 2015, 10:00 am - 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Conference Room 1208/1210

Purpose
To discuss GDUFA reauthorization ground rules and logistics, and to provide an overview of the plan for the negotiation process.

Participants

FDA		Industry	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Mary Beth Clarke	CDER	Kiran Krishnan	GPhA (Apotex)
Keith Flanagan	CDER	Alan Nicholls	BPTF
Ann Marie Montemurro	ORA	Laura Parks	PBOA (Patheon)
Edward Sherwood	CDER	Molly Rapp	GPhA (Frensius-Kabi)
Martin Shimer	CDER	Nawel Rojkjaer	GPhA (Mylan)
		Gil Roth	PBOA
		Cornell Stamoran	PBOA (Catalent)
		Elizabeth Stampa	EFCG (Medichem)
		Tom Thorpe	PBOA (Afton Scientific)
		Scott Tomsky	GPhA (Teva)
		Keith Webber	GPhA (Perrigo)

FDA Supporting Staff
Carter Beach, Heather Brown, Derek Griffing, Michael Neuenschwander, Martha Nguyen, Tawni Schwemer, Katie Stronati, Sharon Thomas, Trang Tran, Lucie Yang

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

Ground Rules & Logistics for Negotiations
Meeting participants discussed the ground rules for GDUFA reauthorization and Industry agreed to review the ground rules and confirm agreement with them at the next negotiation meeting, scheduled for October 21, 2015. Participants agreed to use GDUFA I as a foundation for negotiating GDUFA II, as opposed to renegotiating GDUFA I. FDA discussed the statutory requirements for reauthorization and provided an overview of the negotiation process. FDA also discussed the proposed meeting schedule and agreed to update the proposed schedule based on the progress of the negotiations.

Negotiation Planning
FDA communicated its proposal to begin negotiations with a discussion of broad issues, including Industry's challenges, needs, and priorities for GDUFA II. FDA also proposed having a subgroup

focused on small business issues. The small business subgroup proposal will be discussed further at the next negotiation meeting.

FDA preliminarily framed lessons learned from implementing GDUFA I. FDA discussed the challenge of bridging the gap between its negotiated GDUFA I commitments on the one hand and stakeholder expectations on the other. FDA explained that a fundamental goal for GDUFA II is to align with Industry on a manageable number of high impact changes rather than a large volume of low impact changes that add complexity to the program without meaningful public health benefit.

Industry informed FDA that it is developing a priority list of proposals to discuss at future negotiation meetings. Industry emphasized the importance of understanding the context of the negotiations when implementing changes to the GDUFA program. FDA clarified that members of its negotiation team will participate in GDUFA II implementation.

Next Steps

The next negotiation meeting is planned for October 21, 2015. FDA will elaborate on the small business subgroup proposal and FDA and Industry will present on their priority challenges, needs, and priorities for GDUFA II.