FDA-Industry PDUFA VI Reauthorization Meeting
September 16, 2015, 10:00am-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 75, Room 1535/1540

Purpose

To agree on reauthorization ground rules and provide FDA and Industry perspectives on enhancements for PDUFA VI.

Participants

FDA		Industry	
Josh Barton	CDER	Beatrice Biebuyck	BIO (Alexion)
Steve Berman	CDER	Jennifer Boyer	BIO (Alkermes)
Amanda Edmonds	OC	Andrew Emmett	BIO
Patrick Frey	CDER	Jeffrey Francer	PhRMA
John Jenkins	CDER	Sascha Haverfield	PhRMA
Chris Joneckis	CBER	Kay Holcombe	BIO
Andrew Kish	CDER	Robert Kowalski	PhRMA (Novartis)
Theresa Mullin	CDER	Sandra Milligan	PhRMA (Merck)
Mary Parks	CDER	Michelle Rohrer	BIO (Roche Genentech)
Grail Sipes	CDER	Mark Taisey	PhRMA (Amgen)
Melissa Segal	OC		
Graham Thompson	CDER		
Terry Toigo	CDER		
Brad Wintermute	OIMT		

Ground Rules for Negotiations

The ground rules governing the PDUFA VI reauthorization negotiations were discussed. FDA proposed a new rule generally requiring in-person attendance at meetings. Industry agreed that in-person attendance would generally be the rule but suggested that teleconference remain an option in limited circumstances for meetings. FDA agreed with this provision. A proposed timeline for developing joint communications to the authorizing Congressional Committees was discussed and tentatively agreed upon. It was agreed to review and update this plan based on the progress of the negotiations.

FDA Perspectives on Reauthorization

FDA discussed the overall experience to date in PDUFA V, including FDA's review goal performance and other accomplishments under PDUFA V. FDA also highlighted its goals for PDUFA VI reauthorization, which include enhancements to review processes, to regulatory science and review tools, to post-market surveillance, and to information technology infrastructure. FDA also expressed a goal to better align the fee structure to public health goals while improving the predictability of fee amounts for industry and funding levels for FDA. The FDA-proposed enhancements are grouped according to four areas, pre-market review, regulatory science and decision tools, post-market surveillance, and financial. FDA briefly summarized each of its proposals.

Industry Perspectives on Reauthorization

Industry representatives noted that PDUFA has been a successful program and noted an evolution in the perspective of PDUFA towards the perspective of the patient. Industry representatives communicated their goals for user fee reauthorization and grouped their proposed PDUFA VI enhancements based on three principles. The principles included: 1) to better integrate the patient perspective into drug development and regulatory decision-making; 2) to enhance the scientific expertise, processes, and tools FDA uses to regulate increasingly complex medical products and public health issues; and 3) to promote the long - term stability of the PDUFA program by improving its financial transparency, efficiency, and accountability and ensuring that FDA can recruit, hire, and retain a highly skilled workforce to advance its public health mission.

Plan for Future Meetings

The goal for the next meeting on September 29 will be to have more detailed discussions of FDA and Industry proposals and to refer topics to designated working groups.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.