FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
November 10, 2015, 1:00pm-4:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To provide an overview of the federal hiring process, discuss FDA strategies for hiring, and plan next steps.

Participants

FDA		Industry	
Josh Barton	CDER	Beatrice Biebuyck	BIO (Alexion)
Steve Berman	CDER	Jennifer Boyer	BIO (Alkermes)
Amanda Edmonds	OC	Cartier Esham	BIO
Joe Franklin	OC	Jeffrey Francer	PhRMA
Patrick Frey	CDER	Sascha Haverfield	PhRMA
John Jenkins	CDER	Deborah Henderson	PhRMA (Merck)
Chris Joneckis	CBER	Kay Holcombe	BIO
Melanie Keller	CDER	Laurie Keating	BIO (Alnylam)
Andrew Kish	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Theresa Mullin	CDER	Paula Rinaldi	PhRMA (Novartis)
Mary Parks	CDER	Michelle Rohrer	BIO (Roche Genentech)
Melissa Segal	OC	Mark Taisey	PhRMA (Amgen)
Graham Thompson	CDER		
Terry Toigo	CDER		
Tania Tse	OC		
Brad Wintermute	OIMT		

Overview of Government Hiring Process and FDA Strategies
FDA provided an overview of the rules, regulations, and processes within the federal government for hiring of new employees that are most relevant to FDA's experience. FDA summarized some of the factors that impact its ability to hire qualified personnel in a timely manner, including: small supply of certain technical fields, limited flexibility with pay and incentive options, divestiture requirements, position classification requirements, and significant investment of senior program personnel's time within the process to screen candidates. FDA then provided a summary of efforts to enhance the efficiency and effectiveness of its hiring process that have either recently been implemented, or will be implemented in the next few months. These efforts include improvements to the process for position classification, enhancements to its position management system, contractor capacity support to HR, and a new function dedicated to scientific staff recruitment and retention.

Industry indicated it was supportive of current efforts to improve the efficiency and effectiveness of FDA's hiring process and inquired if FDA could further benefit from additional 3rd party support to assess, plan and implement improvements to FDA's hiring system to positively impact PDUFA VI. FDA indicated it was supportive in principle of this suggestion and would consider it further.

Industry also emphasized its view that an enhanced resource management and capacity planning system and capability would be beneficial to the management of the PDUFA program.

Next Steps
FDA and Industry agreed to continue discussing hiring and resource issues, as well as each side's PDUFA VI priorities in the next Steering Committee meeting.

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