FDA-Industry PDUFA VI Reauthorization Meeting
November 18, 2015, 9:30 -11:30am
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1215

Purpose: To discuss FDA and Industry pre-market review process enhancement proposals.

Participants

FDA		Industry	
Alonza Cruse	ORA	Cartier Esham	BIO
Joseph Franklin	OCC	Sascha Haverfield	PhRMA
Patrick Frey	CDER	Laurie Keating	BIO (Alnylam)
John Jenkins	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Christopher Joneckis	CBER	Mark Taisey	PhRMA (Amgen)
Theresa Mullin	CDER		
Mary Parks	CDER		
Michael Pacanowski	CDER		
Vada Perkins	CDER		
James Smith	CDER		
Sara Stradley	CDER		
Kelly Taylor	CDER		
Kimberly Taylor	CDER		

FDA and Industry continued discussing proposals to enhance the review process.

1. Breakthrough Therapy program. FDA stated that the proposed additional capacity to support the breakthrough program in PDUFA VI was based on the current volume of designation requests and the rate at which requests are granted by the agency. However, FDA noted that this volume may increase due to the growing number of targeted therapies in development. The agency stated that the additional capacity would align with the workload of the disciplines involved in review of these products.

2. NME Program: Industry stated that the agency's proposed modifications to the NME Program could move forward to draft commitment letter language.

3. Meeting management. Industry expressed concern regarding FDA's proposal to have the background package submitted at the time of the meeting request for Type B and C meetings. Industry explained this would create an additional month in which the development program is pending the outcome of the End-of-Phase 2 meeting. Both parties discussed potential alternatives to the current meeting timelines. Industry and FDA also discussed the FDA-proposed option of moving more meetings to Written-Response-Only (WRO) format to give the agency more flexibility in handling the meeting workload. Industry stated it was open to this proposal if the conversion to WRO was made only upon the mutual agreement of both parties. Industry also expressed interest in the option for a follow-up telephone call with the agency should a sponsor need clarification of FDA's written response. FDA and Industry agreed to continue discussing the meeting management proposal.

4. FDA review of labeling supplements, proposed pediatric study requests (PPSRs), and submissions related to post-marketing requirements and commitments (PMRs/PMCs). FDA stated that the agency will continue to work toward meeting its internal goals related to labeling supplements, PPSRs, and submissions related to PMRs/PMCs.

FDA noted that while the agency is not resourced to establish formal tracked goals for these submissions in the timeframes proposed by industry, the agency would be better positioned to meet its internal timeframes for these submissions with additional hiring expected during the remainder of PDUFA V and into PDUFA VI.

5. Controlled Substances Scheduling: Industry and FDA agreed to increase communication with the sponsor during marketing application review regarding FDA's scheduling recommendation for products with abuse potential. Since this generally affects new molecular entities, both parties agreed that language added to the NME Program in the commitment letter would be most appropriate to ensure clarity regarding the scheduling process.

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