FDA-Industry PDUFA VI Reauthorization Meeting
January 12, 2015, 12:30 -2:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208

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

Participants

FDA		Industry	
Alonza Cruz	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		
James Smith	CDER		
Sara Stradley	CDER		
Kelly Taylor	CDER		
Kimberly Taylor	CDER		

Communication, coordination and review division consistency

FDA and industry discussed draft commitment letter language regarding a third-party assessment of current FDA and sponsor communication practices during drug development that would be followed by a public meeting and potential revision of guidance if appropriate. Industry asked for more specific language regarding ongoing training of FDA staff. FDA agreed to this addition.

NME Program

Industry and FDA discussed draft commitment letter language regarding modifications to the NME Program. Industry asked that the language clarify that the Late-Cycle Meeting background package should include, where relevant, the Advisory Committee background package or a reference to it if it had already been sent to the applicant. FDA agreed to this clarification.

FDA review of labeling supplements, proposed pediatric study requests (PPSRs), and submissions related to post-marketing requirements and commitments (PMRs/PMCs)

FDA and Industry discussed inclusion of language that would state FDA's commitment to meeting tracked performance goals and to improve meeting internal performance goals such as those related to pre-approval drug development and post-approval activities for marketed products as referenced in the Good Review Management Principles and Practices for PDUFA Products guidance and the Good Review Management Principles and Practices for Effective IND Development and Review MAPP. Industry expressed its shared commitment to helping FDA meet those goals. Both parties agreed that FDA and industry will periodically and regularly assess progress in meeting those goals, identify emerging challenges and develop strategies to address them.

Combination product review

The agency noted an increase in combination product consultations from CDER to CDRH, and stated this was most likely due to an increase in the complexity of combination products in general. The agency also noted that in FYs 2014 and 2015, about 20% of NMEs and original BLAs were combination products.

FDA discussed a proposal to build review capacity across the required agency product centers and offices to enable timelier, transparent, and better coordinated combination product reviews. The agency proposed to streamline the process for combination product review through business process improvement and the establishment of clear processes and timelines for cross-center consultations. FDA also proposed to develop or revise MaPPs, SOPPs and templates for requesting and providing inter-center consults regarding combination product review. FDA also proposed to establish submission procedures and new review timelines for HF protocol reviews for INDs in addition to providing comprehensive training for all review staff that engage in drug-device and biologic-device combination product review. FDA stated that the additional resources would be needed to undertake the proposed activities. Industry also requested that the agency develop technical guidances regarding human factors/usability testing, labeling, and bridging studies as part of an enhancement for combination product review. FDA stated that the agency intends to provide guidance on human factors/usability testing. FDA and industry agreed to continue discussing this proposal.

Goal extensions and manufacturing facility information

Industry and FDA discussed draft commitment letter language regarding the extension of the PDUFA goal for applications that omit in their list of manufacturing facilities one that FDA identifies for pre-approval inspection. FDA clarified that the length of the extension would be tied to the submission type – original application efficacy supplement (3 months) or manufacturing supplement (2 months).

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