FDA-Industry PDUFA VI Reauthorization Meeting
October 6th, 2015, 1:00pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

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

Participants

FDA		Industry	
Joseph Franklin	OCC	Cartier Esham	BIO
Patrick Frey	CDER	Jeffrey Francer	PhRMA
John Jenkins	CDER	Sascha Haverfield	PhRMA
Christopher Joneckis	CBER	Kay Holcombe	BIO
Lisa LaVange	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Michael Pacanowski	CDER	Michelle Rohrer	BIO (Roche Genentech)
Mary Parks	CDER	Mark Taisey	PhRMA (Amgen)
James Smith	CDER		
Sara Stradley	CDER		
Kellie Taylor	CDER		
Kimberly Taylor	CDER		

Discussion of FDA Review Process Enhancement Proposals

FDA and Industry continued initial discussion of several proposals to enhance the review process. FDA began by discussing proposals to enhance the timeliness of FDA's review of human factor studies and to modernize the software tool used for proprietary name review. Industry discussed proposals regarding the timeliness of FDA's recommendation for controlled substances scheduling of new molecular entities with abuse potential, the use of real-world evidence in regulatory decision-making, improvements in communication, coordination and review division consistency, and enhancements to the qualification pathway for drug development tools.

1. Enhance timeliness of human factor (HF) study review. FDA noted that industry and stakeholder organizations have expressed concern about the review process for HF studies of drug/biologic-led combination products, an area of increasing workload. The agency added that CDER and CBER have recently been working to improve internal processes and to clarify expectations regarding inter-center consultation on HF studies. FDA proposed to establish submission procedures for sponsors, enhance internal processes for HF study review, and establish review performance goals for HF studies. The agency stated that it would need additional resources to meet review performance goals. FDA and Industry agreed to continue discussing this proposal.

2. Modernize FDA's proprietary name review tool. FDA noted that CDER and CBER's proprietary name review tool - POCA (Phonetic and Orthographic Computer Analysis) – was developed over 10 years ago and is now outdated in terms of its software and algorithm. The agency stated that the software operates on an expensive and outdated platform and uses an algorithm that was not designed to account for electronic prescribing in assessing the potential for name confusion. FDA stated that it would need additional resources to modernize POCA. FDA and Industry agreed to continue discussing this proposal.

3. Align timelines for scheduling of new molecular entities (NMEs) with abuse potential with PDUFA goals. Industry expressed concern that FDA's engagement in the drug scheduling process for NMEs is not linked to PDUFA performance goals and that the final HHS recommendation regarding a drug's abuse potential may not be completed until after drug approval. Industry stated that this could delay the final scheduling and timely marketing of a product after FDA approval. Industry emphasized that its main goal is ensuring FDA's portion of

scheduling review is complete at the time of drug approval. FDA and Industry agreed to continue discussing this proposal.

4. Use of real-world evidence (RWE) in regulatory decision-making. Industry stated that RWE is not typically used by FDA to evaluate the benefits of a drug, although the technology to do so is available. Industry proposed FDA hold a public workshop with stakeholders followed by designing and executing pilot studies to better understand issues related to the use of RWE in regulatory decision-making. Industry also proposed that the information learned from these initiatives feed into a draft guidance on how sponsors can use RWE appropriately in regulatory submissions, both for safety and efficacy purposes. FDA and Industry agreed to continue discussing this proposal.

5. Improve FDA communication, coordination and review division consistency. Industry discussed the need to build on the progress regarding communications during drug development that has been made under PDUFA V. Industry proposed that the agency conduct an independent assessment by a third party to identify best practices for FDA-sponsor interactions during drug development, the findings of which would lead to publication of appropriate procedural documents for CDER and CBER. Industry also proposed that FDA develop metrics and reporting procedures for all drug development questions and requests for advice from individual sponsors. FDA expressed significant concern regarding the scope of the proposed evaluation and the substantial expansion of tracked metrics for individual communications given that the agency conducts oversight on thousands of active commercial INDs. The agency noted that a draft guidance on best communication practices is expected to publish soon and may address some of industry's concerns, although FDA's ability to follow any timelines described in the guidance would be based on current resource capacity. Finally, FDA stated that any assessment of communication practices should also assess sponsor behavior as well, as not all sponsors follow best practices in communication with the agency. FDA and Industry agreed to continue discussing this proposal.

6. Proposal for enhancement of the drug development tools (DDT) qualification pathway. Industry expressed interest in enhancing the current FDA qualification process for DDTs, such as biomarkers and patient-reported outcomes (PROS). Industry proposed FDA hold a public meeting with stakeholders to discuss an appropriate taxonomy and framework for biomarkers used in drug development. Industry also proposed FDA revise the current DDT qualification guidance based on feedback from the public meeting, and re-issue it as a draft guidance for public comment. FDA and Industry agreed to continue discussing this proposal.

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