FDA-Industry PDUFA VI Reauthorization Meeting
October 7, 2015, 9:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1300

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

Participants

FDA		Industry	
Joseph Franklin	OCC	Beatrice Biebuyck	BIO (Alexion)
Patrick Frey	CDER	Cartier Esham	BIO
John Jenkins	CDER	Jeffrey Francer	PhRMA
Christopher Joneckis	CBER	Laurie Keating	BIO (Alnylam)
Lisa LaVange	CDER	Robert Kowalski	PhRMA (Novartis)
Sarah Pope Miksinski	CDER	Sandra Milligan	PhRMA (Merck)
Michael Pacanowski	CDER	Michelle Rohrer	BIO (Roche Genentech)
Mary Parks	CDER	Mark Taisey	PhRMA (Amgen)
James Smith	CDER	Sascha Haverfield	PhRMA
Sara Stradley	CDER	Kay Holcombe	BIO
Kellie Taylor	CDER		
Kimberly Taylor	CDER		
Theresa Mullin	CDER		
Issam Zineh	CDER		

Discussion of FDA Review Process Enhancement Proposals

FDA and Industry continued initial discussion of proposals to enhance the review process. FDA began by discussing a proposal to ensure FDA's ability to conduct timely review of manufacturing supplements. Industry discussed a proposal on the use of Patient-Reported Outcomes (PROs), Biomarkers and Drug Development Tools (DDTs) during drug development. Industry and FDA then continued discussing proposals regarding the timeliness of FDA's recommendation for scheduling of new molecular entities with abuse potential and improvements in communication, coordination and review division consistency.

1. Manufacturing supplements. FDA stated that while the agency is currently meeting the PDUFA performance goal of reviewing and acting on Prior Approval Manufacturing Supplements (PAS) within 4 months of receipt, it has become increasingly challenging to do so. FDA further stated that meeting the goal date often results in significant uncompensated staff overtime to resolve product quality issues that could otherwise prevent an approval action. The agency noted that this problem is particularly acute where inspections (notably foreign inspections) are necessary. FDA proposed to revise the PAS performance goal to 6 months, while informing the applicant (or facility) of the inspection findings within 4 months. FDA agreed to provide industry with additional data on the number of complete responses with late foreign inspections to better understand the potential impact of this proposal. FDA and Industry agreed to continue discussing this proposal.

2. Patient Reported Outcomes, Biomarkers, and Drug Development Tools. Industry discussed the increasing use of Drug Development Tools (e.g. Biomarkers and PROs) and the corresponding need for a predictable and coordinated FDA review process for these tools so that there is greater confidence later in drug development that a tool will be accepted by the agency in the context of a specific development program. Industry proposed that FDA-sponsor discussions of study protocols utilizing DDTs be eligible for Type B meetings as well as the Special

Protocol Assessment (SPA) process. FDA noted that the SPA process is used, typically following a sponsor's End-of-Phase 2 meeting, to reach agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA or BLA. FDA expressed concern about applying a similar process and establishing a binding agreement so early in drug development when less is known about the drug's effect. FDA also noted concern about the resource impact of additional meetings given the surge of meeting requests received by FDA thus far during PDUFA V. Industry also proposed that FDA update its current PRO guidance to clarify agency roles and responsibilities and the agency's expectation for acceptance of PROs as part of a product application. FDA and Industry agreed to continue discussing this proposal.

3. Controlled Substances Scheduling. Industry clarified that the goal of this proposal is to align FDA's scheduling recommendation with the PDUFA goal date. FDA and Industry agreed to continue discussing this proposal.

4. FDA communication, coordination and review division consistency: Industry had proposed a third-party assessment that could identify best communications practices and make recommendations to achieve consistency in implementing such best practices. FDA questioned how an independent assessor would be able to evaluate the numerous informal interactions that occur between FDA and sponsors without obstructing the work of the agency. The agency also stated that the primary responsibility of FDA during drug development is to ensure patient safety. FDA must therefore prioritize its review staff resources accordingly. Industry stated that the purpose of the evaluation would be to capture why some divisions seem to have better communication practices than others. FDA observed that the evaluation would also identify that some sponsors have better communication practices with the agency than others. 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.