Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

October 6th, 2020 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to give industry an overview on FDA's program resources, a current status update on PDUFA VI hires, and a walk-through of progress made under the capacity planning and resource management capability.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Rob Blanks	BIO (Ardelyx)
Amanda Edmonds	OC	E. Cartier Esham	BIO
Chris Joneckis	CBER	Danielle Friend	BIO
Andrew Kish	CDER	Carl Garner	PhRMA (Eli Lilly)
Ted Liazos	OC	Brad Glasscock	BIO (BioMarin)
Theresa Mullin	CDER	Kelly Goldberg	PhRMA
Carol Rehkopf	CBER	Mathias Hukkelhoven	PhRMA (BMS)
Khushboo Sharma	CDER	Robert Kowalski	PhRMA (Novartis)
Mary Ann Slack	CDER	Ann Kurowski	BIO (Alkermes)
Peter Stein	CDER	Heidi Marchand	BIO (Gilead and Kite)
Mary Thanh Hai	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER	Lucy Vereshchagina	PhRMA
Patrick Zhou	CDER		

Regulatory Decision Tools High-Level Update

After introductions, FDA presented ground rules and logistics for the upcoming negotiation in the subgroup. FDA then identified several areas for proposed enhancements for regulatory decision tools under PDUFA VII. In the first meeting, FDA discussed its proposals related to Model-Informed Drug Development and in building upon the lessons learned in PDUFA VI to advance the pilot.

CBER Breakout High-Level Update

FDA introduced its proposal to support the Cell and Gene Therapy Program in CBER and ensure that the rapidly growing program can keep pace with the increased workload. Industry presented its interest in additional learnings from the Regenerative Medicine Advanced Therapy Designation

Program and interest in discussing manufacturing issues related to gene therapy technologies. Both FDA and industry agreed that while some discussions may begin in this subgroup, there may be overlap with other subgroups for specific topics as talks progress.

Pre-Market High-Level Update
After introductions, FDA presented ground rules and logistics for the meetings in the subgroup. FDA then introduced the areas of interest to the agency, specifically additional support for human factors and use-related risk analysis review and in rare disease endpoints. In response, industry posed clarifying questions to further understand FDA's needs and rationale for their request.

Digital Health and Informatics High-Level Update
FDA reviewed its proposals to industry and also provided an overview of relevant activities currently underway at the agency. FDA described its key modernization priorities (a cloud forward posture, financial management, and putting modern user experience at the forefront) and described how the agency technology map (TMAP) is driving the IT strategy. FDA and industry then discussed high-level objectives and questions and planned to continue discussions in more detail the following week.

Post-Market High-Level Update
After introductions, FDA presented ground rules and logistics for the meetings in the subgroup. FDA then provided summaries of their thinking on proposals related to modernizing REMS assessments and the Sentinel Initiative and also gave industry an update on the accomplishments FDA has made in both areas. Industry offered thoughts on the discussion and made proposals related to the Sentinel Initiative while expressing interests in real world data, real world evidence, and the need to tap into electronic health records. FDA agreed to review the questions industry raised with the goal of sharing the agency's specific thoughts on those topics.

CMC and Inspections High-Level Update
Industry presented their main themes of interest in manufacturing and inspections. These focused on enhancing communications, increasing understanding of the decision framework around inspections, preparing for emerging technologies, and streamlining quality-related regulatory submission content. In response, FDA posed some clarifying questions. FDA and industry both also acknowledged there were existing workstreams that may address some of industry's interests outside of negotiations.

Finance High-Level Update
FDA began by presenting the agency's progress made to-date in this area including the changes made under PDUFA VI. FDA also highlighted its goals for PDUFA VII to enhance the operational capabilities, efficacy, and agility of the PDUFA program and shared their various proposals. Industry stated their goals for PDUFA VII were to build upon the success of PDUFA VI while ensuring transparency, accountability, and sustainability of the program. Industry then shared its various proposals and agreed to discuss financial enhancements in greater detail in future meetings.

Overview of FDA Program Resources, Status of PDUFA VI Hires, and Progress in Capacity Planning and Resource Management
FDA presented the latest data on resources for the PDUFA VI enhancements and the background for FDA providing quarterly hiring updates to the public website. FDA stated the limitations of focusing on headcounts when talking about FDA's resources and said that focusing on level of

effort and capacity may be more meaningful and gives the program more flexibility. The agency then presented an overview of resource capacity planning defining terms and reviewed the unique challenges of designing a novel capability under a unique operating paradigm. This segment also included a detailed walk-through of how FDA's resource forecast is driven by newly implemented modernized time reporting and advanced analytical approaches to forecast workload. FDA then explained how the resource capacity planning capability is becoming integrated into FDA's operations, the process by which the capacity planning adjustment can forecast future FTE needs, and what the next steps will be for this capability moving forward.

Next Steps

FDA and industry agreed to discuss the independent interim assessment of FDA's human resources and hiring capabilities at the next meeting on October 13th. They also agreed to discuss management's response to the report along with industry's submitted questions regarding the agency's next steps. Additionally, subgroups will continue to provide a high-level read-out as to the progress of their negotiations.

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