Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

September 30th, 2020 | 9:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To begin discussion of the digital health and informatics related topics in the context of the PDUFA reauthorization.

PARTICIPANTS

FDA		Industry	
Boris Brodsky	CDER	Rob Blanks	Ardelyx
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Martin Ho	CBER	Mathias Hukkelhoven	BMS
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Chris Joneckis	CBER	Robert Kowalski	Novartis
Leonard Sacks	CDER	Heidi Marchand	Gilead
Khushboo Sharma	CBER	Camelia Thompson	BIO
Mary Ann Slack	CDER		
Ranjit Thomas	CDER		

At the first PDUFA Negotiation meeting on 09/30, FDA reviewed its proposals to Industry, including an overview of relevant activities currently underway at the Agency. Through an explanation of key modernization priorities such as a cloud forward posture, financial management, and putting modern user experience at the forefront, FDA discussed its focus on harnessing a continuous modernization vision to support capabilities that adjust to changing times. FDA described how the agency technology map (TMAP) is driving the FDA's IT strategy and moving it to prioritize an agile, incremental approach.

1. **Cloud Proposal:** FDA proposed an integrated cloud-based technology environment for collaboration and as a framework for regulatory submission innovation, using pilot projects to test feasibility and to collaboratively design and implement cloud-based capabilities that could be utilized in the regulatory process. In further discussion regarding potential pilots, FDA identified information requests (IR) as a common pain point. Benefits of the cloud proposal include cost efficiencies, improved communications exchange and collaborations. FDA and Industry will continue to discuss this proposal.

2. **Supporting Use of Digital Health Technologies (DHT) Proposal**. FDA proposed to develop a DHT framework for strengthening its capability to leverage DHT-generated data in submissions, including identification and development of needed guidance, building staff capacity to enhance review consistency and efficiency, and ensuring IT support for identifying, storing and utilizing DHT data. During the team's discussion, FDA clarified that they would align with and leverage the recently announced Digital Health Center of Excellence being established in CDRH (DHCoE) to harmonize on policy and practices where applicable, and do not intend to duplicate capability already in CDRH or the DHCoE. Industry inquired whether there was a plan to address telemedicine for more permanent implementation after COVID-19; FDA noted that current work and lessons learned going beyond the COVID-19 pandemic are currently being evaluated, and shared that general guidance is being developed to support decentralized clinical trials (DCT) and potential use of DHTs. FDA and Industry will continue to discuss this proposal.

3. **CBER IT Modernization**. FDA explained how CBER's aged Information Technology (IT) systems were created independently with separate functionalities and siloed databases, resulting in high operations and maintenance cost and failure to provide necessary functionalities for staff to operate in a modern regulatory environment. CBER is modernizing its business, data, and IT to meet current demands of newer and evolving products such as Cellular and Gene Therapies. CBER's modernization continues to build on leveraging other FDA IT systems and in developing integrated IT platforms to meet CBER's diverse needs including PDUFA products. Currently, operating and maintenance account for a majority of FDA's IT costs, leaving very little for modernization. Although FDA has done its part in maximizing its use of resources and training staff, modernization will require more adjustments. FDA and Industry will continue to discuss this proposal.

FDA and Industry then discussed high-level objectives and questions, agreeing to continue negotiations the next week on Wednesday, 10/07. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.