Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

September 15th, 2020 | 10:00am-3:00pm

Virtual Format

PURPOSE

To agree on reauthorization ground rules, explain parameters for virtual environment and provide FDA and Industry perspectives on enhancements for PDUFA VII.

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		

The meeting discussion was focused on the issues of interest to industry and FDA and on planning for the negotiations process.

Ground Rules for Negotiations and Virtual Environment

The ground rules governing the PDUFA VII reauthorization negotiations were reviewed and agreed-upon by both parties. There were no additional comments or edits offered for the draft that FDA presented. FDA also presented the operating processes and rules for conducting negotiations in a virtual environment. There were no additional comments or questions.

FDA Perspectives on Reauthorization

FDA discussed the overall experience to date in PDUFA VI, emphasizing the agency's performance in meeting its core review performance goals and its enhancement commitments. Despite historic workload and operating challenges in the time period, the steps taken in PDUFA VI to protect the

program from financial uncertainty have proven critical and important to maintaining FDA's operations. FDA also highlighted its overall goals for PDUFA VII reauthorization, which are to promote sustainable innovation, enhance regulatory predictability and post-market safety, advance the regulatory infrastructure, and enhance the agency's operational capabilities, efficiency and agility. These include enhancements to address advancements in new technologies and analytical approaches, the influx of cell and gene therapies, improving upon our post-market surveillance approach, and building upon the progress FDA has made in developing its regulatory decision tools. The FDA-proposed enhancements were grouped into six areas: digital health and informatics, post-market, CBER-specific enhancements, pre-market, regulatory decision tools, and finance. FDA briefly summarized each of its proposals and clarified high-level questions from industry.

Industry Perspectives on Reauthorization

Industry representatives noted that their proposals represent an effort to build upon past user fee agreements and to ensure FDA and industry can mutually keep pace with scientific development. They also noted the possibility of lessons learned from the COVID-19 pandemic translating into improved processes for both parties. Industry's proposals revolved around issues such as: strengthening scientific dialogue, enhancing patient-centric drug review, supporting the next wave of advanced biologic therapies, modernizing regulatory evidence generation, advancing digital and IT technologies, enhancing innovation in quality and manufacturing, and optimizing FDA infrastructure, staffing, and resources. Industry briefly summarized each of its proposals and clarified high-level questions from FDA.

Next Steps

The goals for the next meeting on September 22nd will be to have more detailed discussions of FDA and industry proposals and to refer topics to designated working groups.

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