Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
June 17, 2016, 9:00 – 11:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 31, Great Room Section A

Purpose

To provide a status update on the ongoing MDUFA IV negotiations, plan for future stakeholder meetings and obtain stakeholders views on the focus topics of the Digital Health program and the de novo review process.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Bakul Patel	CDRH
Louise Howe	OCC
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Kathryn O'Callaghan	CDRH
Prakash Rath	Office of Legislation (OL)
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH
Sergio de del Castillo	CDRH

Stakeholders

Ellen Blom	National Organization for Rare Disorders
Paul Brown	National Center for Health Research
Jonathan Bryan	Duke University
Ryne Carney	Alliance for Aging Research
Marjorie Connolly	Pew Charitable Trusts
Lisa Goldstein	American College of Cardiology
Marisol Goss	AAOS
Catherine Hille	American Association of Neurological Surgeons
Bennie Johnson	JDRF
Paul Melmeyer	National Organization for Rare Disorders
Caroline Powers	American Cancer Society Cancer Action Network
Andrew Sperling	National Alliance on Mental Illness
Mark Williams	FasterCures
Jeffrey Wojton	Research!America
Jessica Yozwiak	National Organization for Rare Disorders

Meeting Start Time: 9:00 am
FDA welcomed stakeholders and briefly reiterated the role of stakeholder input during MDUFA negotiations.

FDA provided an overview of the minutes from the most recent negotiation meeting held on May 16, 2016.

FDA discussed the current status of proposals

FDA reported that at the May 16th meeting, FDA presented a counter proposal package that included low and high options in performance and cost for many of the elements of the package. FDA explained that this approach was used to address some of the concerns industry had expressed regarding the overall cost of the package. FDA also explained that one mechanism for lowering the total cost of the package is to progressively ramp up improvements to performance over the course of MDUFA IV rather than initiating them all at once in the first year of MDUFA IV; ramping up performance allows FDA to spread out hiring, which helps reduce costs in the earlier years of the program.

More details can be found in the most recently published meeting minutes.

For the focus topics, FDA presented on the Digital Health Program and the de novo review process

For the first focused topic, FDA presented detailed information regarding the digital health framework. FDA described this initiative as a convergence of individuals, patients, and people with information, technology, and connectivity that's creating a potential for better healthcare. FDA explained that this framework focuses on a paradigm of more engaged patients. Software is divided into three categories: software used in the device, software that is the device, and software used in manufacturing. FDA explained that quality is where we are focused in the digital health world. The agency currently relies heavily on the manufacturers following design controls. The digital health landscape is changing rapidly due to new emerging risks like cyber security and connectivity of devices and these areas pose a challenge to the current regulations and paradigm. For example, general software development times have gone from 18 months to now almost continuous. FDA stated that some of the hot trends in software development include mobile, big data, cloud, development and operations (DevOps) and user interface. FDA explained that the agency needs expertise in those areas. FDA indicated that the current state of digital health at the agency includes prolonged review cycles, delays in getting digital health medical devices to patients, and difficulties in fitting complex digital health issues into current review programs. FDA explained that the desired state would be to focus on higher risk products, rely on the quality system regulation and move away from product-by-product review, scale premarket requirements, create a new regulatory paradigm that has the right process, and make sure FDA has the appropriate expertise and sufficient review capacity.

For the second focused topic, FDA presented a high-level overview of the de novo program. FDA explained that the de novo program was created to allow a new and novel product that otherwise would be classified in class III and treated as high-risk (because of the lack of a predicate device) to go through a risk-based classification. FDA provided background information on the history of the de novo program. Manufacturers used to have to submit a 510(k) and receive a decision of not substantially equivalent before they could submit a de novo request. However, Congress amended the statute in 2012 to allow a manufacturer to submit a "direct" de novo, which eliminated the requirement to submit a 510(k) prior to the de novo request; Congress also revised the review timeframe to 120 days. FDA issued draft guidance in 2014 to help stakeholders better understand the program. FDA explained that de novo is a combined process that includes marketing authorization for a specific product and creating a new classification regulation. FDA stated that since 2010 the number of de novos received annually has increased from 10 to 60 submissions. FDA implemented many process improvements that greatly reduced the time it takes to complete a de novo review. However, FDA showed that the surge of submissions since 2012 has created strain on the program. FDA explained that the program is still evolving to consolidate the improvements that were made internally during MDUFA III. FDA stated that although review times have decreased, a deeper analysis of the number of incoming submissions shows signs that the agency is at a tipping point regarding performance. FDA stated that moving forward it wants to ensure there are sufficient resources to improve the performance and success of the program.

The next patient and consumer stakeholder meeting is scheduled for Thursday, July 28, 2016.

End: 10:43am