Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
May 27, 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 and plan for future stakeholder meetings.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Louise Howe	Office of Chief Counsel (OCC)
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Kathryn O'Callaghan	CDRH
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Jonathan Bryan	Duke University
Ryne Carney	Alliance for Aging Research
Beatriz Duque Long	Epilepsy Foundation
Mark Fleury	American Cancer Society Cancer Action Network
Maureen Japha	FasterCures
Bennie Johnson	JDRF
Josh Krantz	Society of Thoracic Surgeons
Paul Melmeyer	National Organization for Rare Disorders
Ben Moscovitch	Pew Charitable Trusts
Tracy Rupp	National Center for Health Research
Andrew Sperling	National Alliance on Mental Illness
Jeffrey Wojton	Research!America

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 Industry negotiation meetings. FDA explained that Industry presented a counter proposal at the April 27 meeting and FDA presented a counter to that at the May 16 meeting after holding technical discussions with Industry on May 2. Meeting minutes that cover the May meetings were still under review as of May 27.

FDA discussed the current status of proposals
FDA clarified that the proposal described in the minutes was presented by AdvaMed, MDMA and MITA.

FDA stated that the Industry's package presented on April 27 was more complete than their previously presented proposal package, yet there were still elements identified as "to be determined," and substantial gaps between their proposed resource and performance levels compared to FDA's latest proposal package.

Industry's counter proposal package included enhancements to the Pre-Submission (Pre-Sub) process. FDA explained that the Pre-Sub consultation process is currently implemented as resources permit, without any specific MDUFA III performance goals attached to the process. For MDUFA IV, FDA and Industry have discussed adding performance goals, which will require additional resources to achieve them. FDA and Industry continue to work on identifying a mix of resources and performance commitments that will achieve meaningful and feasible improvements to the process.

Industry's counter proposal also included resources for establishing a Quality Management system at the level that FDA estimated was needed. Industry's counter proposal regarding establishing a more integrated review process for ODE was below the level of resources that FDA estimated would be needed to make the transition. Industry's counter proposal for the De Novo process also fell short of the resources FDA had estimated are needed to achieve the goals proposed. Likewise, the level of resources Industry proposed for improving the CLIA waiver review process was below the amount FDA had estimated is necessary to achieve the performance goals that Industry proposed. Additionally, FDA noted that the CLIA waiver program proposals will need a legal review before moving forward. Industry's counter proposal also included another Independent Assessment similar to the one conducted during MDUFA III.

Industry's counter proposal included the myDevices web portal; resources for recruitment and retention; and strengthening the third party review program, standards conformity assessment, and digital health reviews. In all cases, except for myDevices and standards conformity assessment, the resources presented by industry were below what FDA estimated as being needed to achieve the proposed commitments.

In response to FDA's prior proposal to include a mechanism for tracking workload and adjusting authorized resource levels if actual workload exceeded planned levels, Industry proposed eliminating the fee offset provision, which would allow FDA to keep and spend any additional fees collected due to higher-than-planned numbers of submissions or registrations, provided that FDA discussed the uses of those additional funds during quarterly meetings. FDA stated that this addressed one problem with the current law, but did not directly address the potential shortfall of capacity to meet performance goals caused by unplanned increases in workload.

Industry's counter proposal package also included a placeholder for real world evidence and patient input, but left the amount of resources as "to be determined." Industry continued to express concerns about how FDA's proposals in these areas would be implemented, and whether they would offer sufficient value to a broad cross-section of the device industry. Industry's overall counter proposal package included further reductions in the shared outcome goals of reduced total time to decision (TTD) for PMA and 510(k) submissions. FDA noted that Industry's proposal for reducing the target number of days for TTD for PMAs reflected "locking in" improvements that FDA and Industry are on track to achieve during MDUFA III. However, industry's proposed reduction in TTD for 510(k)s reflect significant improvements over current performance. FDA noted concern that there are recent signs of strain on the program due to increased workload and maintained that a significant reduction in 510(k) TTD would require additional resources.

FDA noted that at the May 2 meeting there were no new proposals introduced but work was done to try to close the gap between the two groups. FDA reported that at the May 16 meeting, FDA presented a counter proposal package that included low and high options for many of the elements. Industry was expected to present their next counter proposal in June.

The next patient and consumer stakeholder meeting is scheduled for Friday, June 17, 2016.

END 10:24am