FDA – Industry MDUFA IV Reauthorization Meeting
April 27, 2016; 9:30 am – 2:30 pm
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose

To discuss proposals for MDUFA IV reauthorization.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Joni Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Louise Howe	OCC
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Toby Lowe	CDRH
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Darian Tarver	OC
Kim Worthington	CDRH
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Industry

Hans Beinke	Siemens (representing MITA)
Nathan Brown	Akin Gump (representing AdvaMed)
Elisabeth George	Philips (representing MITA)
Allison Giles	Cook (representing MDMA)
Mark Gordon	Abbott (representing MDMA)
Megan Hayes	Medical Imaging & Technology Alliance (MITA)
Donald Horton	Laboratory Corporation of America Holdings (representing ACLA)
Tamima Itani	Boston Scientific (representing MDMA)
Mark Leahey	Medical Device Manufacturers Association (MDMA)
John Manthei	Latham & Watkins (representing MDMA)
Michael Pfleger	Alcon (representing AdvaMed)

Jim Ruger	Quest Diagnostics (representing ACLA)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Pat Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Diane Wurzburger	GE Healthcare (representing MITA)

Meeting Start Time: 9:30 am

Executive Summary

AdvaMed, MDMA, and MITA presented an updated proposal package. The package included potential commitments and proposed resource estimates for several proposal areas, including Pre-Submissions, Quality Management (QM), Total Product Life Cycle (TPLC), *De Novo*, CLIA Waiver, independent assessment, IT improvements, recruitment, Third Party Review Program, Digital Health, and Standards. It also included enhancing the Total Time to Decision goals for PMAs and 510(k)s to capture the efficiencies and process improvements from the investments in the proposal. AdvaMed, MDMA, and MITA did not propose resource estimates for Real World Evidence (RWE), Patient Engagement, and Manager Incentive Pay proposals, stating that they need more information on these topics related to the costs and benefits. FDA expressed appreciation for their proposal package and noted it represented a step forward. FDA also stated there is still work to be done to close the gaps between the two sides.

April 27 Proposal from AdvaMed, MDMA, and MITA

AdvaMed, MDMA, and MITA's proposal included $680 million (using FY15 dollars) plus inflation to maintain MDUFA III performance goals, unless otherwise changed. They proposed to provide an additional $131 million spread out over 5 years, which would support an additional 91 FTE by the end of MDUFA IV. These values do not include resource levels for Real World Evidence, Patient Engagement, and Manager Incentive Pay. As it relates to Real World Evidence, industry requested tangible benefits that would be realized to make the premarket process more efficient. AdvaMed, MDMA, and MITA requested additional information to support their consideration of resource proposals for these areas.

The AdvaMed, MDMA, and MITA proposal would provide:

- 30 FTE to improve the Pre-Submission process, hold 90% of Pre-Submissions meetings within 75 days, and provide written feedback on 90% of Pre-Submissions within 55 days or 5 calendar days prior to the meeting, whichever comes sooner;
- 20 FTE to establish a QM system;
- 6 FTE to establish an integrated review process model (TPLC) for the Office of Device Evaluation;

- 21 FTE to complete 75% of *De Novo* submissions within 120 days;
- 3 FTE to complete 90% of Dual 510(k) and CLIA Waiver applications in 180 days, 90% of stand-alone CLIA Waiver applications without a panel meeting in 120 days, and 90% of stand-alone CLIA Waiver applications with a panel meeting in 320 days. This proposal is pending the review of potential legal impediments;
- $6 million for an independent assessment of the review process, including a more complete assessment of MDUFA III improvements and outcomes;
- $4.5 million for the development of the myDevices Portal. This investment would also include the ability to link Pre-Submissions with subsequent submissions and to track and report data specific to laboratory-developed tests, as proposed by ACLA;
- $2.5 million to implement effective recruitment and hiring strategies through the use of external recruiters;
- $4 million to strengthen the Third Party Premarket Review program;
- 6 FTE to provide consistent review of software and issues related to Digital Health;
- 5 FTE and $2.45 million to improve the Standards program by establishing a conformance assessment program for certified testing laboratories;
- A mechanism to allow for user fee collections in excess of the authorized amount in one fiscal year to be used the following year(s) to support the premarket review process, with no fifth year offset, and with input from Industry at quarterly meetings regarding the use of carryover funds;
- A willingness to explore RWE, based on demonstration of potential premarket benefits, with a request for additional information to further understand FDA's RWE proposal;
- An undetermined amount of resources, to be determined after receiving responses to a request for additional information to further understand FDA's vision for patient engagement; and
- An undetermined amount of resources, to be determined after receiving FDA's response to a request for additional information to further understand more details about implementing an incentive pay system.

AdvaMed, MDMA, and MITA stated that the resources identified above should create efficiencies in the program that enable reductions in the Shared Outcome goals for average total time to decision. Specifically, they proposed that the average total time to decision for 510(k)s

should decrease to 108 days by the end of FY2022 and the average total time to decision for PMAs should drop to 300 days by the end of FY2022.

Discussion

FDA asked clarifying questions about AdvaMed, MDMA, and MITA's proposal package. FDA expressed appreciation for AdvaMed, MDMA, and MITA's proposal, while noting that the proposal package is incomplete in that specific resources were not provided for Real World Evidence, Patient Engagement, and Manager Incentive Pay. AdvaMed, MDMA, and MITA explained that they need more information to better understand the proposals before committing specific resources in these areas. FDA agreed to address the questions provided as soon as possible.

FDA also noted that gaps remain between many individual components of FDA's proposal package and corresponding components of the AdvaMed, MDMA, and MITA proposal package. Specifically, funding levels for many of the proposal areas are significantly less than FDA's estimates for the resources needed to achieve the proposals. FDA's estimates were based on careful analysis of program performance and trends. Recent data indicate FDA is unable to consistently issue decisions on *De Novo* submissions in a timely manner with existing resources and that this program needs more resources than proposed. FDA also stated that 3 CLIA program management FTEs are not sufficient to meet the proposed enhancements to performance goals for CLIA Waiver review times.

FDA noted that its proposals for additional managers and review capacity were not included in the package proposed by AdvaMed, MDMA, and MITA, despite FDA's emphasis that these proposals are needed to shore up the program. FDA expressed concern that without additional review capacity and infrastructure, FDA would not be able to fulfill the request for substantial reductions in the Total Time to Decision Shared Outcome goals.

FDA appreciated the proposal to eliminate the offset provision, but noted that it still leaves FDA vulnerable to shifts in workload. FDA reiterated the need for an adequate mechanism to address workload uncertainty and noted that its resource and submission volume estimates are contingent on such agreement.

Furthermore, AdvaMed, MDMA, and MITA did not include IT operating dollars in their resource estimates for most of the proposals. FDA stated that without user fee support for the necessary changes to legacy IT systems, FDA will not be able to implement IT changes for the review program to reflect MDUFA IV processes and performance goals.

Next Meeting

The next meeting is scheduled for May 2, 2016.

Meeting End Time: 2:30 pm