FDA – Industry MDUFA IV Reauthorization Meeting
May 16, 2016; 9:30 am – 3:30 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
Thinh Nguyen	Office of Combination Products (OCP)
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Jonathan Sauer	CDRH
Darian Tarver	OC
Kim Worthington	CDRH
Barb Zimmerman	CDRH

Industry

Hans Beinke	Siemens (representing MITA)
Nathan Brown	Akin Gump (representing AdvaMed)
Phil Desjardins	Johnson & Johnson (representing AdvaMed)
Sergio Gadaleta	Becton Dickinson (representing AdvaMed)
Mark Gordon	Abbott (representing MDMA)
Megan Hayes	Medical Imaging & Technology Alliance (MITA)
Donald Horton	Laboratory Corporation of America Holdings (representing ACLA)
Mark Leahey	Medical Device Manufacturers Association (MDMA)
John Manthei	Latham & Watkins (representing MDMA)
Michael Pfleger	Alcon (representing AdvaMed)

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

After holding some technical working discussions on May 2, FDA presented an updated proposal package on May 16. The package included potential commitments and proposed resource estimates for the following proposal areas: Quality Management (QM), independent assessment, MyDevices IT portal, managerial capacity, review capacity, recruitment, retention incentive pay, fee setting provision, Pre-Submissions, *De Novos*, CLIA Waiver by Application submissions, Third Party Review Program, Digital Health, Patient Input, Real World Evidence (RWE), and Standards. FDA also proposed reductions in the Shared Outcome goals for 510(k) and PMA total time to decision based on the core infrastructure components of the package. AdvaMed, MDMA, and MITA expressed appreciation for FDA's proposal package and noted that although progress has been made, gaps still remain between the parties' proposal packages.

May 16 FDA Proposal

FDA's proposal included a base of $680 million plus inflation to maintain the performance goals that will be in place in the final year of MDUFA III, unless otherwise changed by the MDUFA IV agreement. FDA proposed two counterproposal options with different levels of performance targets and associated resource needs. The low option included an additional $291 million spread out over 5 years to support an additional 186 FTE by the end of MDUFA IV. The high option included an additional $321.7 million spread out over 5 years to support an additional 215 FTE by the end of MDUFA IV. Both the high and low options are calculated based on FY 2015 dollars, which are the latest actual costs available, and would be adjusted for inflation to reflect the MDUFA IV years. FDA noted that the components of the two options could be reorganized to create a hybrid counterproposal. FDA further noted that all proposed performance goals assume agreement on a fee setting algorithm with inflation and volume adjusters, as described below.

The FDA counterproposal includes:

- Funding for 20 FTE to establish a dedicated MDUFA QM framework;
- $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 submission and tracking portal;

- Funding for 20 FTE to hire additional supervisors to reduce the ratio of supervisors to reviewers, thus increasing the capacity of Branch Chiefs to provide greater oversight and ensure consistency of review procedures;

- Funding for 36 to 43 FTE to hire reviewers to increase premarket review capacity.

- $4 million to implement more effective recruitment and hiring;

- $8.5 million to improve employee retention through incentive pay for managers using existing authorities and policies.

- A mechanism to allow user fee setting to include a volume adjuster in addition to the existing inflation adjuster, each with 4% caps, and to allow for collections in excess of the authorized amount in a given fiscal year to be used the following year(s) to support the premarket review process, with no fifth-year fee offset;

- Funding for 34 to 44 FTE and $3 million to improve the Pre-Submission process and provide written feedback on 80 to 85% of Pre-Submissions (depending on number of FTEs supported) within 70 days or 5 calendar days prior to the meeting, whichever comes sooner;

- Funding for 28 to 38 FTE and $1 million to complete 70% of *De Novo* submissions within 120 to 150 days (depending on number of FTEs supported). This proposal assumes a workload of 50 *De Novo* submissions per year, which is lower than the assumptions for previous proposals;

- Funding for 3 FTE to establish central program management for CLIA Waiver by Application submissions, with an option to fund an additional 2 FTE plus $1 million in special operating costs to complete 90% of stand-alone CLIA Waiver applications that do not have a panel meeting in 180 to150 days (depending on number of FTEs supported), 90% of Dual 510(k) and CLIA Waiver applications in 210 to 200 days, and 90% of stand-alone CLIA Waiver applications that have a panel meeting in 330 to 320 days. This proposal is pending the review of potential legal impediments;

- $12 million to strengthen the Third Party Premarket Review program;

- Funding for 13 FTE and $3.6 million to provide for consistent review of software, streamlining and aligning FDA review processes with software lifecycles, continued engagement in international harmonization efforts related to software review, and other activities related to Digital Health;

- Funding for 12 FTE and $3.5 million to develop internal FDA expertise on patient engagement, support the increased use of patient preference information (PPI) and patient

reported outcomes (PROs) in premarket submissions, outline a flexible framework for PRO validation, and clarify the optional use of PROs;

- Funding for 15 FTE and $30 million to contribute to the implementation of a system that improves the quality of RWE and linkages among data sources to enable greater use of RWE in the premarket setting; and

- Funding for 5 FTE and $2.45 million to establish a conformance assessment program for certified testing laboratories who evaluate medical devices according to certain FDA-recognized standards;

FDA noted that there has been no change on the QM, independent assessment, and myDevices proposals because there is tentative agreement between FDA and AdvaMed, MDMA, and MITA in these areas. FDA further reduced the cost of its proposal package by removing the proposal to establish an integrated review process model (TPLC) for the Office of Device Evaluation from further consideration.

FDA stated that the resources identified above to improve the review process infrastructure, including investments in QM, myDevices Portal, increasing manager capacity, and increasing review capacity, should create efficiencies in the program that enable reductions in the Shared Outcome goals for average total time to decision. Specifically, FDA proposed that the totality of the low option proposals should result in a reduction of average total time to decision for 510(k)s to 120 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. FDA proposed that the totality of the high option proposals should result in a reduction of average total time to decision for 510(k)s to 119 days by the end of FY2022 and the average total time to decision for PMAs should drop to 290 days by the end of FY2022.

FDA also presented additional high and low estimates for retention incentive pay in the event that legislation currently being considered by Congress is enacted that would permit FDA to increase pay for qualified scientific, technical, or professional positions that support the development, review, and regulation of medical products. FDA noted that under this scenario, additional funding would be needed to keep CDRH salaries competitive with other FDA Centers and the private sector, which may help prevent loss of expertise to other Centers that have sufficient funding to offer higher salaries. FDA noted that this scenario would only apply if the bill becomes law.

Discussion

FDA provided the following additional information on the medical device review program, as requested by AdvaMed, MDMA, and MITA: details on the IT components of the special operating costs for each proposal, 510(k) unit cost for each year since 2007, and the volume of each fee-paying submission category for the years FY13 through FY15.

Industry asked clarifying questions about FDA's proposal package. AdvaMed, MDMA, and MITA expressed appreciation for FDA's proposal and the progress that has been made, while noting that gaps remain between FDA's proposal package and the AdvaMed, MDMA, and MITA proposal package. Industry noted that they considered FDA's proposed reduction in the Shared Outcome goal for 510(k)s to be very modest under the high and low option proposals, and that they considered the reduction in the Shared Outcome goal for PMAs as not a significant improvement over current performance. Industry also noted that FDA's methodology to calculate the overall cost of this proposal differed from earlier FDA proposals. In previous proposals, FDA used FY18 estimates based on FY15 actual costs plus estimated inflation for FY16 through FY18. In the current proposal, FDA used the latest available actual costs from FY15, which would be increased for inflation during the remainder of MDUFA III and MDUFA IV, resulting in inflation-adjusted costs at the beginning of MDUFA IV that would be higher than the amounts stated in FY15 dollars. FDA had discussed this approach with industry during the April 7 working session as a way to ensure that the total amount of fees to which both parties agreed would be based on actual costs, to be adjusted based on actual inflation rates, thereby avoiding the need to incorporate estimates of future inflation rates for FY16 through FY18 into the total fee amounts that are included in proposed statutory language.

FDA noted that its counterproposal requests significantly fewer resources than its previous proposals. FDA recognized that there is still work to do to come to agreement, but that progress has been made. FDA stated that they welcome edits on the proposed commitments for each proposal, and Industry agreed to provide edits at an upcoming negotiation meeting.

Next Steps

AdvaMed, MDMA, and MITA agreed to prepare a counterproposal.

Next Meeting

A series of weekly working teleconferences and face-to-face meetings have been scheduled through June.

Meeting End Time: 3:30 pm