

FDA – Industry MDUFA IV Reauthorization Meeting
July 26, 2016; 9:00 am – 1:00 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)
Elizabeth Hillebrenner	CDRH
Louise Howe	OCC
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Don St. Pierre	CDRH
Darian Tarver	OC
Kim Worthington	CDRH
Jacqueline Yancy	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)
Tamima Itani	Boston Scientific (representing MDMA)
Mark Leahey	Medical Device Manufacturers Association (MDMA)
John Manthei	Latham & Watkins (representing MDMA)
Michael Pflieger	Alcon (representing AdvaMed)

James Ruger	Quest Diagnostics (representing ACLA)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Pat Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)

Meeting Start Time: 9:00 am

Executive Summary

After holding working discussions on June 7, AdvaMed, MDMA, and MITA provided an updated proposal package on June 9. On July 26, FDA presented a counter proposal that incorporates as many performance improvements and other commitments from AdvaMed, MDMA, and MITA's June 9 proposal as the Agency could, while respecting existing policies and maintaining a focus on cost effectiveness.

June 7 Working Discussion

In response to questions from AdvaMed, MDMA, and MITA, FDA provided information on the space utilization at the FDA White Oak campus and the rent component of the fully loaded FTE cost. FDA noted that it has taken all possible steps to maximize space utilization. FDA is approaching the cost per FTE for MDUFA negotiations in the same manner that it has approached other medical product user fee programs by using program-specific pay costs and Agency-wide non-pay and rent costs. This assures that certain costs like rent and centralized IT are the same across all medical product user fee programs. FDA also presented additional analysis on MDUFA III workload, in response to Industry's request to understand how FDA's proposed fee-setting algorithm would have applied during MDUFA III. FDA showed that workload over the course of MDUFA III increased over planned levels. The current fee-setting algorithm resulted in lower fees on individual submissions due to increasing submission and registration volumes. FDA noted that even if the fee offset provision were to be suspended, as AdvaMed, MDMA, and MITA have proposed, the increased collections would not have been sufficient to fully cover the increased workload. FDA's proposed fee-setting algorithm would have provided additional resources to relieve strain and improve performance during MDUFA III.

June 9 AdvaMed, MDMA, and MITA Proposal

AdvaMed, MDMA, and MITA provided a counter proposal electronically on June 9. The package included the following:

- Funding for 20 FTE to establish a dedicated MDUFA QM framework;
- \$4.5 million for the development of the myDevices submission and tracking portal;

- \$3 million for IT improvements for Pre-Submissions, *De Novos*, CLIA Waivers, and Digital Health;
- \$6 million for an independent assessment of the review process, including a more complete assessment of MDUFA III improvements and outcomes;
- \$3 million to implement more effective recruitment and hiring;
- \$5 million to improve employee retention through incentive pay for managers using existing authorities and policies;
- 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 and agreement from Industry at quarterly meetings regarding the use of carryover funds;
- Funding for 34 FTE to improve the Pre-Submission process and provide written feedback on 85% of Pre-Submissions within 65 days or 5 calendar days prior to the meeting, whichever comes sooner;
- Funding for 21 FTE to complete 75% of *De Novo* submissions within 150 days;
- Funding for 4 FTE to establish central program management within the Office of In Vitro Diagnostics and Radiological Health for CLIA Waiver by Application submissions and to complete 90% of stand-alone CLIA Waiver applications that do not have a panel meeting in 150 days, 90% of Dual 510(k) and CLIA Waiver applications in 180 days, and 90% of stand-alone CLIA Waiver applications that have a panel meeting in 320 days. This proposal is pending agency review of potential legal impediments;
- \$4 million to strengthen the Third Party Premarket Review program;
- Funding for 6 FTE 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 5 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 2 FTE and \$10 million to contribute to the implementation of a system that improves the quality of real world evidence (RWE) and linkages among data sources to enable greater use of RWE to support premarket activities and to enable FDA to explore

opportunities and applicable criteria for expanding the use of alternatives to MDR requirements; and

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

AdvaMed, MDMA, and MITA proposed that the totality of the proposals should result in a reduction of average total time to decision for 510(k)s to 108 days by the end of FY2022 and a reduction of average total time to decision for PMAs to 290 days by the end of FY2022.

AdvaMed, MDMA, and MITA did not include funding for additional managers or review capacity, which FDA had included in its prior proposals.

July 26 Negotiation Meeting; FDA Proposal

FDA considered the June 9 proposal provided by AdvaMed, MDMA, and MITA and developed a counter proposal that incorporates many of the performance improvements and commitments of Industry's June 9 proposal. FDA noted that this package represents a cost-effective, feasible, and substantial advancement of the MDUFA program, and helps position the device ecosystem to harness advances in science and technology for robust innovation through the MDUFA IV authorization period and beyond.

- Funding for 113 FTE and \$7.5 million to:
 - Improve consistency through enhanced supervisory oversight and routine quality audits,
 - Establish a dedicated Quality Management team,
 - Restructure Additional Information and Major Deficiency letters to improve quality and consistency,
 - Improve tracking and reporting of performance commitments,
 - Reduce average total time to decision to 108 days for 510(k)s and to 290 days for PMAs by the end of FY2022,
 - Improve the CLIA process by establishing a centralized program management group within the Office of In Vitro Diagnostics and Radiological Health, implementing substantive interaction and “no submission left behind” milestones, offering CLIA Waiver vendor days, and completing 90% of stand-alone CLIA Waiver applications that do not have a panel meeting in 150 days, 90% of Dual 510(k) and CLIA Waiver applications in 180 days, and 90% of stand-alone CLIA

Waiver applications that have a panel meeting in 320 days. This proposal is pending agency review of potential legal impediments, and

- \$7.5 million for IT improvements for Pre-Submissions, *De Novos*, CLIA Waivers, Digital Health;
- \$6 million for an independent assessment of the review process, including a more complete assessment of MDUFA III improvements and outcomes;
- \$3 million to implement more effective recruiting and hiring strategies;
- \$41.7 million to improve employee retention through incentive pay using anticipated new legislative authorities and policies;
- Funding for 2 FTE and \$5 million to increase time reporting sample from two to four weeks each quarter and to work towards full time reporting by the end of MDUFA IV;
- Use of a new Fee Setting Algorithm with an inflation adjuster and submission volume adjuster, each with a 4% cap, that allows 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. FDA would provide reports to Industry at quarterly meetings regarding the use of carryover funds;
- Funding for 77 FTE to improve the Pre-Submission process and provide a ramp up to written feedback on 85% of Pre-Submissions within 65 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner;
- Funding for 32 FTE with a ramp up to completing 75% of *De Novo* submissions within 150 days;
- \$14 million to strengthen the Third Party Premarket Review program by offering training to Third Party review entities, conducting audits, and publishing performance reports of individual Third Party entities. FDA will also evaluate the feasibility of harmonizing the third party review program with international review programs like the Medical Device Single Review Program (MDSRP);
- 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, publish a PRO validation guidance,

hold one or more public meetings, and clarify that PROs can be one mechanism for demonstrating safety and effectiveness or substantial equivalence;

- 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, to develop guidance and hold a public meeting on the use of RWE, and to use RWE in the context of medical device reporting for certain devices; 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.
- Agency-wide changes to FDA's IT infrastructure, which may have an adverse impact on the previous MyDevices proposal for electronic submission receipt and tracking, have recently been identified. Based on this new information, FDA presented new options for IT enhancements that retained much of the original core functionality of the previous proposal, but modified implementation methods to minimize any effect the agency-wide changes would have on the proposal. The options were based on functionality:
 - The first option retains the auditing of structured data, which supports implementation of a robust Quality Management system. In this option, FDA would develop smart memos for FDA reviewers to complete during review and develop eSubmission templates for Industry to use in the preparation of premarket submissions. Both the smart memos and eSubmission templates would contain structured data that would be extracted and used for reporting and auditing activities related to Quality Management. The total cost for this option is \$14.7 million, of which the cost to industry in MDUFA IV fees is \$8.2 million due to the use of \$6.5 million in MDUFA III carryover balance funds.
 - The second option retains the real-time submission tracking functionality. FDA would develop and maintain a secure web-based application that allows sponsors to view individual submission status in real-time. The total cost for this option is \$11 million, of which the cost to industry in MDUFA IV is \$4.5 million due to the alternative use of \$6.5 million in MDUFA III carryover balance funds.

FDA noted that its proposal package as a whole incorporates synergies and efficiencies obtained by considering the totality of resources and their impact on the review system as a whole. These synergy and efficiency adjustments have reduced the overall FTE estimates of FDA's proposals by around 20% when compared to what the sum of the individual components otherwise would have been.

Discussion

FDA noted that its proposal package was intended to incorporate Industry's priorities on performance goals as expressed in the June 9 counter proposal, and adopted their suggested approach to find synergy and efficiencies across the proposals, particularly with regards to 510(k) and PMA TTD reduction proposals. FDA also noted that the package provides important benefits to industry, FDA, and the American public. These benefits include substantially improved outcomes for timely access to safe and effective medical devices through reductions in total time, which FDA estimates would result in a return on investment to Industry that is almost twice the cost of FDA's counterproposal. Through investments in quality management, improved management oversight, and other aspects of premarket review program infrastructure and review capacity, FDA will work with Industry to build on the success of MDUFA III to further enhance program productivity and quality of experience. FDA further discussed how the investments in the future of the program will position the Agency and Industry to harness advances in science and technology and maintain a robust device ecosystem well into the future.

FDA stated that the implementation of a Workload Adjustment/Fee Setting Methodology that is tied to submission volume is a key component to ensure that FDA has the appropriate resources to achieve performance commitments even when faced with increases in workload. FDA observed that in MDUFA III the fee-paying submission volume had exceeded the predicted volume by approximately 10% annually, while the total revenue amounts available to FDA remained at inflation-adjusted statutory amounts. Moreover, there was an unintended consequence caused by the higher submission volumes and establishment registration volumes because the fee-setting process divided the total revenues by the larger volumes, resulting in base (individual) submission and establishment registration fees that were lower than what the base (individual) fee amounts would have been if adjusted for inflation. This resulted in lower base fees, but placed a corresponding strain on the premarket programs because the increases in FDA workload did not result in commensurate increases to FDA resources. FDA's proposal includes a provision to eliminate the final-year fee offset provision and incorporate a workload adjustment algorithm that changes the current fee-setting methodology to address this problem and ensure FDA has sufficient resources to achieve its performance commitments when FDA experiences increasing submission-based workload. In order to minimize potential swings in annual fees and temper the impact to industry, the algorithm places a fee adjustment cap at 4% over the inflation-adjusted base fee amounts. As designed, the algorithm is intended to have a small impact on individual companies. FDA applied the algorithm to MDUFA III using actual submission volumes from FY13 through FY15 and assumed a constant, stable submission volume from FY16 through FY17. Based on these assumptions, the algorithm calculated a \$45 million dollar deficit when comparing the total MDUFA III inflation adjusted statutory revenue target (\$623 million) to the workload and inflation adjusted algorithm based revenue target (\$668 million). However, the adjustments to fees would have only been around 3% above inflation-adjusted base fee amounts to produce the additional revenue. FDA's proposal aims to minimize the changes to

the statutory language and make the fee setting calculations transparent by adding assumptions on FY18 submission volume and weighting factors to the commitment letter and the opportunity to discuss the fee-setting parameters during quarterly meetings.

AdvaMed, MDMA, and MITA expressed concern about tying user fees to a workload adjuster, and noted that submission volume had bounced around since the beginning of the MDUFA program. . Specifically, industry noted that under FDA’s proposal, an increase in submissions for one year would trigger an increase in fees and FTEs in the following year, even if submission levels dropped back to lower levels. Industry noted their June 9th proposal package included 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, which Industry believes would offer a significant source of funding. Industry noted that they are considering revising their June 9th proposal to add a provision to address the details of fee setting in their forthcoming counterproposal.

FDA also discussed recent external factors that have complicated FDA’s ability to deliver the MyDevices/eSubmitter proposal for the originally stated price and timeline. FDA has devised alternative solutions to retain much of the functionality while trying to manage costs. FDA presented these alternatives as separate options based on functionality. In response to a question from ACLA, FDA clarified that it would still be capable of separately tracking and reporting data on laboratory-developed tests (LDTs) under any of the options under consideration.

FDA and Industry both expressed regret in the changes to this proposal caused by factors outside the negotiations. Industry stated that they needed to review the information that FDA presented before providing a response.

In the afternoon, Industry and FDA discussed their different perspectives on the optimal scope and cost for the MDUFA IV reauthorization package.

Next Steps

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

Next Meeting

FDA and Industry are planning a series of working sessions in August; the next formal negotiation meeting date is still being scheduled.

Meeting End Time: 1:00 pm