

FDA – Industry MDUFA IV Reauthorization Meeting
February 18, 2016; 9:40 am – 3:50 pm
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose

To discuss details of Industry’s updated proposal package 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)
Eric Rechen	CDRH
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)
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)
Michael Pflieger	Alcon (representing AdvaMed)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Patricia Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Diane Wurzbarger	GE Healthcare (representing MITA)

Meeting Start Time: 9:40 am

Executive Summary

AdvaMed, MDMA, and MITA presented an updated proposal package, which included continuation of MDUFA III base resources to maintain the MDUFA III FTE levels and maintaining FDA’s current performance, and proposals to invest in IT upgrades, continue the Independent Assessment, support Patient Engagement, and develop a Quality Management system. They also identified areas for continued consideration during the negotiations. FDA asked clarifying questions regarding this proposal and regarding Industry’s concerns with some elements of FDA’s January 27, 2016 proposal.

Proposal from AdvaMed, MDMA, and MITA

AdvaMed, MDMA, and MITA reiterated their support for patients’ access to high-quality, safe and effective medical devices first in the world. They also emphasized that significant progress was achieved under MDUFA III and that there are now additional opportunities to improve consistency and accountability. They suggested that many improvements to the premarket review program can be achieved in a revenue-neutral manner by implementing the Booz Allen Hamilton (BAH) recommendations. Their ultimate objective is to make the premarket review process more effective, efficient, and consistent. To this end, AdvaMed, MDMA, and MITA proposed:

- to provide resources to maintain the level of staffing agreed to under MDUFA III and current FDA performance supported by MDUFA III user fees. They further suggested that the FDA performance goals for MDUFA III remain the same, but that FDA should strive to maintain current actual performance where such performance exceeds the current performance goals.
- to provide \$4.5 million for the development of the myDevices Portal and eSubmitter/Tracker, as described in FDA’s January 27 proposal.
- to provide \$6 million to continue the Independent Assessment of the premarket review process. While FDA previously proposed to continue the Independent Assessment during years 1 and 2 of MDUFA IV at a cost of \$3 million, AdvaMed, MDMA, and

MITA proposed to continue the assessment during years 4 and 5 as well. Expansion of the assessment to cover four years would allow for continued evaluation of FDA's corrective actions and other actions recommended in an initial assessment.

- to provide resources to support patient engagement activities and establishment of a quality management (QM) system along the lines that FDA proposed. They indicated further discussion is needed on the details of these proposals and associated resources and FTEs.

Proposed Areas for Continued Consideration from AdvaMed, MDMA, and MITA

AdvaMed, MDMA, and MITA provided a two-tiered listing of other topics for continued consideration and discussion, but not included in the current proposal. Tier 1 topics included Pre-Submission improvements, process improvements related to deficiencies and final decisions following approvable decisions, performance goals for De Novo requests, an Integrated Review Process, and improvements to the CLIA waiver process. Tier 2 topics included recruitment support, manager performance incentive, Third Party 510(k) review, and Standards proposals. They noted that there is merit in continuing discussions on these topics but expressed concern on potential obstacles to developing actual proposals. In particular, there are challenges in determining the return on investment for proposals that are not easily measured as well as concerns about proposals that are not broadly applicable to the industry. Moreover, AdvaMed, MDMA, and MITA questioned how FDA came up with projected FTE needs for some of these proposals, and noted that greater consistency and predictability might actually reduce workload in areas like Pre-Submissions.

Proposed Areas for Exclusion from Further Consideration from AdvaMed, MDMA, and MITA

AdvaMed, MDMA, and MITA explicitly removed their previous proposals regarding review summaries for 510(k) sponsors and 513(g) performance goals from further consideration.

Discussion

FDA asked clarifying questions on AdvaMed, MDMA, and MITA's proposal. FDA noted that additional performance goals may exacerbate some of the challenges FDA has had in meeting current performance goals by reducing flexibilities in the system that FDA currently relies upon during workload surges. FDA agreed to discuss the details of the inflation adjustment formula and estimation of the amount of user fees needed throughout MDUFA IV to maintain the level of staffing and other activities supported by MDUFA III user fees in FY 2017 (the final year of MDUFA III). FDA and Industry discussed the proposal for continuing the Independent

Assessment. AdvaMed, MDMA, and MITA stated that they are developing a list of potential topics for the assessment's focus.

ACLA asked if the IT proposal, as presented by AdvaMed, MDMA, and MITA, would cover tracking of and reporting on Laboratory Developed Test (LDT) submissions as ACLA proposed in November 2015. FDA confirmed that the IT enhancements would allow for tracking of and reporting on LDTs.

FDA raised concern that many elements of their January 27th proposal were not included in AdvaMed, MDMA, and MITA's proposal package or in the areas for continued consideration. FDA noted that the following FDA proposals were excluded from AdvaMed, MDMA, and MITA's presentation: Enhanced supervisory oversight and recruitment support, Device Coordinators, Workload Adjuster, Submission Issue Meetings, Digital Health, Real World Experience (RWE), and Device-Specific Guidance proposals. FDA conveyed the importance of some of these proposals to the Agency and noted that, in particular, the supervisory oversight and recruitment support, Device Coordinators, Digital Health, and RWE proposals are high priorities for FDA. AdvaMed, MDMA, and MITA indicated that these initiatives were not industry priorities for user fee negotiations, and may be advanced through other channels. In addition, FDA expressed concern about the lack of a mechanism for addressing workload uncertainty. AdvaMed, MDMA, and MITA clarified that they are willing to consider a workload mechanism and indicated that a greater understanding of the proposed inflation adjustment formula and financial baselines would facilitate discussion on the development of a workload mechanism. FDA noted that ACLA has raised the uncertainty of whether, and the extent to which, regulation of, LDTs will increase FDA's workload and stated that the proposals are based on current workload assumptions; a workload mechanism would provide the means for managing uncertainty about future workload. Industry requested that FDA provide more detail on any proposed formula for the workload adjuster, including projections of the increased workload FDA expects during the MDUFA III and IV periods from any anticipated policy changes (e.g., LDT regulation). FDA agreed to present a more detailed workload mechanism proposal for Industry's consideration. FDA conveyed its desire to continue discussions on the Agency's priority proposals.

Next Meeting

The next meeting is scheduled for March 4, 2016.

Meeting End Time: 3:50 pm