

**FDA – Industry MDUFA V Reauthorization Meeting**  
**September 22, 2021, 12:30 am – 4:00 pm EST**  
**Virtual Via Zoom**

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**Purpose**

To discuss MDUFA V reauthorization.

**Attendees**

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauers, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Robert Marcarelli, *OC OO*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

*AdvaMed Team*

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pflieger, *Alcon*
- Danelle Miller, *Roche*
- Nicole Taylor Smith, *Medtronic*

*MITA Team*

- Peter Weems, *MITA*
- Diane Wurzbarger, *GE Healthcare*
- Elisabeth George, *Philips*
- Nicole Zuk, *Siemens Healthineers*

*MDMA Team*

- Mark Leahey, *MDMA*
- John Manthei, *Latham & Watkins*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

*ACLA Team*

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic*  
*Laboratories*

**Meeting Start Time:** 12:30 am EST

**Executive Summary**

During the September 22, 2021 user fee negotiation meeting, FDA presented a financial package for MDUFA V.

## **FDA's Presentation**

FDA presented a package for MDUFA V that addressed proposal elements and cost estimates.

FDA's package included new resources to support the following categories of work:

*Pre-submissions.* FDA proposed additional resources to address the rising volume in Pre-submissions, to enhance the Pre-submission performance goal, and to enhance the Pre-submission program operation (i.e., increase number of topics per submission and increase meeting duration). FDA explained that Breakthrough and STeP interactions for devices not included in the TAP pilot would be handled as categories within the Pre-submission program.

*Back to Basics / Filling MDUFA Gaps.* As a follow-up to Industry's proposal, FDA proposed resources to sustain performance at pre-pandemic levels by addressing aspects of MDUFA program for which resource needs (e.g., workload, payroll) exceeded MDUFA IV projections. This proposal reflects three categories of resource needs: (1) resources to account for unanticipated growth in the Breakthrough program; (2) targeted additional bench strength needed to address increases in De Novo submissions; increasing complexity of 510(k) submissions; and need for greater interactive review and efficiencies to address 510(k) total time to decision (TTD); and (3) MDUFA review infrastructure and program support needed to maintain operations (e.g., workforce management, financial management, acquisition services, program analysis, submission and collaboration tools, training, and quality management). FDA described related concerns that MDUFA IV projections underestimated actual increases in workload for these functions, and that the agreement had not included a workload adjustment mechanism to account for unanticipated increases in workload growth. FDA explained that operating costs for this proposal include resources to address higher costs to maintain current FTE level (e.g., mandatory cost of living increases, increases in retirement benefit contributions), for Cures pay for current and new hires, and for improvements to CDRH's IT system for the quality management program.

*TPLC Advisory Program (TAP) Pilot.* FDA proposed resources to pilot a voluntary program for more comprehensive and frequent interactions, with more rapid FDA feedback, earlier in the device development process. The package presented two scenarios based on alternative ramp-up assumptions for the TAP Pilot. Scenario 1 assumed that all new products in a participating OHT granted Breakthrough designation or request for inclusion in STeP would be eligible for the TAP Pilot. Participating OHTs would ramp-up to four (total) during MDUFA V. Scenario 2 assumed a soft launch during the first year of MDUFA V, followed by a ramp up to all OHTs with up to 25% of new Breakthrough-designated or STeP-included products in a participating OHT. FDA explained how the projections for new resources for the TAP Pilot and the pre-submission program were related—namely, if more Breakthrough and STeP interactions were handled as part of the TAP Pilot (Scenario 1), fewer new resources would be needed to handle the rising volume of pre-submissions; conversely, if the TAP Pilot was streamlined (Scenario 2), more new resources would be needed in the pre-submission program. In addition, FDA explained the composition of cost estimates for the TAP Pilot scenarios—i.e., additional device review and engagement capacity, TAP advisors, professional development capacity, programmatic support, and operating costs.

*Patient Science and Engagement.* FDA presented revised cost estimates to expand the programmatic capabilities of the patient science and engagement program, which would be used to support: training and integration of skilled patient advisors to collaborate and/or work with industry; greater incorporation of the patient voice (preferences and experiences) in the medical device evaluation process; creation and qualification of tools for use in clinical trials to create efficiencies; and development and collection of patient-generated health data to facilitate remote clinical trials and to create voluntary patient or shared decision aids for certain breakthrough device areas.

*Standards.* FDA proposed to expand programmatic capabilities in this area by resourcing, e.g., tools and templates to streamline conformity assessment, work to improve international standards and support international harmonization, potential expansion of ASCA with stakeholder input, and programmatic improvements through guidance and performance tracking.

*International Harmonization for Premarket Review.* FDA proposed building programmatic capabilities by resourcing, e.g., creating dedicated program to develop foundation for international harmonization of premarket review and work with at least one other regulatory authority to explore feasibility pilot.

FDA's package also included new resources to support the following categories of work, with the understanding that these would represent "one-time" costs that would not become part of the MDUFA baseline program without further discussion in future negotiation cycles:

*Real World Evidence (RWE).* Consistent with Industry's proposal of August 10, 2021, FDA proposed to continue to resource RWE at the MDUFA IV level.

*Third Party Review.* FDA proposed to continue to resource the existing Third Party Review program using funds that would be carried over from MDUFA IV. No new funds were proposed during MDUFA V to support the Third Party Review program.

*Recruitment.* FDA proposed to sustain recruitment contracts to provide supplemental recruitment and staffing support to augment FDA Human Resources services.

*Independent Assessments.* FDA proposed to continue resourcing an independent assessment for review processes and to add independent assessments for financial and work force management.

FDA estimated total five-year costs for Scenario 1 (i.e., including the expanded TAP Pilot) of \$2,629,806,000 and for Scenario 2 (i.e., including a streamlined TAP Pilot and more Breakthrough/STeP products utilizing the pre-submission process) of \$2,436,898,000. FDA noted that these cost estimates did not include FDA's Device Safety proposal, which remained under discussion. FDA also noted that additional discussion was needed about the inflation adjustment, and therefore that these proposals did not include any inflation adjustment.

Industry asked clarification questions throughout FDA's presentation regarding the proposal details.

**Next Meeting**

The next meeting is scheduled for October 7, 2021.

**Meeting End Time:** 4:30 pm EST