

**FDA – Industry MDUFA V Reauthorization Meeting**  
**June 16, 2021, 12:30 pm – 2:54 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*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Hanah Pham, *CDRH*

Industry

*AdvaMed Team*

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- 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*
- Mark Gordon, *Alcon*
- 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 pm EST

**Executive Summary**

During the June 16, 2021 user fee negotiation meeting, Industry presented on their principles and proposals for MDUFA V and responded to FDA’s proposals related to device safety and a capacity adjustor. FDA reviewed the Agency’s goals for MDUFA V negotiations; shared

feedback from the stakeholder consultations meetings; and provided an update on performance of MDUFA IV commitments related to information technology.

### **Industry's Principles and Proposals and Response to FDA's Proposals**

Industry began by reviewing the principles underlying the MDUFA user fee program:

1) Supporting timely patient access to safe and effective medical devices, and to maintain the U.S. review process as the gold standard in the world for patient safety; 2) That Congressional appropriations remain the primary source of CDRH's funding, such that user fees are additive and are not the first source of funding; 3) That user fees are used solely for the premarket review process and are used for agreed purposes, while Industry is supportive of additional general appropriations for appropriate postmarket initiatives; 4) Recognition that Industry has made significant and material investments in building up the program through MDUFA I through IV, such that there has been a sizable growth in resources and the program is now on very stable footing; and, 5) That user fees should support mutually shared goals and process improvements to help achieve timely patient access to safe and effective devices. Industry noted, in light of disagreements about MDUFA IV commitments, that it will be important to ensure the MDUFA V agreement avoids potential misunderstandings.

Industry next addressed its remaining questions about the MDUFA program baseline. Industry indicated that it continues to want to understand how many MDUFA-funded FTE positions are currently vacant, and noted that in the past, FDA had been able to identify the number of device program FTE vacancies and what percentage of those were MDUFA-funded. Industry also noted that FTEs have frequently been used in MDUFA discussions as a measure of resources needed to meet certain goals or carry out certain initiatives, such that MDUFA funding has been translated into actual FTEs as well as other non-FTE expenditures. Without this understanding, Industry indicated that it is difficult to evaluate additional needs beyond the existing program baseline. In follow-up to this discussion, FDA reiterated that the Agency does not identify positions as "MDUFA-funded." However, as part of MDUFA IV, FDA received funding for 217 new FTEs. To enable tracking of FDA's progress hiring new staff, the Agency implemented a position management system and designated 217 positions as "MDUFA IV hires." Industry responded by stating that in 2016, FDA publicly stated that 27% of the MDUFA funded FTEs were vacant and that Industry was puzzled as to how FDA was able to determine MDUFA funded vacancies in 2016, but unable to do so in 2021.

With regard to the baseline, Industry also requested additional detail on how the carryover balance of \$209M is being used or is intended to be used. Industry noted the 2019 MDUFA Financial Report provided an explanation for the planned use of the carryover.

Industry raised the supplemental Congressional appropriation tied to COVID-19 related work and asked how much of that appropriation has gone or will go to CDRH. Given that COVID-related workload will increasingly represent premarket submissions that fall within the process for the review of device applications, it is germane to understanding additive resource needs through user fees.

Finally, Industry noted the cost-per-FTE discussion that had begun in previous meetings, noting the need for an accurate cost-per-FTE for purposes of evaluating resource needs and to track

vacancies. Industry also noted the specific limitations placed by Congress, beginning in 2023, with what may be included in the cost-per-FTE calculation for user fee purposes.

With regard to its proposed approach to MDUFA V, Industry identified key elements of its focus on program fundamentals, including the importance of ensuring that MDUFA IV commitments and goals can be achieved and addressing the backlog in device submissions that accrued during the public health emergency. FDA raised concerns that Industry's presentation suggested that the Agency had not been successful in meeting MDUFA IV goals. FDA noted that, prior to the COVID-19 public health emergency, the Agency was meeting or exceeding almost all of the MDUFA IV goals. Although the Agency has had to divert staff time to emergency response work, FDA has been transparent about the potential impact of the emergency on the Agency's ability to meet MDUFA goals and the plans for next steps. In response, Industry clarified that the presentation was meant to highlight goals that Industry thinks are important, not to suggest that FDA is failing to meet all goals.

In terms of the carryover balance, Industry recommended establishing a process to reach agreement with FDA on the use of these funds, and identified as key objectives for the use of these funds enhancements to support device reviews and pre-submissions, consistent citation of scientific justification in Additional Information/Major deficiency letters, and total time to decision goals.

MDUFA IV's commitment letter included numerous initiatives that were "one-time" costs. Industry requested that for any of these one-time costs that FDA believes should be renewed, that the Agency provide an accounting of the resources used, indicate whether commitments were met, and suggest potential success measures tied to a renewal of funding of those initiatives. Industry reiterated those one-time costs that it supported carrying into MDUFA V, such as patient engagement, retention and recruitment, and independent assessments—all subject to agreement on the specific initiatives and resources.

Industry provided a response to FDA's proposal relating to postmarket device signals. Industry noted that FDA is the global gold standard for device safety, which the Industry supports. Industry indicated that discussion of a postmarket device safety program should not be included in the MDUFA discussion, given that MDUFA is a program relating to premarket review and does not include authority for funding the types of postmarket activities proposed by FDA. Industry confirmed its support for working with stakeholders on additional appropriations for appropriate postmarket activities. In response, FDA noted that other user fee programs offer a model for including postmarket surveillance in user fee commitments. FDA and Industry disagreed about whether FDA had provided sufficient detail about the goals and metrics for a potential postmarket device safety proposal under MDUFA V, but the Agency affirmed that it is ready to work with Industry to incorporate support for certain postmarket device safety activities as part of MDUFA V.

Regarding FDA's proposal for a capacity adjustor, Industry noted that in MDUFA IV, Industry accepted FDA's proposal to eliminate the offset provision so that if the Agency received more submissions, it could collect and use additional fees. During MDUFA IV, the Agency has generated a carryover balance available for use of approximately \$209 million. This indicates to

Industry that there is no need for a separate capacity adjuster. FDA disagreed. FDA expressed its view that the current size of the carryover balance is not material to a future-state discussion of how to ensure that the MDUFA program is financially stable. In FDA's view, a capacity adjuster would address a potential future sustained increase in workload above what was projected as part of negotiations.

### **FDA's Presentation**

FDA presented feedback from the stakeholder consultations meetings held on April 14<sup>th</sup>, May 12<sup>th</sup>, and June 9<sup>th</sup>. FDA noted that top areas of feedback from stakeholders included device safety, digital health, real world evidence (RWE), and patient science and engagement. Regarding device safety, stakeholder recommendations included that MDUFA V include a performance goal on safety; support improved safety communications from FDA and manufacturers; improve data transparency and access for real world data sources, particularly regarding safety signals; improve diversity in clinical trials and RWE; and include stakeholders (including patients, sponsors, and clinicians) early in the total product lifecycle (TPLC) to best utilize all stakeholder resources. Regarding digital health, stakeholder recommendations included digitalizing implant cards to facilitate device tracking; and fostering further collaboration with federal partners to ensure alignment and harmonization. Regarding RWE, recommendations included further developing a regulatory framework for use of these data as adjuncts to, but not in lieu of, clinical trials; and continuing to support adoption and transparency regarding unique device identifiers. Regarding patient science and engagement, stakeholders recommended that FDA explore techniques to proactively interact with and empower patients; that FDA increase use of existing patient-reported outcome tools and develop new ones for regulatory and health care decision-making; support data linkages across various sources (e.g., patient reports of adverse events); and consider patient perspectives from various patient populations, including patients with rare diseases, pediatrics, and patients who have experienced harm from medical devices.

FDA also presented on its progress towards meeting MDUFA IV commitments related to information technology (IT) infrastructure. FDA has completed, or is in the process of completing, all IT-related commitments. Specifically, FDA has developed electronic review templates (SMART templates) for all main submission types, including standardized format and fields that support review consistency and more systematic audits of submissions. FDA is in the process of developing electronic submission templates that will serve as guided submission preparation tools for industry. FDA launched the electronic Submission Template and Resource (eSTAR) pilot in February 2020. FDA plans to add a De Novo template later this year and additional templates during MDUFA IV. FDA has fully implemented and adopted a document control system for all internal procedures, work instructions, and templates to further enhance consistency across the Center. FDA completed a soft launch of the Customer Collaboration Portal on March 8, 2021, and had 95 applicants as of June 9. Feedback is being collected to support a full launch later this year. FDA issued an update to the eCopy guidance per the commitment and will continue to update or issue new guidances to support electronic submissions. Lastly, FDA reported that it had created a mechanism to link pre-submissions to a subsequent premarket decision when identified by the applicant.

FDA reiterated its three overarching goals for MDUVA V—i.e., to enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; to optimize FDA infrastructure, staffing, and resources to keep pace with scientific development; and to improve device safety across the total product lifecycle.

### **Administrative**

FDA and Industry agreed to establishing a work group meeting focused on real-world evidence and NESTcc and discussed setting up additional work group meetings for additional topics.

### **Next Meeting**

The next meeting is scheduled on June 30, 2021.

**Meeting End Time:** 2:54 pm EST