FDA – Industry MDUFA VI Reauthorization Meeting
October 29, 2025, 9:00 am – 1:00 pm EST
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose: To discuss MDUFA VI reauthorization.

Attendees

FDA
Eli Tomar, *CDRH*
Owen Faris, *CDRH*
Barbara Marsden, *CDRH*
Jonathan Sauer, *OO*
Kathyrn Capanna, *CDRH*
Malcolm Bertoni, *Consultant*
Cherie Ward-Peralta, *CBER*
Virginia Knapp Dorell, *OCC*
Jaycie Gibney, *OCC*
Alexandra Hauke, *CDRH*
Thomas Szivos, *CDRH*
Sara Doll Aguel, *CDRH*

Industry

AdvaMed Team
Janet Trunzo, *AdvaMed*
Zach Rothstein, *AdvaMed*
Patrick Hope, *AdvaMed* (substituting for Diane Wurzburger, *GE Healthcare*)
Yarmela Pavlovic, *Medtronic*

MDMA Team
Mark Leahey, *MDMA*
Melanie Raska, *Boston Scientific*
Nicole Zuk, *Siemens Healthineers*
April Lavender, *Cook Medical*

Meeting Start Time: 9:05 am EST

Introductions and Ground Rules

FDA opened the meeting with introductions and established ground rules for MDUFA VI Reauthorization negotiations. During the meeting both Industry and FDA confirmed receipt of the ground rules. The ground rules were agreed upon by all parties with no additional questions or concerns.

Stage Setting - FDA Perspective on Reauthorization

FDA emphasized that MDUFA V has created a more predictable, transparent, and efficient regulatory environment. Looking toward MDUFA VI, FDA does not believe major reforms are needed. Instead of growth and expansion experienced in recent reauthorization cycles, modest programmatic enhancements and targeted investments will allow FDA to maintain high performance and strengthening of review fundamentals.

FDA set the stage by sharing the MDUFA VI Negotiation timeline and reauthorization process including highlighting all the parties involved. In response to a request from industry, FDA clarified that summaries of the stakeholder meetings would be relayed in future negotiation meetings as well as posted to FDA's website.

FDA articulated three interconnected sub-goals for MDUFA VI: 1) Strengthen Core Review Fundamentals through timely reviews, strong scientific assessments, and efficient decision-making; 2) Elevate the Quality of the Journey by further integrating strategic programs to work in concert supporting innovation and regulatory predictability; and 3) Optimize Transparency and Accountability through clearer expectations and more meaningful engagement throughout the submission lifecycle.

FDA acknowledged current staffing and resource strains but emphasized the workforce's resilience and the agency's commitment to right-sizing operations. FDA noted efforts to ramp up hiring while acknowledging that detailed staffing projections for the end of FY 2027 are unknowable. FDA clarified that leadership's approach focuses on achieving efficiencies through contracts, centralized operational support, and infrastructure rather than solely increasing headcount. FDA presented the MDUFA V financial footprint as the proposed baseline for MDUFA VI.

FDA shared its view that targeted programmatic enhancements that are mutually beneficial to industry, FDA and public health will be needed by FY 2032. To the extent user fee increases are needed to achieve agreed-upon programmatic enhancements, FDA believes the increases should be nominal and would like to explore ways this could be accomplished without increasing user fees on American businesses operating in the United States.

FDA also conveyed the agency's intention to negotiate the user fee structure and certain other aspects of MDUFA's statutory framework, to align with agency and broader Administration priorities for simplicity, programmatic alignment, and to advance certain aims such as promoting American business, and particularly small business. In the prior cycle, FDA and industry agreed to a revised MDUFA fee structure that included fee adjustments associated with hiring goals and add-on payments associated with performance, as well as modified goals and hiring targets in later years based on early performance. FDA believes that these elements of the MDUFA V agreement added complexity for the agency, and would like to streamline the fee structure for MDUFA VI.

Industry expressed concerns about modifying the fee structure, and noted that unique features of MDUFA, relative to drug user fee programs, was deliberate based on unique characteristics of the medtech sector. FDA acknowledged Industry's concerns, agreed that MDUFA should remain unique and targeted to the device sector, but that some of the divergence is unjustified and unhelpful; the agency noted that this topic is important to both parties and should be discussed early in negotiations.

Looking at the MDUFA V Commitment letter, FDA identified elements that the agency considers ripe for programmatic enhancements, elements that should remain relatively unchanged (i.e., steady state), and elements that should be eliminated. FDA referenced the ground rules, in which the parties agreed to provide a complete accounting of all initial proposals of significance in the first six meetings. Industry expressed appreciation for the transparency regarding scope of negotiations, but reserved the right to further discuss and negotiate on some of the elements FDA earmarked for simplification, steady state, and modification.

Industry Perspective on Reauthorization

Industry reaffirmed support for the MDUFA program while emphasizing their key principles.

AdvaMed advocated maintaining the current MDUFA V framework with potential refinements, noting that after five reauthorization cycles, the program has reached a steady state with well-designed goal structures that are appropriately tailored to the medical device industry. AdvaMed emphasized that user fees should remain additive to the FDA device budget and should not be the majority source of funding.

AdvaMed referenced the FDA Commissioner’s remarks at the public meeting complimenting the MDUFA program and urged that the negotiation process be completed in a timely manner. AdvaMed outlined critical elements to preserve in MDUFA VI, including accountability and transparency measures, statutory trigger provisions, the goal structure which captures review times and total time to decision, hiring goals, and add-on payments that incentivize meeting specific targets.

AdvaMed would like to reevaluate “one-time costs” to determine whether to maintain or reallocate them. AdvaMed highlighted two main targeted areas for improvement: (1) the need for greater consistency of performance across the Offices of Health Technology (OHTs); and (2) improving the De Novo process.

MDMA outlined their fundamental principles for reauthorization, emphasizing that delivering safe and effective devices to patients is the ultimate objective. MDMA stressed the importance of ensuring appropriations remain the primary source of funding. MDMA noted the significant ramp up in user fees under MDUFA V, especially in the last two years of the program. MDMA also stated that the use of fees should be solely to support premarket review process, and voiced appreciation for the Administration’s efforts to drive efficiencies. MDMA asserted that user fee

funded staff should be exempt from the federal hiring freeze, and broader reforms and reorganizations given the nature of their work and source of their funding.

MDMA suggested exploring ways to make the premarket process more predictable, efficient, and effective, including revisiting the pre-submission program to focus on further categorization and more real-time issue resolution, increased recognition of international standards, reforms to the Third Party 510(k) Review Program to eliminate re-reviews, and reforms to De Novo classification.

MDMA discussed the core elements of MDUFA V, noting the new goals for pre-submissions, enhanced goals for De Novos, enhanced goals for quality of deficiency letters, and that many FDA day review goals are legacy goals implemented in MDUFA III. MDMA observed that other Centers have hiring reports detailing net new hires, which they would like to have for CDRH.

MDMA highlighted the importance of establishing an accurate "baseline" for MDUFA VI noting that the MDUFA V agreement provided funding to support just over 500 hires during MDUFA V. MDMA also raised questions on how the increased user fees from FY25 to FY27 would be invested given the reports that CDRH staffing is down 20% and a federal hiring freeze remains in place. The FY27 funding level also includes many MDUFA V "one-time" costs that should be reexamined during this negotiation.

After each party's presentation, FDA and Industry discussed several key areas of mutual interest including potential refinements to the pre-submission program, staffing transparency, data and assessments for promoting consistency across OHTs, training and quality management.

Premarket Performance Goals - FDA Perspective on Reauthorization

FDA noted that in MDUFA V, both industry and FDA, created a "well-oiled machine" that was successful in meeting performance goals – program inputs have delivered the desired outputs. FDA noted that areas for potential refinements could include the De Novo program, the pre-submission program, and the 510(k) total time to decision goal and calculation. FDA noted that the agency has met or is on track to meet FY23, FY24, and FY25 goals. FDA proposes a steady state for continuing FY27 review goals for FY28-32. Regarding staffing challenges, FDA noted that for the bulk of 2025, staff have been focused solely on review work, which has created some system strain, but FDA believes it can be overcome and is working hard to reduce the strain to continue successfully implementing MDUFA V.

Discussion & Recap

FDA asked Industry to come to the next meeting prepared to identify any additional areas that they wish to raise for potential inclusion in the reauthorization. Industry raised questions about unspent resources in MDUFA V and carryover funds that may be projected to extend to MDUFA VI. FDA concluded by noting the sustainable foundation for the program involves fine-tuning

while still assessing fundamentals. Industry added that further discussions are necessary for FDA and Industry to agree on an accurate MDUFA VI baseline.

Next Meeting: The next meeting is scheduled on November 4, 2025.

Meeting End Time: 12:36 pm EST