FDA – Industry MDUFA VI Reauthorization Meeting
December 11, 2025, 8:30 am – 12:30 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*
Kathryn 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*
Stephen Sobieski, *Consultant*
Corina Ploscaru, *Consultant*
Kai Kadoich, *CDRH*
April Marrone, *CDRH*
Daniel Caños, *CDRH*
Rebecca Torguson, *CDRH*

Industry
AdvaMed Team
Janet Trunzo, *AdvaMed*
Zach Rothstein, *AdvaMed*
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: 8:31 am EST

Opening, Presentation of Stakeholder Feedback

FDA opened the meeting and presented the agenda. FDA then summarized feedback from stakeholders received during the August 4th public meeting, through the public docket, and in the stakeholder consultation meetings on November 18, 2025, and December 2, 2025. This feedback reflected perspectives from a diverse array of organizations and communities, including representatives of patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts. Feedback relevant to this meeting focused on two key areas: the Total Product Life Cycle Advisory Program (TAP) and real-world evidence (RWE).

Industry Feedback on Topics from Meeting #4

Industry provided feedback on proposals FDA presented during the December 2 meeting. Industry noted their need for confirmation that the new hires funded under MDUFA V will be realized by the end of FY 2027 and indicated that an accurate FY 2028 baseline should also reflect an updated review of MDUFA V "one-time costs."

Industry expressed support for reforming MDUFA's statutory operating reserve. Industry also shared that they are open to further discussion on the spending trigger but that they opposed elements of FDA's proposal. Industry opposed reforming MDUFA's appropriations trigger proposal. Industry expressed opposition to both components of FDA's proposal on Resource Capacity Planning and Management (RCPM).

Following Industry's feedback, FDA noted Industry's areas of opposition and indicated FDA may respond and address some of those concerns without necessarily accepting all underlying assumptions. Both FDA and Industry confirmed the feedback exchange was constructive and provided information to advance negotiations.

Total Product Life Cycle Advisory Program (TAP) 2.0 – FDA Perspective on Reauthorization

FDA presented their Total Product Life Cycle Advisory Program (TAP) 2.0 proposal and began by providing an overview of the major commitment areas for the pilot in MDUFA V. To meet those commitments, TAP provides three main service offerings: 1) TAP Advisors with a complement of regulatory and non-regulatory expertise, to help facilitate more strategic FDA and non-FDA party engagement; 2) a regulatory service line providing more interactive pre-market engagement through informal meetings and TAP-specific feedback mechanisms; and 3) a non-regulatory service line facilitating strategic insights from non-FDA parties including patients, healthcare providers, and payers, to inform key decisions such as device design, patient user adoption, and clinical evidence needs.

TAP pilot participants currently include over 65 non-FDA collaborating partners and over 100 developers of breakthrough designated devices and Safer Technologies Program (STeP) participants (also known as TAP Innovators). FDA highlighted positive early outcomes outlined in an independent assessment report available on its website, including hundreds of FDA and non-FDA interactions, multiple regulatory milestones, and high levels of satisfaction among TAP Innovators, along with anticipated and actual cost savings from streamlined testing and reduced FDA feedback wait times. FDA also shared examples of impact for the MedTech

ecosystem more broadly that arise from Agency partnerships enabled by more robust TAP information exchange such as: closer collaboration between FDA and CMS including opportunities for programmatic alignment, as evidenced by the FDA TEMPO for Digital Health Devices Pilot with connection to CMMI ACCESS program; partnership with CMS New Technology Liaison office for fast-tracking TAP support; expanded connections between CDRH and CMS Coverage and Analysis Group (CAG); and participation in AMA CPT code creation process and private payer horizon scanning to anticipate near-term future technologies with coding and payment needs and reduce time to implementation.

FDA noted several key lessons learned from the TAP Pilot experience that inform the rationale for future stages of the program. First, while rapid FDA feedback mechanisms were considered highly valuable, streamlined options may optimize utilization. Second, updated TAP enrollment criteria could focus on a more impactful subset of breakthrough technologies, with companies that are "TAP-ready" to make use of the rapid regulatory feedback and other strategic services. Other limitations in scope were proposed and discussed.

For MDUFA VI, FDA proposed to continue TAP 2.0 as a significantly smaller-scale, permanent program, which reflects a narrowed scope and incorporates lessons learned from the TAP pilot. Industry raised questions about the benefits of the program and anticipated achievements and requested additional information.

Real World Evidence (RWE) – FDA Perspective on Reauthorization

FDA presented their proposal on Real World Evidence, outlining 6 key areas where both real world data and real world evidence provide value on the regulatory evidence generation ecosystem: 1) generating hypotheses early in development by identifying clinical needs and potential treatment effects, 2) informing clinical trial design through refined eligibility criteria and endpoints while improving efficiency, 3) serving as control arms when traditional randomization is challenging, 4) providing infrastructure for pragmatic clinical trials through registries and electronic health records (EHR) systems, 5) supporting post-authorization studies to collect long-term performance information in real-world populations, and 6) enabling indication expansions that bring improved technologies to patients.

FDA noted that while MDUFA IV and V investments focused on regulatory clarity, staff training, and ecosystem engagement, success through 2032 requires increased investment in expert review and knowledge management while developing RWE generation infrastructure across all clinical and therapeutic areas.

For MDUFA VI, FDA outlined three focus areas: 1) infrastructure and methods development through enhanced NEST collaboration and systematic rather than study-by-study approaches, 2) expert review and knowledge management to improve consistency and predictability, and 3) FDA public engagement and reporting for transparency.

510(k) Total Time to Decision Goal and Methodology – FDA Perspective on Reauthorization

FDA presented proposed revisions to the 510(k) Total Time to Decision Goal and Methodology. FDA opened by emphasizing that establishing meaningful and achievable goals is important to both FDA and Industry by motivating staff while providing Industry and the program with greater accountability.

FDA outlined numerous improvement efforts implemented since MDUFA IV, including revamped guidance, enhanced eSTAR help text, technical screening feedback, safety and performance-based pathways, general wellness policy clarification, interactive review training, day 10 follow-up policy, single round decision-making training, improved deficiency writing, least burdensome flag processes, and appropriate decision-making authority levels. FDA noted that other factors impacting TTD include device reclassifications, exemptions from premarket notification, and increasing device complexity, while maintaining that the substantial equivalent decision rate has consistently remained above 80% since 2014.

FDA recommended simplifying the TTD calculation by using median time rather than average, which would be less sensitive to outliers and could support more realistic goal timelines.

FDA also presented several alternative options and concluded by noting that effective performance goals must balance encouraging best practices with establishing realistic timelines that maintain staff motivation and system credibility.

Industry proposed establishing a working group to address TTD challenges beyond FDA's presented options, which FDA agreed with.

Discussion & Recap

Industry raised interest in understanding the current staffing levels in MDUFA V in comparison to the expected staffing levels at the end of MDUFA V. In consideration that the next negotiation meeting is the following day, FDA and Industry agreed that Industry will provide feedback in January on the FDA proposals presented December 11 and 12.

Next Meeting: The next meeting is scheduled for December 12, 2025.

Meeting End Time: 12:15 pm EST