FDA – Industry MDUFA VI Reauthorization Meeting
November 4, 2025, 9:00 am – 1:00 pm EST
Virtual Via Microsoft Teams

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*
Suzanne Schwartz, *CDRH*
Cyndi Grossman, *CDRH*
Eric Franca, *CDRH*
Scott Colburn, *CDRH*
Ed Margerrison, *CDRH*
Jessica Paulsen, *CDRH*
Ty Kayam, *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: 9:03 am EST

Presentation of Stakeholder Feedback

FDA summarized feedback from stakeholders received during the August 4th public meeting, through the public docket, and in the first stakeholder consultation meeting held on October 27, 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. Stakeholders provided feedback on multiple topics. Feedback relevant to this meeting focused on three key areas: patient-centric development, consensus standards and conformity assessment, and digital health.

Patient Science - FDA Perspective on Reauthorization

FDA presented their patient science enhancement proposal, which represents a direct outgrowth of prior MDUFA investments. The initiative's fundamental goal is to place patients' health and wellbeing at the center of medical device innovation. To date, FDA has built comprehensive patient-centered infrastructure by expanding partnerships with patient groups and incorporating patient-reported outcomes and patient preference information into regulatory decisions. FDA has observed growing industry use of patient-reported outcome measures and patient preference studies, creating increased need for FDA capacity to provide feedback on appropriate tool selection and timing.

Under MDUFA V commitments, FDA is expanding expertise and capacity through patient science focal point programs and training initiatives while improving regulatory predictability through case examples and new medical device development tools. Looking toward MDUFA VI, FDA anticipates increased submission volumes that will require enhanced capacity and more strategic guidance. FDA seeks to further strengthen expertise in patient-generated health data, multi-modal datasets, and use of these tools to facilitate decentralized clinical studies. This targeted expansion will improve upon FDA's ability to actively shape patient-centered tools and methods that support device safety and innovation.

Standards and Conformity Assessment, including Testing - FDA Perspective on Reauthorization

FDA's Consensus Standards program strengthens patient safety by leveraging recognized consensus standards as a foundation for medical device quality and safety assurance. Standards provide consistent, science-based criteria that manufacturers can leverage to guide safe, effective device design and to support their premarket submissions. Leveraging international standards brings efficiency to the process for both industry and FDA.

FDA's Accreditation Scheme for Conformity Assessment (ASCA) Program builds on that foundation. It is a voluntary initiative that streamlines premarket review by using qualified laboratories to assess conformance to science-based standards without compromising safety. The

ASCA program provides manufacturers with a list of accredited testing laboratories capable of delivering high-quality data, which can significantly reduce the likelihood of data integrity risks if one of these labs is used.

Under MDUFA V commitments, FDA successfully transitioned ASCA from a pilot to a permanent program, published ASCA Pilot feasibility report, continuously trained staff and testing laboratories on program operations, and reported annually. FDA has observed ASCA submissions doubling year-over-year, and case studies highlight the program's effectiveness, showing how problematic 510(k) submissions were resolved quickly after manufacturers utilized ASCA-accredited testing laboratories, resulting in faster market access. FDA highlighted proposed opportunities for growth, such as continuing staff and industry training opportunities, and ensuring only high-quality laboratories maintain ASCA accreditation status. For MDUFA VI, FDA proposes continued funding and additional resources to enhance the ASCA program through industry education, enhanced training offerings, improved audit capabilities, and program expansion to include potential additional standards and test methods, including potential standards and tests relating to the development of chemical characterization methods that would potentially be a prerequisite for the inclusion of the associated international standard into the ASCA program.

Digital Health - FDA Perspective on Reauthorization

The Digital Health program has demonstrated strong performance since its establishment under MDUFA IV, evolving from a central digital health unit into today's Digital Health Center of Excellence (DHCoE). The agency has successfully strengthened internal capabilities, published key guidance documents, developed public-facing resources, and advanced international harmonization efforts related to digital health devices.

FDA presented on several significant trends that drive the need for enhanced capacity and resources. First, there has been unprecedented growth in digital health submissions. For example, FDA has authorized over 1,200 AI-enabled devices to date, including over 250 in FY25, and DHCoE handles hundreds of submission consultations and inquiries related to regulatory policies and technical matters each year. Second, digital health submissions are becoming increasingly complex. FDA is seeing products with multiple software or AI functions, pre-determined change control plans (PCCPs) which involve assessing modifications rapidly and prospectively, and innovations in the pipeline involving generative AI and agentic AI. Third, digital health and AI have transitioned from niche markets to mainstream focus areas, with major economic, FDA workload, and public health implications.

To address these challenges, FDA's proposal focuses on three key elements: 1) sustained expert support, 2) increased clarity and predictability, and 3) modernized digital health reviews. A significant focus is on sustaining expert support for technical reviews, including PCCPs and pre-submissions, as well as consistency across the Center.

Fee Structure Reform, Foreign & Domestic - FDA Perspective on Reauthorization

FDA is exploring fee structure changes to ensure that foreign firms are contributing an appropriate share of user fees in light of additional resources that are required to oversee foreign firms marketing products in the United States.

FDA is modeling fee structure modifications to annual establishment registration fees, small business determinations, and other fees of the MDUFA framework. The agency proposed that FDA and Industry work collaboratively on potential solutions.

Negotiation Meeting 3 Open Discussion Topics - FDA Perspective on Reauthorization

In order to support a more productive negotiation meeting on November 20th, FDA briefly presented FDA's observations regarding existing challenges in four key medical device regulatory areas: pre-submission program, De Novo program, 510(k) Third Party Review program, and the 510(k) Total Time to Decision (TTD) goal and calculation.

Discussion & Recap

Industry reflected that the proposals FDA presented were areas that Industry has historically supported and wants to continue supporting, with further discussion on how best to optimize these areas going forward. FDA and Industry agreed that a period of time in the upcoming meeting on November 20th, and future meetings, will be devoted to Industry feedback on the proposals presented by FDA.

Next Meeting: The next meeting is scheduled for November 20, 2025.

Meeting End Time: 12:53 pm EST