FDA – Industry MDUFA VI Reauthorization Meeting
December 12, 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*
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*
Corina Ploscaru, *Consultant*
Ellen Olson, *CDRH*
Erin Cutts, *CDRH*
Tammy Beckham, *CDRH*
Lisa Lim, *CDRH*
Linda Ricci, *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: 9:02 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: International Harmonization (including global supply chain resilience) and MDUFA Premarket Goals & Programs.

Information Technology (IT) Tools – FDA Perspective on Reauthorization

FDA presented their IT Tools proposal, focusing on building upon existing IT infrastructure to enhance efficiency and customer service. FDA highlighted the success of the CDRH Customer Collaboration Portal, which provides progress tracking and online submission capabilities. This tool dramatically improved submission process intake, dissemination, transparency, and product review facilitation and regulation. Building on this success, FDA has identified strategic opportunities to improve efficiencies, allow more timely feedback, reduce potential holds, and enhance customer service.

FDA's proposed approach focuses on building upon current IT investments in three key areas: 1) incorporating automation into processing and routing of electronic submissions, 2) incorporating real-time validation of user fee and formatting compliance for CDRH portal documents, and 3) enhancing portal capabilities to allow secure interactions between FDA and official correspondents, providing a comprehensive repository of interactions.

FDA outlined leveraging automation across three critical functions: 1) information ingestion (collecting and importing submission information into CDRH systems), 2) submission processing (reviewing and identifying administrative concerns in real-time), and 3) submission routing (directing documents to appropriate CDRH employee queues for timely review).

FDA explained how modest technology enhancements can significantly improve submission processing through automated routing that reduces manual intervention while maintaining quality and accuracy. FDA outlined additional benefits including increased processing accuracy, enhanced transparency, and better customer experience.

Continuous Improvement: Deficiencies – FDA Perspective on Reauthorization

FDA presented their deficiency communication proposal, noting that clear deficiency communication is hard but fits well within MDUFA VI's vision to advance regulatory excellence by strengthening core review fundamentals and elevating the quality of the review journey. Good deficiency policy provides guidelines for determining when and whether to request additional information, helps ensure requests include clear, complete, and consistent information aligned with FDA’s statutory "least burdensome” principles, and can help improve the quality of an applicant’s response as well as future submissions. FDA also outlined challenges in systemically improving deficiency communication, including multiple different types of review issues, high volume of submissions and letters, and the diverse scientific and technical experts involved in writing a deficiency letter.

Despite these challenges, FDA reported meeting and exceeding all six MDUFA V deficiency commitments to date, including a 50% improvement in performance in 3 years and 90% of marketing submission deficiencies now including a "statement of basis for the deficiency." FDA attributed this success to hard work by both QMOE's audit team and volunteer efforts from over 30 ground-level review staff as well as the building of a successful continuous improvement program. Key pillars of this successful continuous improvement program include: 1) timely, robust data from the Center's internal audit team, 2) clarified policy and multi-modality training, 3) targeted, data-driven support and resources, and 4) collaborative engagement with review staff. FDA noted that while MDUFA V progress tackled major cross-cutting issues first, remaining challenges are more varied and unique.

For MDUFA VI, FDA stated it will be difficult to sustain a more stringent 95% performance and advance a broader vision of clear, consistent, Least Burdensome communication without a modest increase in dedicated resources. FDA proposed building on the strong foundation of the existing continuous improvement program while advancing its maturity and sustainability. FDA outlined three enhancement areas: 1) staff support for new training focused on good communication generally, beyond just the "statement of basis," 2) staff support to help improve clarity and consistency of review policy in targeted areas, and 3) industry feedback integration through recurring surveys.

International Harmonization – FDA Perspective on Reauthorization

FDA presented their International Harmonization proposal, explaining that this work advances US public health interests by reducing redundant regulatory requirements across jurisdictions; conducting outreach to support harmonization, reliance, and resilience; providing expertise to other US government agencies; and identifying approaches for emerging regulatory topics. FDA's approach centers on sustained, strategic relationships that enable regulatory trust and coordinated global health solutions. This impacts FDA, US industry, and US patients across all clinical and therapeutic areas.

FDA reported strong performance meeting all seven MDUFA V international harmonization commitments. For MDUFA VI, FDA proposed further maturing and modernizing CDRH International Affairs by expanding US global leadership through bilateral and multilateral engagements that drive harmonization, reliance, and resilience while supporting coordination of innovative solutions to complex global challenges. FDA outlined four focus areas: 1) exploring harmonized premarket review development, 2) working with other regulatory authorities and industry on joint activities including building supply chain resilience, 3) expanding attendance and support of meetings of global importance, and 4) conducting outreach activities supporting regulatory capacity building and reliance.

Proposed resources in MDUFA VI would administer coordinated review pilots, develop global submission template governance approaches, establish collaborative forums for emerging

regulatory topics including resilience, drive actions in global meetings, create and deepen relationships, and would support engagement and outreach, training, workshops, and investment in public-private partnerships for innovative approaches to global challenges.

Mid-Point Assessment – FDA Perspective on Reauthorization

FDA offered a mid-point assessment of the negotiations, level-setting on current status including proposals presented, outstanding topics, and corresponding resource needs for MDUFA VI targeted investments, as well as comparison to total FY27 fee amounts.

FDA presented a snapshot of each proposal presented during negotiations, depicting proposed amounts for each program area seeking targeted investments, including total estimated level of effort in full time equivalents (FTEs) over the five-year cycle and annual operational amounts. FDA presented the financial footprint representing the "steady state" baseline to carry into MDUFA VI. By reallocating substantial portions of MDUFA V one-time fees, FDA can reinvest in critical existing programs that strengthen core review fundamentals and elevate journey quality, enabling fulfillment of premarket review and process improvement commitments through 2032. FDA emphasized that with modest fee structure revisions, any increase can be borne by foreign establishments such that entities operating within the United States should see flat or decreased user fees in MDUFA VI.

Discussion & Recap

FDA and Industry concluded the sixth negotiation meeting by discussing the path forward. Both parties acknowledged that major proposals had been put on the table and future meetings would focus on refining existing proposals rather than introducing new ones, with exceptions for ongoing workgroup activities and fee structure standardization issues.

Next Meeting: The next meeting is scheduled for January 8, 2026.

Meeting End Time: 12:40 pm EST