FDA – Industry MDUFA VI Reauthorization Meeting
March 18, 2026, 9:00 am – 10:00 am EST
Virtual Meeting

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*

Industry
AdvaMed Team
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: 9:10 am EST

Opening, Industry Feedback

FDA opened the meeting to present the agenda. Industry then presented an update on their position across all FDA proposals. Industry expressed support for proposals on Real World Evidence (RWE) and transparency reporting. FDA and Industry agreed to move forward with drafting Commitment Letter language for these proposals.

In regard to Real World Evidence, Industry re-emphasized that the agreement to fund full time equivalents (FTEs) was conditional on the adoption of the NEST Mark. Industry also highlighted that agreement on MDUFA VI RWE funding is conditional on those funds being used solely for premarket submission activities, housed under NEST, and governed by the NEST Governance Committee. Industry acknowledged that FDA may receive funding for other purposes but emphasized that MDUFA RWE funds should be restricted to premarket activities within NEST.

FDA and Industry confirmed reaching an agreement in principle and resolution on all remaining MDUFA VI proposals.

MDUFA VI Targeted Investments: Final Assessment

FDA shared a final assessment of the MDUFA VI target user fee revenue amounts and planned investments for targeted programmatic enhancements, including marginal increases in staffing and operational expenses above the MDUFA V baseline. The vast majority of the MDUFA VI financial footprint will carry forward the core MDUFA V user fee program. Submission fees and domestic registration fees will be decreased by changes to the statutory fee structure such that most firms should see lower fees in FY 2028.

FDA noted that the initial fee modeling was conducted in FY 2026 dollars, but that the MDUFA transmittal will need to be represented in FY 2027 dollars.

Industry requested FDA include language to reflect that funding to fulfill the staffing levels agreed to under MDUFA V will be carried into MDUFA VI. FDA acknowledged the shared intent to hire substantial numbers of additional review staff.

FDA committed to providing updated fee modeling with final target revenue and fee amounts to input in the statutory redline, and described which figures are best estimates that may change during fee-setting for FY 2028, though changes will not impact the target revenue.

Next Steps

Industry shared that they appreciated working with FDA throughout the negotiation and also emphasized that the next step is ensuring draft Commitment Letter language accurately reflects the agreement in principle. FDA reciprocated these sentiments, expressing appreciation for the

collaboration and collegiality demonstrated to date and agreeing that additional collaboration to finalize the MDUFA transmittal documents remains. FDA noted that additional meetings would be scheduled if controversies or disagreements arise in the context of finalizing these documents memorializing the agreement.

Meeting End Time: 9:45 am EST