FDA – Industry MDUFA VI Reauthorization Meeting
March 11, 2026, 9:00 am – 1:00 pm 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*
Stephen Sobieski, *Consultant*

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: 9:16 am EST

Opening, Presentation of Stakeholder Feedback
FDA opened the meeting and presented the agenda. FDA then summarized feedback from stakeholders received during the stakeholder consultation meeting on February 25, 2026.

Feedback relevant to this meeting focused on key areas with new topics including FDA resources to evaluate complex AI devices, requesting transparency and reporting of data quality submitted in premarket applications, and how data quality is connected to MDUFA performance benchmarks for premarket review goals. Industry expressed a desire that future MDUFA negotiation meetings that report stakeholder discussion would be more comprehensive in describing the stakeholder concerns raised and FDA responses.

Discussion
FDA presented an overview of the proposals that FDA and Industry had not come to an agreement on yet, and FDA and Industry discussed each proposal.

On Real World Evidence, FDA presented a revised proposal regarding real world data source development to address previous industry concerns, in which this activity would be funded through and overseen by NEST. Industry shared concerns about investments in data source development and asked for assurance from FDA that MDUFA funding for this activity would focus solely on premarket uses of RWE. FDA stated that while there could be RWE applications across the device lifecycle, the focus for MDUFA funds related to RWE would be on developing data sources for premarket use and that the agency is open to clarifying in the Commitment Letter. This topic will require further discussion.

FDA shared that they agreed to move forward with Industry's proposal on periodic reporting to include staffing levels by office within CDRH. Industry proposed a modified approach that such reporting also include certain summary information at the sub-office level. FDA expressed concerns with the modification and noted this change would need to be taken back for consideration and will require further discussion. Industry appreciated FDA exploring this option and reiterated that the intent was to help ensure that the commitments around hiring under MDUFA agreements would be realized.

Next Steps
Industry conveyed alignment on proposals on Continuous Improvement: Review Consistency, the Total Product Life Cycle Advisory Program (TAP) 2.0, Trigger Reform (both the appropriations and spending triggers), Carryover, and Operating Reserve. FDA and Industry agreed to move forward with drafting Commitment Letter language for these proposals.

Industry and FDA are continuing discussions on Real World Evidence and transparency reporting. FDA noted that Fee Structure changes were also agreed to, and any final refinements in modeling revisions would be sent to Industry soon.

Next Meeting: March 18, 2026

Meeting End Time: 11:22 am EST