

FDA – Industry MDUFA VI Reauthorization Meeting  
January 8, 2026, 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*  
Stephen Sobieski, *Consultant*

Industry

*AdvaMed Team*  
Janet Trunzo, *AdvaMed*  
Zach Rothstein, *AdvaMed*  
Diane Wurzbarger, *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: 9:07 am EST

FDA opened the meeting and presented the agenda. Industry then presented feedback on all FDA proposals from previous negotiation meetings—specifically on how they view the proposals that have been discussed, including which proposals they generally support and which ones they oppose. FDA asked clarifying questions to obtain clarity on Industry’s negotiation positions.

Industry asked FDA questions regarding financials, and requested details be provided on FTE activities for certain FDA proposals.

FDA then presented a roadmap with timeline process expectations for completing MDUFA VI negotiations, outlining the remaining meeting schedule and upcoming milestones. Industry asked clarifying questions regarding the timing for transmitting the MDUFA reauthorization package to Congress, which FDA will address in an upcoming meeting.

FDA also presented their perspective on the current negotiation status from a substantive standpoint to determine next steps for each topic. FDA reemphasized that resources associated with all proposals largely fit within the fiscal year 2027 financial footprint (as detailed in prior negotiation meetings), with some rebalancing of programs for better efficiency and continued support for application review activities.

Based on the morning presentations, FDA and Industry then identified topics on which the parties are well aligned, such as Patient Science and Digital Health; topics that required additional details, such as De Novo, Pre-Submissions, 510(k) Total Time to Decision, and Fee Structure Reform; and topics requiring further negotiation, such as the Total Product Life Cycle Advisory Program (TAP) 2.0, Appropriations Trigger, and Resource Capacity Planning and Management. Both parties acknowledged substantial progress had been made with significant alignment on items ready for next steps, clear identification of items needing focused discussion, and items requiring further negotiation.

Industry shared that they aim to provide information supporting an expanded proposal of consensus standards in a future meeting. Industry asked FDA questions regarding the CDRH quality management and organizational excellence program (QMOE), and FDA agreed to provide information in a future meeting.

**Next Meeting:** The next meeting is scheduled for January 14, 2026.

Meeting End Time: 12:32 pm EST