

FDA – Industry MDUFA VI Reauthorization Meeting
February 4, 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*
Corina Ploscaru, *Consultant*
Ed Margerrison, *CDRH*
Scott Colburn, *CDRH*
Eric Franca, *CDRH*
Emily Galloway, *OC*
Paul Conant, *OC*
April Marrone, *CDRH*
Kai Kadoich, *CDRH*

Industry

AdvaMed Team
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: 9:00 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 January 27, 2026. Feedback relevant to this meeting focused on key areas: staffing and resources, support for the Total Product Life Cycle Advisory Program (TAP) 2.0, concerns about adequate funding for postmarket surveillance, and about the perception of balance and transparency of MDUFA VI negotiations.

Industry Proposal: Consensus Standards

Industry presented a proposal for advancing consensus standards recognition by establishing a working group consisting of FDA and industry representatives, who would meet multiple times per year to identify high-impact opportunities and pathways towards the recognition of standards. Between formal meetings, smaller technical teams with subject matter experts would conduct detailed work.

Industry also proposed that working group progress would be included in MDUFA quarterly updates to industry, and that at one quarterly meeting per year FDA would provide an annual update including: standards recognized in the past year that FDA identifies as substantial, standards FDA is seeking to recognize in the current year, and newly identified standards of mutual interest for the working group to prioritize.

FDA indicated they would discuss the proposal internally before providing feedback at the next negotiation meeting.

Industry Feedback on FDA Proposals

Industry then presented an update on all FDA proposals, providing updated feedback on ones they support, ones that are trending in the right direction, ones that have potential to trend in the right direction with more discussion, and ones they still oppose. Industry expressed support for revised proposals on International Harmonization, 510(k) Total Time to Decision, and Resource Capacity Planning and Management (RCPM) capability development excluding a capacity planning adjustor (CPA).

Industry also proposed updates to MDUFA quarterly reporting to include staffing levels by office, refine commitment letter language to reflect specific actions taken by CDRH to assess performance variability, implement training activities to reduce variability and reassess performance at least twice per year. Industry further proposed a commitment to hire consistent with the agreement.

FDA indicated they would discuss these proposals internally before providing feedback at the next negotiation meeting.

Total Product Life Cycle Advisory Program (TAP) 2.0

FDA opened the discussion acknowledging that FDA and Industry still had different perspectives on key aspects of TAP 2.0.

In December, FDA presented their proposal on TAP 2.0, outlining three focus areas: 1) TAP Advisors with a complement of regulatory and non-regulatory expertise, to help facilitate more strategic FDA and non-FDA party engagement; 2) a regulatory service line providing more interactive pre-market engagement through informal meetings and TAP-specific feedback mechanisms; and 3) a non-regulatory service line facilitating strategic insights from non-FDA parties including patients, healthcare providers, and payers, to inform key decisions such as device design, patient user adoption, and clinical evidence needs. In meeting 10, FDA presented refinements to the TAP 2.0 proposal, which reflects a narrowed scope and incorporates lessons learned from the TAP pilot and highlighted cross-agency collaborations and other opportunities facilitated by TAP.

During the discussion Industry provided initial feedback on the revised proposal and asked additional questions regarding the TAP program structure, eligibility, and funding. Industry questioned the proposed TAP 2.0 resource allocations and refined enrollment criteria and suggested that FDA should ensure TAP's expertise and benefits extend beyond the subset of enrolled TAP products. The topic will require further discussion.

Fee Structure Details

FDA first presented a revised estimated MDUFA VI financial footprint based on recent refinements to proposals. FDA then presented their position on prioritizing fee structure changes incorporating America First principles and the MDUFA fee modeling done by FDA economists. FDA stated their opposition to Industry's proposal to factor compliance with the United States-Mexico-Canada Agreement (USMCA) into the proposed registration fee differential between foreign and domestic establishments.

FDA then walked through fee estimates and modeling assumptions of the proposed fee differential between foreign and US establishments. In response to questions from Industry, FDA will also provide further granularity on the economic modeling and will clarify details on the underlying economic analyses.

Industry expressed general support for the revisions to the fee structure, and the Parties will continue discussions on fee structure details.

Discussion & Recap

FDA shared with Industry the request for a mid-cycle briefing to Congress, and both parties agreed to jointly prepare for that upcoming briefing. FDA asked attendees to hold March meeting dates in order to finalize MDUFA VI negotiations and begin the commitment letter writing process.

Next Meeting: The next meeting is scheduled for February 11, 2026.

Meeting End Time: 12:45 pm EST