FDA – Industry MDUFA VI Reauthorization Meeting
February 18, 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*
Kira Moore, *CDRH*
April Marrone, *CDRH*
Kai Kadoich, *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: 9:00 am EST

Opening and Industry Feedback on FDA Proposals
FDA opened the meeting and presented the agenda.

Industry then presented an update on their position across all FDA proposals, identifying ones they support, ones that have potential to trend in the right direction with more discussion, and ones they still oppose. Industry expressed support for proposals on Information Technology (IT) Tools, De Novo, and Pre-Submissions.

Industry requested updates on fee structure modeling and clarity on hiring commitment language, including current status and future projections for hiring to help with mapping the end of MDUFA V into MDUFA VI and level-setting expectations.

Carryover, Fee Structure, and Trigger Reform
FDA provided an update on subtopics within these proposals that FDA and Industry had come to an agreement on as well as outstanding items that still needed to be resolved.

FDA and Industry reached agreement on modifying Commitment Letter language to provide direction for the use of carryover funds between the operating reserve floor and ceiling, prioritizing allocation of carryover funds to specified categories to support the process for review of device applications and retaining a mechanism to offset registration fees in the following fiscal year when amounts in the carryover exceed the ceiling. FDA agreed to Industry's request to discuss the status of the carryover balance and potential allocation of funds at two quarterly meetings. FDA and Industry agreed on opportunity to elevate certain allocation decisions to the Agency for reconsideration within a specific notification window, subsequent reporting on final allocation of carryover funding, and the preservation of existing process checks for allocating carryover funding.

FDA and Industry discussed the operating reserve floor and ceiling, with the parties still not aligned on the appropriate number of weeks.

FDA and Industry confirmed agreement on fixing drafting errors in the spending trigger, as discussed at prior negotiation meetings. FDA and Industry agreed on resetting the baseline year. FDA has consulted on how the elimination of small business determinations for foreign submitters is consistent with its international trade obligations and FDA is confident in moving forward with that proposal.

FDA confirmed the agency will integrate a pre-submission fee into the fee structure model. As proposed, a flat fee would apply only to original pre-submissions, not supplements, follow-ups, or informational Q-submissions, and the pre-submission fee will be credited to the related subsequent marketing submission.

The parties considered fee structure negotiation topics to be resolved, and FDA intends to provide industry with updated dollar amount projections across fee types based on refinements to the agency's modeling.

Continuous Improvement: Review Consistency

FDA proposed addressing review consistency with a more systematic, holistic, and structured improvement program, building on the success seen through FDA's MDUFA V commitments on continuous improvement of deficiencies.

FDA proposed the commitment letter state that FDA will make improvements to facilitate appropriately consistent and effective review in one specific, high-impact topic area per year and provide industry with an update on these improvements once per year.

Industry expressed support for the proposal and had suggestions for minor revisions.

After FDA shared the FTEs and operating dollars needed for the proposal, Industry asked if additional resources would allow FDA to evaluate two specific topic areas per year instead of one. FDA indicated they would take that back. Overall, FDA and Industry are in agreement on the proposal, and that this proposal will negate the need for a separate report out on MDUFA return-on-investment (ROI) in MDUFA VI.

Total Product Life Cycle Advisory Program (TAP) 2.0

FDA answered questions Industry posed during the February 4th negotiation meeting. FDA then provided a summary of TAP 2.0's refined focus for MDUFA VI, including enhancing the breakthrough review experience and focused engagement and collaboration with CMS. The revised proposal also included benefits for non-TAP devices, revised enrollment criteria to include additional firms with a U.S. presence, refined metrics and reduced operating expenses. FDA also shared modeling which demonstrated anticipated growth in the program into MDUFA VI under different scenarios.

Industry asked additional questions on enrollment criteria and program scope and asked if FDA was open to Industry proposing additional metrics. FDA indicated openness to Industry feedback. Industry also requested more information regarding the rationale about TAP 2.0's operating expenses. This topic will require further discussion.

Discussion and Recap
FDA and Industry agreed to not include the MDUFA V Independent Assessment Commitment in the MDUFA VI agreement. Industry emphasized that they are invested in CDRH's teams' wellbeing and adequate resourcing.

FDA and Industry have agreed to the following proposals and will move forward with drafting Commitment Letter language for Patient Science, Digital Health, Third Party 510(k) Review Program, Continuous Improvement: Deficiencies, International Harmonization, 510(k) Total Time to Decision, Consensus Standards, De Novo, Pre-Submissions, Resource Capacity Planning and Management (RCPM) capability development excluding a capacity planning adjustor (CPA), and IT Tools.

Next Meeting: March 11, 2026

Meeting End Time: 11:40 am EST