FDA – Industry MDUFA VI Reauthorization Meeting
January 14, 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*
Ellen Olson, *CDRH*
Daniel Caños, *CDRH*

Industry
AdvaMed Team
Janet Trunzo, *AdvaMed*
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: 9:01 am EST

FDA opened the meeting and presented the agenda. FDA provided updates and, in some cases, presented refined proposals to Industry for discussion and feedback on the Operating Reserve &

Carryover, Fee Structure Reform: Foreign and Domestic, Trigger Reform, Resource Capacity Planning and Management, and on Real World Evidence.

Operating Reserve & Carryover

FDA and Industry discussed the operating reserve and the MDUFA carryover balance, which is the funding that carries over from one year to the next. FDA further clarified their proposed mechanism for ensuring there is a minimum operating reserve each year, for example, an adjustment that could be made at the time of the annual fee setting notice. Setting the minimum operating reserve somewhere within the six-to-ten-week range was discussed, as well as a potential corresponding adjustment to the number of weeks of operating reserves that could be carried over from year to year. In addition, Industry discussed the possibility of including language in the commitment letter to ensure there is a collaborative approach utilized in spending carryover funds. The topic is still under discussion and will require further negotiation.

Fee Structure Reform: Foreign and Domestic

FDA provided additional details regarding their proposal on fee structure changes in registration fees and small business determinations to reflect additional FDA costs and administrative burdens associated with overseeing foreign establishments. FDA reported that agency economists are finalizing comprehensive models to assess the interplay of the proposed changes. FDA expects to model different scenarios in the coming weeks for discussion at an upcoming meeting. In the meeting, Industry did not oppose FDA's proposals to realign foreign and domestic fees. Industry shared that they want to propose suggestions and exemptions to these fee structure changes and indicated that they would share more details with FDA in advance of the next negotiation meeting. In December, FDA proposed reforms to the appropriation threshold condition specified in Section 738(g) of the FD&C Act and the budgetary spending threshold specified in Section 738(h)(2). FDA proposed various changes to the provisions reflecting both the agency's priority of standardizing and streamlining core elements across user fee programs as well the need to correct various technical issues with the provisions.

In December, Industry agreed in principle that adjustments to the spending trigger would be appropriate to address perceived defects but disagreed with the other elements of the proposal. In response to that feedback, FDA presented an updated version of the spending trigger reform proposal and restated the importance of appropriations trigger reform. Specifically, increasing the threshold by which the spending trigger can be missed, and adopting an agency-wide appropriation trigger. Industry remained opposed to all aspects of the proposal except for the technical corrections.

FDA acknowledged the ongoing disagreements and that both topics would require further negotiation.

Resource Capacity Planning and Management
FDA provided additional context on their Resource Capacity Planning & Management proposal, which builds on existing activity-based time reporting and quality management capabilities to enhance workload planning and resource allocation across the device review program.

FDA's RCPM proposal focused on two main components: 1) Resource Capacity Planning and Management (RCPM) capability development, and 2) implementation of a resource capacity adjustment to fees that provides a mechanism to ensure that MDUFA program review capacity stays in alignment with workload under changing and uncertain future conditions.

FDA responded to Industry's concerns and questions about FDA's current quality systems management and provided additional proposed details regarding RCPM capability development (Part 1). FDA acknowledged Industry's ongoing opposition to a Capacity Planning Adjustment (Part 2).

Real World Evidence
In December, FDA presented their proposal on Real World Evidence (RWE), outlining three focus areas: 1) infrastructure and methods development through enhanced NEST collaboration and systematic rather than study-by-study approaches, 2) expert review and knowledge management to improve consistency and predictability, and 3) FDA public engagement and reporting for transparency.

Industry had expressed concerns with certain elements of the proposal and asked questions about how FDA's current RWE expertise is being utilized and the resources FDA would need to meet expectations for evidence-gathering in a way that is helpful to sponsors and reviewers. In response to Industry feedback, FDA provided additional information about current RWE activities and important gaps that could be filled with additional resources and presented several refinements to the proposal.

Next Meeting: The next meeting is scheduled for January 21, 2026.

Meeting End Time: 12:47 pm EST