FDA – Industry MDUFA VI Reauthorization Meeting
December 2, 2025, 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*

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: 9:02 am EST

Opening

FDA opened the meeting and presented the agenda.

Financials, Workforce, Carryover – FDA Perspective on Reauthorization

FDA presented information on MDUFA target revenue and net collections and the MDUFA carryover balance, which is the funding that carries over from one year to the next, and explained how that balance is related to existing user fee obligations. FDA also provided an overview of MDUFA process costs and process Full Time Equivalents (FTEs), which reflect resources that go into supporting the program. FDA then provided MDUFA user fee obligations by component, historical CDRH budget authority, and MDUFA enacted funding and CDRH workforce data. The majority of these data derive from various sources of publicly reported information, including annual and quarterly MDUFA reports required by statute, but are subject to change during the ongoing reconciliation and clearance processes.

FDA noted that in FY23-24, MDUFA V resources were adequately aligned with established goals. In FY25, FDA reached a high point in terms of CDRH headcount and MDUFA process FTEs. While acknowledging that CDRH has recently experienced a reduction in staffing levels, FDA emphasized its active recruitment efforts and commitment to maintaining or achieving appropriate staffing levels to meet all MDUFA V goals and performance commitments.

Resource Capacity Planning and Management – FDA Perspective on Reauthorization

FDA noted that MDUFA IV and V included commitments regarding complete time reporting that would support workload analysis and capacity planning. While these commitments were met, FDA believes additional opportunities exist to enhance these processes to attain the next level of maturity and capability in MDUFA VI, commensurate with the overall growth and maturity of the MDUFA program.

FDA's 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. The RCPM capability development component would focus on assessing current capabilities for tracking and forecasting workload and corresponding review resource needs, identifying capability gaps, and designing the optimal staffing, analytical approach, and reporting requirements, which FDA believes would serve as a necessary foundation for implementing the resource capacity adjuster.

Industry noted that previous reforms the MDUFA fee structure, including establishing a registration fee, provided more funding stability. FDA noted that funding stability only partially addresses resource capacity.

Trigger Reform – FDA Perspective on Reauthorization

FDA proposed reforms to MDUFA's statutory operating reserve amount and two statutory provisions: an appropriation threshold condition specified in Section 738(g) of the FD&C Act and a budgetary spending threshold specified in Section 738(h)(2).

Specifically, FDA proposed: 1) Addressing structural issues with the spending threshold; 2) Increasing both thresholds; 3) Increasing the operating reserve to cover extended lapses in funding; and 4) Making additional technical corrections. FDA articulated an agency priority to standardize and streamline core elements across user fee programs.

Industry agreed in principle that adjustments to the spending trigger would be appropriate to address perceived defects. Industry stated they would provide substantive responses on other elements of FDA's proposal in future meetings, noting reservations about some of the proposed changes.

Discussion & Recap

Industry expressed appreciation for the information shared by FDA and FDA's insights regarding areas where additional programmatic adjustments may be beneficial.

Industry noted that a lot of information was shared during the meeting and that it would provide additional feedback at the outset of the next meeting.

Industry raised concerns that MDUFA V provided resources for net new hire increases, and that FDA is currently operating below that baseline with fewer staff on board relative to the funding provided. Industry emphasized the importance of understanding how current staffing levels align with commitments and resource allocations and reiterated the need to align on understanding of MDUFA V baseline and MDUFA VI resources.

Next Meeting: The next meeting is scheduled for December 11, 2025.

Meeting End Time: 12:57 pm EST