FDA – Industry MDUFA VI Reauthorization Meeting
November 20, 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*
Peter Yang, *CDRH*
Marta Gozzi, *CDRH*

Industry
AdvaMed Team
Janet Trunzo, *AdvaMed*
Zach Rothstein, *AdvaMed*
Yarmela Pavlovic, *Medtronic*
Diane Wurzburger*, GE Healthcare*
Geeta Pamidimukkala*, AdvaMed*

MDMA Team
Mark Leahey, *MDMA*
Melanie Raska, *Boston Scientific*
Nicole Zuk, *Siemens Healthineers*
April Lavender, *Cook Medical*

Meeting Start Time: 9:03 am EST

Opening

FDA opened the meeting and presented the agenda.

Industry Feedback on Topics from Meeting #2

FDA invited Industry to provide feedback on proposals presented during the November 4 meeting. Industry expressed support for the substance of the Patient Science and Digital Health proposals and willingness to start working on commitment letter language, while noting the importance of better understanding current resources before determining whether additional resources are needed for each proposal before final agreement. Industry also voiced support for a MDUFA VI proposal to support enhanced use of consensus standards, including continuing the Accreditation Scheme for Conformity Assessment (ASCA) program. Industry noted that FDA may better leverage consensus standards without requiring ASCA's participation. Industry also noted an interest in additional commitments regarding testing and consensus standards. Industry agreed to provide more details regarding consensus standards commitments in a future meeting.

FDA and Industry Brainstorming Session

FDA and Industry briefly presented problem statements, observations, and potential solutions regarding existing challenges in the De Novo, Pre-Submission, and Third Party 510(k) Review (3P510(k)) programs.

Three challenges were identified for the De Novo program: 1) De Novo classification requests have a lower granting rate and more declines, withdrawals, and deletions than other marketing submission types; 2) De Novo decision and follow-up industry response options are limited (other than new submission or appeal); and 3) Limited options for De Novo ineligible devices, especially for "second-place finishers" (De Novo submissions that were initially eligible to submit a request for classification and were accepted for review, but had not yet received a decision when another De Novo submission that could serve as a predicate device is authorized).

Three challenges were identified for the Pre-Submission program: 1) Resource Strain due to growth in Pre-Submission requests; 2) Suboptimal Pre-Sub Utilization, and 3) Timeline Inefficiencies, including consideration of whether certain Pre-Submissions could be answered before the applicable 70-day goal timeframe.

FDA and Industry presented additional data, observations, and potential solutions to confront these challenges.

Two challenges were identified for 3P510(k): 1) Routine FDA re-review of 3P510(k) submissions may limit the program's value to industry and ability to help reduce FDA review burden; and 2) low volume in any one product area for individual review organizations limits experience to provide high quality reviews.

Following the presentations, FDA and Industry discussed potential solutions.

The parties agreed to take the potential solutions presented by each side back for further internal deliberation and offline discussions to bring proposals to an upcoming negotiation meeting.

Discussion & Recap

FDA presented a roadmap for upcoming negotiation meetings, outlining FDA's plan to present remaining key proposals over the next three meetings.

FDA noted that several topics may require follow-up discussions after the initial six negotiation meetings to allow for further consideration and refinement. FDA also indicated plans to incorporate a mid-point assessment in the sixth meeting.

FDA shared plans to discuss any needed internal audits or independent assessments in January and expressed interest in receiving Industry feedback on audit-related matters. Industry agreed that discussing audits should follow resolution of the programmatic elements of MDUFA VI.

Industry reiterated the importance of better understanding FDA's current MDUFA resource and staffing capacity, as well as projections for FY26 and FY27 before assessing whether additional resources are needed under MDUFA VI.

FDA confirmed that a proposal on the Total Product Life Cycle Advisory Program (TAP) pilot was scheduled for an upcoming negotiation meeting in December and Industry response and further deliberation is anticipated.

While FDA previewed a discussion of 510(k) Total Time to Decision (TTD) goal and calculation during the November 4 meeting, the topic was not further discussed at this meeting. This topic is planned for discussion in an upcoming meeting.

Next Meeting: The next meeting is scheduled on December 2, 2025.

Meeting End Time: 12:57 pm EST