FDA – Industry MDUFA VI Reauthorization Meeting
January 21, 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*
Erin Cutts, *CDRH*
Tammy Beckham, *CDRH*
Susannah Gilbert, *CDRH*
Peter Yang, *CDRH*
Marta Gozzi, *CDRH*

Industry
Geeta Pamidimukkala, *AdvaMed*
Josh Silverstein, *Stryker*

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: 9:04 am EST

FDA opened the meeting, presented the agenda and provided updates to Industry on key outstanding issues and questions from previous negotiations, including operating reserve, capacity planning, appropriations trigger, and fee structure changes, including “America First” principles.

Industry then presented their feedback on Real World Evidence (RWE). Industry expressed strong support for the National Evaluation System for Health Technology (NEST) and emphasized that NEST Mark is potentially an important future tool for evaluating RWE quality. Industry noted that collaboration appears to be going well. Industry requested more specifics on FDA's proposed RWE investment regarding the full-time equivalents (FTEs) and operational dollars to better understand how the funds will be spent, explain more detail on data sources that would be leveraged and how they translate to premarket review, and what current FTEs are doing in RWE at this time. FDA indicated it will work on providing that information.

FDA and Industry agreed to leverage the MDUFA V commitment letter language in drafting the MDUFA VI commitment for funding NEST.

Industry closed by noting they would provide feedback on other topics presented in the January 14 meeting during the next negotiation meeting on February 4, 2026.

De Novo & Pre-Submission Programs
Through internal deliberation and offline discussions, FDA and Industry developed proposals for the De Novo and Pre-Submission Programs and provided readouts from their working groups on areas of agreement and disagreement.

De Novo: 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).

Progress was reported, with FDA and Industry reaching alignment on the majority of proposals while identifying one area in a proposal requiring further deliberation—committing to regular discussion meetings during the review cycle. FDA and Industry agreed additional discussion is still needed and would be discussed in a future negotiation meeting.

Pre-Submission: 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.

Progress was reported, with FDA and Industry reaching alignment on the majority of areas within the proposals while identifying two areas that would require further deliberation – faster feedback options and bundling of traditional pre-submissions. FDA and Industry agreed that Pre-Submission follow-up discussion would be slated for February 11, 2026.

510(k) Total Time to Decision (TTD)
FDA and Industry agreed on a set of 510(k) Total Time to Decision (TTD) goals which will leverage the same calculation methodology as in previous MDUFA cycles. The agreed upon TTD goal will ramp down from 128 days in fiscal year 2028 to 112 days in fiscal year 2032.

International Harmonization
FDA presented an update on FDA's International Harmonization proposal that initially included four elements. FDA sought to address Industry questions about the International Harmonization proposal, as well as concerns and general opposition voiced by Industry in prior meetings about the global supply chain resilience element being an expansion in scope of the international harmonization activities under MDUFA, which they did not support. After discussion, FDA indicated it was receptive to moving forward with a subset of the initially proposed elements without including global supply chain resilience activities.

Discussion & Recap
FDA proposed holds in March for additional negotiation meetings, if needed, and requested Industry confirm if those times would be feasible for them.

Next Meeting: The next meeting is scheduled for February 4, 2026.

Meeting End Time: 12:42 pm EST