

FDA – Industry MDUFA V Reauthorization Meeting
February 8, 2022, 3:00 pm – 4:38 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauer, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Scott Colburn, *CDRH*
- Melissa Torres, *CDRH*
- Robert Sauer, *CDRH*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pflieger, *Alcon*
- Nicole Taylor Smith, *Medtronic*

MITA Team

- Peter Weems, *MITA*
- Diane Wurzbarger, *GE Healthcare*
- Nicole Zuk, *Siemens Healthineers*

MDMA Team

- Mark Leahey, *MDMA*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic*
- Amy Leiser, *Covington & Burling*

Meeting Start Time: 3:00 pm EST

Executive Summary

During the February 8, 2022 user fee negotiation meeting, FDA presented data and analysis regarding the shared outcome total time to decision (TTD) goals for 510(k) and PMA submissions. Based on this information, FDA proposed ambitious but achievable shared outcome

goals for 510(k) and PMA TTD. Industry and FDA discussed the workload projections, goals, and options for defining the cohorts for MDUFA V.

Analysis of 510(k) Total Time to Decision Shared Outcome Goals

FDA presented analysis of workload data, trends, and performance outcomes from MDUFA IV that inform what can be expected for 510(k) TTD during MDUFA V. FDA noted that 510(k) TTD outcomes are affected by the volume of 510(k) submissions, the increasing complexity of those submissions, the impact of pandemic-related workload and review hold policies, and overall program workload, given that 510(k) submission review must be managed as part of the entire portfolio of MDUFA work. FDA noted that pandemic-related work will continue to have an impact on 510(k) TTD during MDUFA V due to (a) the increased workload from some of the products that were granted emergency use authorization (EUA) transitioning to 510(k) submissions, and (b) the impact of 510(k) submissions that had extended hold times (more than the standard 180 days) coming off hold and back into reviewer queues.

FDA presented an analysis requested by Industry that estimated the impact on 510(k) TTD if the submissions on extended hold were to be removed from the TTD cohort, noting that this simplified analysis is not an accurate model for actual TTD outcomes. FDA then presented a couple options for setting 510(k) TTD shared outcome goals that are ambitious but achievable, considering current trends and the extenuating circumstances of pandemic-related impacts on the program. The options involved different assumptions about how the trimmed mean calculations could be applied at the beginning of MDUFA V and their impact on the TTD target for FY 2023.

Analysis of PMA Total Time to Decision Shared Outcome Goals

FDA presented an analysis of current trends for the PMA TTD shared outcome goal, noting that the PMA TTD is calculated using a 3-year average that smooths out the year-to-year variations observed in these smaller data sets. After noting that FDA and Industry previously had discussed holding the PMA TTD shared outcome goal at 290 days, FDA presented an option for improving the PMA TTD targets in FY 2025-27 if additional resources were to be provided.

Meeting End Time: 4:38 pm EST