

FDA – Industry MDUFA V Reauthorization Meeting
November 9, 2021, 1:30 pm – 5:11 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*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauer, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *CBER*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Melissa Torres, *CDRH*
- Erin Cutts, *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*
- Michael Pflieger, *Alcon*
- Danelle Miller, *Roche*
- Nicole Taylor Smith, *Medtronic*

MITA Team

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

MDMA Team

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

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic*
Laboratories

Meeting Start Time: 1:30 am EST

Executive Summary

During the November 9, 2021 user fee negotiation meeting, FDA presented its proposals for international harmonization and the 510(k) total time to decision shared outcome goal. FDA also

responded to Industry's accountability proposals related to hiring and vacancies, and provided an update related to funds available in the carryover balance.

FDA's Proposal related to International Harmonization

As a follow-up to discussions during prior meetings, FDA presented a proposal to enhance the Agency's role in international harmonization initiatives including: (1) Expanding engagement in international harmonization and convergence efforts through participation in working groups, projects, and committees to promote alignment with international best practices and internationally developed policies; (2) Further supporting regulatory convergence by creating a separate mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information or policies and practices as needed and consistent with applicable disclosure law and policy; (3) Assessing the extent of CDRH's implementation of International Medical Device Regulators Forum (IMDRF) technical documents and making this information publicly available to enhance clarity and transparency; and (4) Supporting creation of a venue to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision making.

Industry expressed support for including International Harmonization in MDUFA V, but inquired whether the commitment letter could include more concrete deliverables. FDA noted that its proposal included high-level commitments to collaborate with external parties, given that international harmonization activities necessarily include collaboration with other entities that are not parties to the MDUFA agreement. As a next step, FDA and Industry agreed to further consider whether additional, more specific commitments could be incorporated to help measure progress under MDUFA V (e.g., a performance report).

FDA's Response to Industry Proposals Related to Hiring and Vacancies

In follow-up to the October 20th meeting, FDA presented information on the concepts that had been discussed related to hiring and vacancies.

In response to Industry's proposal for quarterly hiring targets with subsequent registration fee off-set if targets are missed, FDA proposed FDA to calculate MDUFA V fees by applying an assumption of quarterly hiring to the calculation of full time equivalent (FTE) costs for the year in which new hires are made. FDA noted that the assumption could reflect various intervals (e.g., semi-annually or quarterly), but that FDA's proposal reflected Industry's interest in quarterly hiring targets. Rather than develop a mechanism to refund user fees through quarterly offsets that would be difficult to administer, FDA explained that this approach of adjusting the on-boarding assumption would produce lower FTE costs for the year in which new hires are made, resulting in front-end cost savings to Industry.

In addition, FDA proposed the following hiring commitments: FDA and Industry would set annual hiring goals for new MDUFA V hires. After the close of each fiscal year, FDA would provide a report to industry and the public on whether FDA met the annual hiring goal for the preceding year. If actual hiring was 90% or less than the goal for two years in a row and MDUFA fees were returned to the carryover balance, FDA would report on why the goals for

those years were not met, and FDA and Industry would meet to discuss how carryover balance funds should be reinvested in the MDUFA program. If the goals were missed and no funds were returned to the carryover balance (as could happen, for example, if user fees were needed for other payroll or programmatic costs in a given year), FDA would report on how the fees had been utilized. During discussion of this proposal, Industry expressed concern that the accountability measures would not apply unless FDA missed the hiring target for two years, and concern that missing the hiring target would result only in transparency rather than an offset of future registration fees. FDA and Industry noted that further discussion of commitments related to hiring accountability would be needed.

FDA also proposed to apply user fee funds to support recruitment, as had been done under MDUFA IV. Specifically, FDA proposed to engage a qualified contractor(s) or other service provider(s) to supplement recruitment and staffing support during MDUFA V. FDA and Industry discussed how FDA had used a contract with the Office of Personnel Management during MDUFA IV for recruitment services.

Regarding vacancies, FDA reiterated that it did not have a mechanism to track MDUFA “positions” prior to MDUFA IV, and therefore, the vacancy rate for positions added as part of MDUFA I-III cannot be determined. FDA explained that positions are not designated by one funding type (e.g., budget authority, user fees), meaning that staff performing MDUFA process work may be paid with both budget authority and user fee allocations. FDA maintained that the MDUFA process FTE represents the most accurate measure of level of effort devoted to MDUFA work each year. To address Industry’s interest in the vacancy rate, however, FDA proposed to retain a qualified, independent contractor to assess current methodologies and data/metrics available to represent MDUFA process FTE resources, including the subset funded by user fees, for each applicable FDA Center and Office; and to develop recommendations for improved methodologies and data/metrics to represent MDUFA process FTE resources, including the subset funded by user fees. Industry expressed the perspective that the contract for this assessment should be awarded early in MDUFA V, if not sooner.

Carryover Balance Update

FDA provided updated information on the carryover balance with estimates for FY 2021, including additional potential funding that could be applied to MDUFA V. In addition, FDA and Industry discussed options for more regular meetings to address use of carryover balance funds during MDUFA V.

FDA’s Proposal for the 510(k) Total Time to Decision Goal

FDA presented a proposal for the 510(k) shared outcome total time to decision (TTD) goal. FDA detailed the factors that impact 510(k) TTD, and which contributed to the goal proposed for MDUFA V. FDA presented data related to rising page counts of 510(k) submissions, a rough proxy for complexity and level of effort, which showed that the average number of pages per submission increased from approximately 1,100 in FY13-17 to approximately 1,500 in FY18-20. FDA also forecasted a tsunami of 510(k)s that the Agency expected to receive in the early years of MDUFA V, due to the confluence of receiving both new submissions and responses from sponsors for 510(k)s that had been on extended hold pursuant to the COVID-19 policy that

provided sponsors with up to 360 total days (rather than 180 days) to respond to additional information and deficiency letters. Finally, FDA noted that because 510(k) TTD was projected to be approximately 140-145 days for FY21-22 (plus or minus five days), it would not be realistic to expect improvement to 108 days by the early years of MDUFA V, as Industry had proposed.

To address these factors, FDA noted two potential solutions to establish an ambitious but achievable 510(k) TTD goal for MDUFA V: (1) additional reviewers on teams with high volumes of 510(k) submissions, and (2) scoping 510(k) TTD to submissions that used the “electronic Submission Template And Resource” (eSTAR) templates. The eSTAR is an electronic submission template built within a structured dynamic PDF that guides a user through construction of an eSubmission. FDA noted that, because of the structured nature of eSTAR, it helped improve submission quality and 510(k) review efficiency. FDA presented data from 2021, which compared the average number of days to reach a MDUFA decision for 510(k) submissions that used or did not use eSTAR, and which showed approximately 20 fewer days for submissions that used eSTAR.

In consideration of these challenges and potential mitigations, FDA proposed that the 510(k) TTD goal be scoped to the cohort of eSTAR submissions and reflect improvement over time to reach 108 days by the end of MDUFA V as follows: FY23: 145 days; FY 24: 135 days; FY 25: 124 days; FY26-27: 108 days.

Next Meeting

The next meeting is scheduled for November 18, 2021.

Meeting End Time: 5:11 pm EST