FDA – Industry MDUFA V Reauthorization Meeting
October 7, 2021, 12:30 am – 3:55 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 Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Scott Colburn, *CDRH*
- Gail Rodriquez, *CDRH*
- Melissa Torres, *CDRH*
- Erin Cutts, *CDRH*

Industry

AdvaMed Team

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

MITA Team

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

MDMA Team

- Mark Leahey, *MDMA*
- Mark Gordon, *Alcon*
- Jen Bolton, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

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

Meeting Start Time: 12:30 am EST

Executive Summary

During the October 7, 2021 user fee negotiation meeting, FDA responded to Industry's previous questions on Office of Product Evaluation and Quality (OPEQ) staffing, manager-to-staff ratio, the carryover balance, and 510(k) hold times. FDA and Industry discussed FDA's proposals on patient science and engagement, standards, and international harmonization.

FDA Response to Industry Questions

FDA shared the number of OPEQ staff that fall into the following categories: Office of Health Technology (OHT) TPLC Reviewers; OHT TPLC Medical Officers; Statisticians, Epidemiologists and TPLC Policy/Program Staff; Managers; and Administrative Support staff. FDA noted the limitations of the information as a proxy for estimating staff involved in the MDUFA process—namely, that the information included all OPEQ employees, not only individuals involved in MDUFA process work; that OPEQ staff spend different portions of their time on MDUFA work; and that MDUFA process work is also performed by other parts of CDRH and by CBER, ORA, and FDA headquarters staff. For further clarity, FDA noted that, in FY21, approximately 75% of CDRH staff recorded time for MDUFA process activities and considerably more staff recorded time for work that supports MDUFA (e.g., management functions).

FDA provided clarification on the manager-to-staff ratio. Based on data from September 2020, the ratio for review staff to front-line supervisors in OPEQ was 10:1, reflecting a decrease from 12:1 in the former Office of Device Evaluation (ODE) and 11:1 in the former Office of In Vitro Diagnostics and Radiological Health (OIR). In addition, FDA noted that this ratio does not account for the team lead position that was created during MDUFA IV and performs managerial duties, nor does it include additional division and office management positions. The total manager-to-staff ratio when accounting for these positions is slightly lower than 8:1.

FDA shared a breakdown of funds from the FY 2020 carryover balance, including estimated amounts to support a portion of Digital Transformation expenses in FY21-24; to address personnel costs in FY22; to support continuation of the Third Party Review Program during MDUFA V; and the remaining balance that was subject to further discussion with Industry through the negotiations. In response to Industry questions regarding personnel costs, FDA clarified that the impacts of rising personnel costs were absorbed in earlier years of MDUFA IV because of challenges with hiring new staff; however, as hiring processes improved and FDA achieved the MDUFA IV hiring projections, the increasing payroll costs (e.g., mandatory cost of living increases; increases in benefit contributions) could no longer be absorbed without use of carryover balance funds. In response to Industry questions regarding digital transformation, FDA walked through the information that had been provided at prior negotiation meetings regarding funding for this initiative. Industry expressed its view on the importance of improving transparency and discussion between FDA and Industry around the use of carryover balance funds as part of MDUFA V. In response to Industry questions regarding the FY21 carryover balance, FDA explained that the Agency would provide an update as soon as possible as the Agency completed the accounting following the end of the fiscal year.

FDA provided data on the impact of the policy that FDA implemented during the pandemic to address challenges faced by sponsors in responding to additional information (AI) and deficiency

letters. Specifically, FDA's Guidance "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised)" (Updated December 2020) stated that "for marketing submissions and applications on hold where the response is on or before the date this guidance is withdrawn, FDA does not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date." For example, under this policy, a 510(k) may potentially be on hold for 360 days after receipt of an AI letter (rather than the typical 180 days). In response to Industry questions during prior negotiation meetings, FDA explained how sponsors' use of this policy had impacted 510(k) Total Time to Decision during MDUFA IV and FDA's projections for 510(k) Total Time to Decision goals under MDUFA V.

Discussion of Three FDA Proposals

FDA shared proposals to expand the Agency's programmatic capabilities related to patient science and engagement; enhanced use of consensus standards; and international harmonization.

Patient Science and Engagement

FDA presented details of its revised proposal to expand the patient science and engagement program through new MDUFA V resources to support additional staff and operating costs. FDA noted that, in response to Industry's cost estimates presented on August 10th, FDA had scaled back its initial proposal, while continuing thoughtfully to consider how the program could move forward in key ways. The proposal would continue to include three prongs—the patient science evidence accelerator; the patient engagement incubator; and the concept of a shared decision-making team—but the scale of the activities related to conducting research (e.g., patient preference studies) as part of the evidence accelerator and to developing new training curricula as part of the patient engagement incubator would be narrowed. In FDA's view, even with these changes, the revised proposal would continue to be responsive to the feedback that the Agency had heard from Industry and patients about the successes of the program under MDUFA IV and opportunities for further enhancement.

Enhanced Use of Consensus Standards

FDA presented details of its proposal to advance the Accreditation Scheme for Conformity Assessment (ASCA) program through new MDUFA V resources to support additional staff and operating costs. FDA's proposal included working with stakeholders to explore expansion of standards recognized in the program; updating guidance documents to accommodate improvements identified during the pilot period and the possibility of additional standards; implementing additional training for FDA staff to further develop internal expertise; exploring how to improve standards for regulatory use, global harmonization efforts, and other programs; and tracking appropriate performance metrics.

International Harmonization

FDA shared its view that, with a modest investment of new MDUFA V resources, the Agency would be able to expand its bilateral and multilateral work with foreign regulators to advance

regulatory convergence efforts, as well as expand its engagement in international fora such as the International Medical Device Regulators Forum (IMDRF) to promote international harmonization. In addition, FDA would be able to accelerate its evaluation of international guidance and other technical documents, and make related information publicly available to enhance transparency about the Agency's work in this area.

Next Meeting

The next meeting is scheduled for October 20, 2021.

Meeting End Time: 3:55 pm EST