FDA – Industry MDUFA V Reauthorization Meeting
August 10, 2021, 11:30 am – 3:30 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*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- 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*
- Daniel Montgomery, *CDRH*
- Daniel Krainak, *CDRH*
- Scott Colburn, *CDRH*
- Melissa Torres, *CDRH*
- Erin Cutts, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Michael Pfleger, *Alcon*
- Danelle Miller, *Roche*
- 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*
- John Manthei, *Latham & Watkins*
- 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: 11:30 am EST

Executive Summary

During the August 10, 2021 user fee negotiation meeting, FDA presented on the TPLC Advisory Program (TAP) proposal and responded to Industry's proposals for use of the MDUFA IV carryover balance. Industry also presented a proposed MDUFA V financial package.

FDA's Presentation

FDA opened the meeting by reviewing the Agency's goals for the MDUFA negotiation: (1) To enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; (2) To improve device safety across the total product lifecycle; and (3) To optimize FDA infrastructure, staffing, and resources to keep pace with scientific development.

TPLC Advisory Program (TAP) proposal

FDA provided additional detail regarding the TAP Proposal, with a particular focus on responding to concerns and questions that Industry had identified during the July 21, 2021 meeting.

FDA explained that, given the exponential growth in the Breakthrough Devices Program and anticipated growth of the Safer Technologies Program (STeP), the rapid feedback performance ("sprint" performance) is unsustainable without additional review team capacity. To demonstrate the demand for early interaction for Breakthrough-designated products, FDA provided updated data on the growth in Breakthrough designation requests—noting that, by the end of FY 2021, FDA expects to have granted nearly 500 Breakthrough device designations over the preceding four years. FDA further showed how Breakthrough designations translate into year-over-year increases in the number of Breakthrough "sprint" requests that FDA receives. Specifically, in FY 2018, FDA received 30 of this type of early interaction request. Four years later, by the end of FY 2021, data indicate that FDA will receive more than 9 times that amount—*i.e.*, an 860% increase in sprint requests. Projecting out to the end of MDUFA V in FY 2027, and including projected growth of STeP, FDA expects to receive over 900 requests for early feedback per year. To provide a better understanding of how these requests translate into workload, FDA noted that Breakthrough sprint interactions are considered a type of Pre-submission and that, on average, the number of hours worked per Pre-submission is 80 hours.

FDA further noted that the TAP proposal was not just about resourcing the growth in the current programs, but also building on lessons learned both from the existing programs as well as interactions with sponsors of COVID-19-related products. In response to questions Industry had previously raised regarding whether some aspects of the proposed TAP program would require statutory changes to implement, FDA provided further clarification of its vision for TAP. For example, FDA explained that enhanced, iterative interaction between sponsors and review teams—plus sufficient review capacity in important scientific and technical disciplines, as well as time for professional development so staff can remain current on technological advancements and participate in experiential learning opportunities—were the key, defining features of the TAP proposal.

FDA described the envisioned role of the TAP Advisor. This new position would support industry sponsors and FDA review teams by coordinating early and strategic planning, clarifying FDA processes, supporting timely and meaningful interactions, building relationships with a variety of stakeholders, and providing guidance to optimize the quality of the sponsor's future marketing submission.

Regarding assessment of the TAP program during the MDUFA V time period, FDA noted that because TAP interactions would be focused early in the product development process, it could be multiple years between a product's entry into the TAP program and FDA's decision on a marketing submission. Accordingly, initial assessment of the new program would need to focus on leading indicators of success that could be measured during MDUFA V. Moreover, because the core of the TAP would be focused on increasing review capacity, deepening FDA's technical and scientific expertise, and enhancing a culture of continuous improvement and learning, FDA expected that TAP's value would extend beyond products in the program to improve the experience of sponsors of non-TAP products as well.

Finally, FDA invited Industry to clarify what, if any, aspects of TAP Industry thought were not supported by existing statutory authority. Industry said they would take back the clarifications provided during the meeting today and revert back with any questions.

FDA's Response to Industry's Proposal for New FTE

To help inform FDA's consideration of Industry's July 21, 2021 program regarding use of carryover balance funds to hire new FTE, FDA inquired about Industry's goals for the allocation of FTE and expected timeline. FDA noted that, in its view, use of carryover balance funds to offset MDUFA V costs would need to be considered in the context of the overall MDUFA V package.

Industry's Presentation

Industry began its presentation by reviewing its principles for the MDUFA user fee program: (1) Supporting timely patient access to safe and effective medical devices, and to maintain the U.S. review process as the gold standard in the world for patient safety; (2) That Congressional appropriations remain the primary source of funding for the device review program; (3) That user fees are used solely for the premarket review process and are used for agreed purposes, while Industry is supportive of additional general appropriations for patient safety as well as other appropriate postmarket initiatives; (4) Recognition that Industry has made significant and material investments in building up the program through MDUFA I through IV, such that there has been a sizable growth in resources and the program is now on very stable footing; and, (5) That user fees should support mutually shared goals and process improvements to help achieve timely patient access to safe and effective devices.

Industry presented the following priorities for MDUFA V: that FDA maintain pre-COVID performance and meet MDUFA IV commitments; that all deficiency letters include a statement of the basis for the deficiency; that FDA and Industry reach agreement on use of MDUFA carryover balance funds and credit remaining carryover balance funds to MDUFA V; that FDA and Industry recommend updates to the statutory triggers; and that MDUFA V include a provision offsetting fees in the fifth year of the program for unused hiring funds that exceed 5% of MDUFA-funded vacancies.

Industry presented a financial proposal for MDUFA V consisting of two parts: use of MDUFA IV carryover balance funds, and new or revised funding for MDUFA V.

Consistent with Industry's proposed use of carryover balance funds, as presented on July 21, 2021, Industry provided its perspective that funds should be used to support hiring 50 additional new reviewers; hiring 6 additional supervisors; seeding a "rainy day" fund; an independent human resources assessment; a small TAP pilot; and an independent financial audit. In total, Industry estimated that the proposals would be funded by $127M in carryover balance funds.

In addition, Industry proposed that user fee funds collected during MDUFA V would be used to support the existing MDUFA base program; recruitment and retention; program capabilities related to use of consensus standards, real world evidence, patient science and engagement, third party review, and international harmonization; and independent assessments of program operations and finances. In total, Industry estimated that those areas of the MDUFA program would be funded by $1.117B in MDUFA V user fees. Combined with funds from the carryover balance, Industry estimated that its total proposed MDUFA V package would cost $1.244B.

Meeting End Time: 3:30 pm EST