FDA – Industry MDUFA V Reauthorization Meeting
October 20, 2021, 12:30 pm – 4:30 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*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *CBER*
- Claire Davies, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- 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 Pfleger, *Alcon*
- Danelle Miller, *Roche*
- Nicole Taylor Smith, *Medtronic*

MITA Team

- Peter Weems, *MITA*
- Nicole Zuk, *Siemens Healthineers*

MDMA Team

- Mark Leahey, *MDMA*
- John Manthei, *Latham & Watkins*
- Melanie Raska, *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 20, 2021 user fee negotiation meeting, Industry presented a package of proposals focused on accountability measures as well as a financial counter-proposal to FDA's proposal of September 22.

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 maintaining 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 updated priorities for MDUFA V: Industry proposed that FDA should maintain pre-COVID performance, including pre-submissions, and meet MDUFA IV commitments. Industry stated that in FY2018-2019, 90% of pre-submissions received written feedback within 70 days. Industry proposed that 99% of additional information and deficiency letters include a statement of the basis for the deficiency. Industry proposed that FDA and Industry reach agreement on use of MDUFA carryover balance funds and credit remaining carryover balance funds to MDUFA V. Industry proposed that FDA and Industry recommend updates to the statutory triggers.

In support of these priorities, Industry proposed actions aimed at increasing the Agency's accountability under the MDUFA V agreement:

Industry proposed establishing an Accountability Committee that would include representatives from AdvaMed, ACLA, MDMA, MITA and FDA. This group would meet on a quarterly basis to review progress towards meeting performance goals and on an annual basis to reach mutual agreement on the use of remaining carry-over balances.

Industry proposed the following changes to the independent assessment process: that the proposed Accountability Committee meet to refine the scope and outline the structure of the independent assessment report; that Industry have an opportunity to review and provide additional information to the independent assessor and approve publication of the final report, and that FDA and Industry have the opportunity to provide a written response to accompany the final report. In addition, Industry proposed that the independent assessment be conducted with an interim step whereby, by March 31, 2025, the assessor would prepare a mid-term report to identify areas in which commitments were not met or likely not to be met, if any. Then, after consultation with the Accountability Committee, the mid-term report would identify steps that FDA could take to meet its commitment for the remainder of MDUFA V.

Industry proposed the following measures related to hiring accountability: establish quarterly hiring targets during MDUFA V; by June 30, 2023 and annually thereafter, assess progress on meeting hiring targets; any unused hiring funds be used to offset facility registration fees in the following year; by June 30, 2023 and annually thereafter, assess current vacancy rate for all MDUFA-funded full time equivalents (FTEs) from MDUFA I through MDUFA V; and, if the

vacancy rate exceeds 5% for the MDUFA program, that any unused funds be used to offset facility registration fees in the following year.

Industry proposed a novel user fee structure that would involve "add-on" payments if certain specified performance measures were met. The concept was, if by June 30, 2024 and every 12 months thereafter, FDA met the following performance goals, the Agency would receive an additional $50 million in fees the following fiscal year: the goals for average total time to decision for 510(k)s and PMAs would be the same as FY22 under the MDUFA IV agreement (i.e., 108 days and 290 days, respectively); the review performance goal for de novo decision would be the same as for FY22 under the MDUFA IV agreement (i.e., FDA would issue a de novo decision within 150 FDA days of receipt of the submission for 70% of de novo requests received); FDA would meet the other FDA decision goals and the substantive interaction goals specified in the MDUFA IV agreement; FDA would meet a new goal that 90% of pre-submissions would receive written feedback within 70 days; and FDA would meet a new goal that 99% of deficiency letters include a statement of the basis for the deficiency. These goals would be consistent for each year of MDUFA V. If the add-on payment was achieved, Industry proposed that 10% of the amount could be used to initiate the TAP Pilot and that use of the remaining amounts would be discussed between FDA and Industry.

Finally, Industry presented a financial counter-proposal to FDA's proposal of September 22nd, consisting of two parts: use of MDUFA IV carryover funds, and new or revised funding for MDUFA V.

Regarding use of the MDUFA IV carryover balance funds, Industry proposed that funds be used to support hiring 50 additional new reviewers; hiring 6 additional supervisors; establishing a "rainy day" fund; and funding an independent assessment related to human resources. To estimate the cost of new hires, Industry used a cost per full time equivalent (FTE) of $299,329. Industry estimated $36 million would be retained for the rainy day fund, and $3 million would be used for the human resources assessment. In total, Industry estimated that the proposals would be funded by $137.7 million from the carryover balance.

In addition, Industry proposed user fee funds collected during MDUFA V would be used to support the existing MDUFA base program; to hire 75 new staff to assist the Agency in meeting review performance goals; to hire 17 new staff to support the patient science and engagement, consensus standards, and international harmonization programs; and to support one-time costs related to real world evidence and independent assessments.

Including both MDUFA IV carryover funds and MDUFA V user fees, Industry estimated that the five-year cost of MDUFA V would be $1.475B in guaranteed funding, plus a potential additional $150M in add-on payments.

Discussion

During the discussion of Industry's proposal, FDA raised the following key questions:

FDA expressed concern about the significant gap in understanding between the Agency and Industry about the amount of resources needed to meet the performance goals proposed by Industry, particularly related to pre-submissions. Industry clarified that its pre-submission resource estimates were based on a predicted volume of approximately 3,000 pre-submissions per year; potential process changes by FDA that would mitigate further volume increases (e.g., through clarification of what types of inquiries do not need to be handled as pre-submissions); and the possibility that FDA could use resources in the proposed "rainy day" carryover balance fund. FDA expressed concern that Industry's proposed performance goals and associated cost estimates would leave the Agency with considerable risk, and would need to be the subject of further discussion.

FDA also noted that Industry's proposal did not appear to address the gap in payroll funding that FDA had described during the September 22nd meeting. Industry indicated that the estimate of $299,329 as a cost per FTE was meant to address the funding gap. FDA explained, however, that the cost per FTE was an estimate of the cost of new FTEs that would be added to the program under MDUFA V, but that the methodology did not address the payroll challenge with staff already on-board and performing MDUFA work.

FDA noted that, while the add-on payments were an interesting concept, the Agency had questions and concerns about the proposal as described. FDA questioned whether the concept should include total time to decision goals for 510(k)s and PMAs, since they are shared outcome goals and, by design, not wholly within FDA's control. FDA expressed the perspective that a total time to decision goal of 108 days for 510(k) submissions would not be achievable in FY23, given the impact of sponsors' use of the additional hold time described in FDA's COVID-19 guidance. FDA questioned how the add-on payments would be used (other than for TAP) since, if FDA were to achieve the add-on payments, it would be because all of the applicable MDUFA V performance goals were being met. FDA expressed the perspective that missing performance goals would most likely be related to a lack of adequate funding to do the work, not a lack of effort that could be incentivized with an add-on payment. In closing, FDA noted that the Agency would continue to consider the add-on payment concept to see whether it could be refined to fit within the FDA user fee payment structure, while achieving Industry's goal that add-on payments would be a tool to increase accountability.

FDA and Industry also discussed how the concept for an Accountability Committee would differ from the existing process for providing quarterly MDUFA performance updates to Industry, and how Industry envisioned the process for the Independent Assessment in the future. Industry clarified that it did not mean to suggest that the assessment would become subject to Industry "approval" prior to issuance, but that Industry would have an opportunity to review the draft report for accuracy and to provide a separate written response if desired.

Regarding hiring, FDA noted that it could not agree to quarterly hiring targets, because the length of time needed to complete the hiring process could result in variability from quarter to quarter. However, FDA could agree to annual hiring targets, which would provide accountability while still being achievable. Likewise, FDA noted the challenges with administering a program that would calculate refunds for missed hiring goals on a quarterly basis, which would roll up into an annual registration fee offset. However, FDA mentioned the concept of reducing Industry

user fees on the front-end to reflect an assumption of quarterly hiring throughout the year, rather than tallying refunds through the back-end accounting that Industry had proposed. Industry and FDA noted this topic for further discussion in a future negotiation meeting.

Next Meeting

The next meeting is scheduled for November 9, 2021.

Meeting End Time: 4:30 pm EST