FDA – Industry MDUFA V Reauthorization Meeting
November 18, 2021, 9:00 am – 11:30 am 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*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *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*
- Ellen Olson, *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*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

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

Meeting Start Time: 9:00 am EST

Executive Summary

During the November 18, 2021 user fee negotiation meeting, FDA presented a response to Industry's proposal of October 20th. FDA's proposal addressed hiring accountability, performance accountability, shared outcome total time to decision goals, FDA review

performance goals, a new goal for additional information/deficiency letters, and the financial package to support MDUFA performance.

FDA's Presentation

Hiring Accountability: FDA incorporated the hiring accountability proposals that it had previously presented to Industry during the November 9th negotiation meeting.

Performance Accountability: FDA disagreed with the concept of establishing an Accountability Committee as initially proposed by Industry. As an alternative, FDA proposed to enhance the existing process for quarterly meetings with Industry to include not only a discussion of progress toward goals (i.e., the categories of information enumerated in the quarterly and annual reports section of the commitment letter), but other topics of interest including an annual discussion of use of funds available in the carryover balance and the status of the independent assessment(s).

Review Performance:

Pre-submissions: FDA noted the significant gap between Industry's projections for pre-submission volume (approximately 3,000 pre-submissions per year) and FDA's projections (an escalating volume of pre-submissions that would grow to approximately 5,500 per year). FDA explained that the Agency's estimates were based on increases in traditional pre-submission volume during MDUFA III and IV plus growth in the Breakthrough and Safer Technologies (STeP) programs, which programs generally involve a higher volume of pre-submissions per product.

FDA noted that, on September 22nd, the Agency had proposed a goal of providing written feedback within 70 days for 95% of pre-submissions beginning in FY 2023, and had estimated under Scenario 2 that the Agency would need to hire up to 190 new full time equivalents (FTE) during MDUFA V to meet that goal. FDA retained this estimate in the current proposal. However, in light of Industry's October 20th proposal and the divergence in workload projections between FDA and Industry, FDA said that it would be open to discussing an approach that would accommodate a lower projected volume (and a lower cost estimate) with certain risk mitigations: (1) that MDUFA V incorporated a lower performance goal than 95%—for instance, an escalating goal of providing written feedback within 70 days for 70% of pre-submissions in FY 2023, increasing to 90% of pre-submissions in FY 2027; (2) that FDA would generally not be able to accept pre-submissions beyond a maximum annual number, to ensure that FDA did not receive more work than the Agency was resourced to handle; (3) that Industry's idea for "add-on" payments be adapted and applied to pre-submissions such that, if the pre-submission performance goal were to be met in FY 2023 and/or FY 2024, then FDA would receive an add-on payment in FY 2025 and FY 2026-2027 with which the Agency would be able to hire additional staff and increase the maximum number of pre-submission that it generally would be able to accept and address within goal.

FDA and Industry debated the root causes of the increase in pre-submission requests and the Agency's projections for growth. Industry expressed the view that the Agency should handle a larger portion of inquiries through interactive review, including phone calls or email responses,

rather than as pre-submissions. In addition, Industry expressed concern with capping the number of pre-submissions that the Agency would handle in a year. FDA noted that it shared the concern that pre-submission receipts might exceed a cap, but that this concept was designed to lower the MDUFA V cost estimates while assuring that the pre-submission workload would not exceed the resourced amount, as had occurred during MDUFA IV. Also, if actual receipts were more in line with Industry's projections, the cap would not be reached. Finally, in response to Industry's clarifying questions, FDA explained that projected interactions for products in the TAP Pilot had been excluded from pre-submission projections so they would not be counted twice in the resource estimates. Finally, FDA noted it had presented the mitigations as a potential alternative to the current proposal; the Agency noted that it would develop cost estimates for the alternative, if that was of interest to Industry.

Back to Basics / Filling MDUFA Gaps: FDA's resource estimate to address "Back to Basics / Filling MDUFA Gaps" included FTE and operating expenses to address shared outcome total time to decision (TTD) and review performance goals.

Consistent with the Agency's November 9th presentation, FDA proposed a 510(k) TTD goal that would be scoped to the cohort of eSTAR submissions with an executive summary and reflect improvement over time to reach 108 days by the end of MDUFA V as follows: FY23: 140 days; FY 24: 135 days; FY 25: 124 days; FY26-27: 108 days.

For PMA TTD, FDA agreed with Industry's proposal to maintain the goal at 290 days throughout MDUFA V.

For the FDA review performance goal related to De Novo requests, FDA agreed with Industry's proposal to maintain the goal that FDA will reach a MDUFA decision within 150 FDA Days for 70% of such requests.

For other FDA review performance goals, FDA agreed with Industry's proposal to maintain the MDUFA IV goals throughout MDUFA V.

To meet these commitments, FDA estimated that the Agency would need to hire up to 129 FTE during the course of MDUFA V. FDA also estimated that funding would be needed each year to address what the Agency has referred to as "gaps" from MDUFA IV, largely associated with rising payroll expenses for existing and new staff, as well as use of Cures hiring and pay authority to attract and retain the necessary scientific and technical expertise, with the combined total of approximately $380 million in costs during MDUFA V.

Goal for Additional Information/Deficiency Letters: In response to Industry's proposal of October 20th, FDA signaled its agreement to including a percent-based performance goal related to providing a statement of the basis for a deficiency in AI and Deficiency Letters. FDA explained the challenges of administering the 99% goal that was proposed by Industry; as an alternative, FDA proposed a steadily improving goal that would begin at 75% and reach 90% by the end of MDUFA V. FDA noted that performance would be monitored by annual audits of AI and Deficiency Letters by CDRH's Quality Management and Organizational Excellence team. In addition, FDA proposed to update the 2017 guidance, "Suggested Format for Developing and

Responding to Deficiencies in Accordance with the Least Burdensome Principles of FDAMA," to clarify what constitutes an adequate statement of the basis of a deficiency. Finally, FDA proposed a commitment to retrain MDUFA program staff and managers on the updated guidance and take other steps, as appropriate, to improve the quality of deficiency letters consistent with that guidance. No separate resources were associated with this proposal.

TPLC Advisory Program (TAP) Pilot: Noting that, on September 22nd, FDA had proposed two scenarios for scaling TAP, FDA's current proposal incorporated only the Scenario 2 pilot concept. This scenario provided that up to 25% of new Breakthrough and STeP products in participating Offices of Health Technology (OHTs) would be eligible for entry into the pilot. Participating OHTs would ramp up to full OHT participation during MDUFA V with a soft-launch of up to 16 products in one OHT in FY 2023; two OHTs in FY 2024; four OHTs in FY 2025; and all OHTs in FY 2026-27. To handle this workload, FDA resource estimates reflected hiring up to 226 FTEs during MDUFA V and projected five-year total operating expenses of $113.6 million.

Patient Science and Engagement: FDA incorporated the revised patient science and engagement proposal that it had presented to Industry on October 7th. FDA resource estimates reflected hiring up to 13 FTE during MDUFA V and projected five-year total operating expenses of $17.5 million.

Standards: FDA incorporated the standards proposal that it had presented to Industry on October 7th. FDA resource estimates reflected hiring up to 6 FTE during MDUFA V and projected five-year total operating expenses of $2.5 million.

International Harmonization: FDA incorporated the international harmonization proposal that it had presented to Industry on November 9th. FDA resource estimates reflected hiring up to 5 FTE during MDUFA V.

One-time Costs: FDA's proposal also maintained the one-time costs that it had presented in the September 22nd cost estimates for real world evidence (continuing to resource these activities at the MDUFA IV level), third party review (exclusively using funds received during MDUFA IV), recruitment activities (to sustain contracts to provide supplemental recruitment and staff support), and two independent assessments, including a MDUFA Workforce Data Assessment.

Financial Framework:

Carryover Balance: FDA proposed to apply approximately $100M in carryover balance funds to conduct review team pre-hires in FY 2022, offset user fees in FY 2023, and maintain additional funds in the operating reserve. Specifically, FDA estimated that the cost of pre-hires in FY 2022 would be approximately $8.6 million; that an estimated fee offset in FY 2023 would be $65.7 million, and that the remainder would be retained in the carryover balance for the "rainy day" concept that Industry had proposed.

Application on the on-boarding assumption: FDA noted that, as an update from the September 22nd proposal, the FTE cost estimates now incorporated savings from the on-boarding assumption concept that FDA had presented during the November 9th meeting.

Postmarket device safety: FDA noted that the total cost of the package did not include FDA's proposal related to postmarket device safety. Resource estimates for that proposal reflected hiring up to 33 FTEs during MDUFA V and projected five-year total operating costs of $55 million. FDA maintained its view that postmarket device safety should be included as a component of MDUFA V, but recognized that Industry did not agree with the use of MDUFA user fees for postmarket activities, which is why the Agency had not included it in the financial total. Industry clarified that it supports the use of user fees for device safety assessments as part of premarket review, consistent with statutory authority.

Total cost estimate: The total five-year costs of the package was $2,213,484,000. FDA noted that the estimates were presented in FY 2021 dollars, and that the estimated cost per FTE was $291,509.

In addition, Industry inquired about FDA's response to its proposal to increase the statutory triggers. FDA said the Agency continued to evaluate that proposal and would respond at a future meeting.

Discussion

Following FDA's presentation, Industry stated that the parties were not close to an agreement. Industry said it would be helpful for FDA to prepare a new version that excludes postmarket device safety, excludes operating costs, makes initiating the TAP Pilot contingent on showing all MDUFA IV goals have been met, and includes more concrete accountability measures. FDA thanked Industry for the feedback and provided its perspective that it was imperative that the Agency have sufficient resources to meet the performance goals and ensure the stability of the program during MDUFA V. FDA recommended that Industry respond with a counter-proposal. The meeting adjourned.

Meeting End Time: 11:30 am EST