FDA – Industry MDUFA V Reauthorization Meeting
March 15, 2022, 2:00 pm – 3:05 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth*, OC OP*
- Sara Aguel*, CDRH*
- Kathryn Capanna*, CDRH*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone*, CDRH*
- Jonathan Sauer*, CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman*, CDRH*
- Cherie Ward-Peralta*, CBER*
- Angela Granum, *CBER*
- Claire Davies*, OCC*
- Louise Howe, *OCC*
- Malcolm Bertoni*, Consultant*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein*, AdvaMed*
- Nathan Brown*, Akin Gump*
- Nicole Taylor Smith*, Medtronic*

MITA Team

- Peter Weems, *MITA*
- Elisabeth George*, Philips*

MDMA Team

- Mark Leahey, *MDMA*
- Melanie Raska*, Boston Scientific*

ACLA Team

- Thomas Sparkman, *ACLA*
- Amy Leiser, *Covington & Burling*

Meeting Start Time: 2:00 pm EST

Executive Summary

During a series of working group meetings between March 8 and March 15, 2022, FDA and Industry discussed commitments that were documented in a draft Commitment Letter. After the discussion on March 15th, FDA, AdvaMed, MDMA, MITA, and ACLA agreed to the draft Commitment Letter.

The following provides a high-level summary of the agreed-upon commitments for the medical device user fee program for the five years beginning in fiscal year (FY) 2023:

Shared Outcome Goals and Review Performance Goals

- Improvements to MDUFA IV Goals: The charts at the end of these minutes summarize the details of the shared outcome goals and review performance goals that will be strengthened during MDUFA V.

- Other review performance goals will be maintained from MDUFA IV.

Opportunity for Performance Improvements

- MDUFA V will provide for increases in fee revenue above the annual total revenue amount to support performance improvements in FY2025-2027 ("add-on" payments) if specified goals are met in FY2023-2025. The add-on concept will apply to specified 510(k) goals, PMA goals, the De Novo decision goal, and the Pre-submission written feedback goal.

Infrastructure

- FDA will continue to use user fee resources to support the CDRH Quality Management and Organization Excellence (QMOE) Program. At least once per year, FDA will discuss with Industry the specific areas it intends to incorporate in its ongoing QMOE audit plan. At a minimum, FDA audits in the following areas will be completed: Pre-submissions and the Third Party Review Program.

Financial Transparency and Hiring

- FDA will publish a MDUFA 5-year financial plan no later than the 2nd quarter of FY 2023, and it will update the plan annually. The financial plan and updates will include information specified in the commitment letter, including information related to increases in personnel compensation and benefits costs.

- MDUFA V will include commitments regarding funds in the carryover balance that are available for use. Specifically, the agreement provides for a 13-week ceiling on the carryover balance funds and, if funds exceed that amount, a registration fee offset in the following fiscal year. In addition, during MDUFA V, FDA will use funds in the carryover balance to support the Total Product Lifecycle Advisory Program Pilot (TAP) Pilot and the Third Party Review Program. No less than annually, FDA and Industry will work together to seek alignment on how best to utilize funds in the carryover balance to improve the process for the review of device applications.

- FDA will establish annual hiring goals for each year of MDUFA V, as specified in the Commitment Letter. If the annual hiring target is missed by more than 15% in FY 2023, FDA will apply a registration fee offset for FY 2025. If the annual hiring target is missed by more than 10% in FY 2024 or FY 2025, FDA will apply a registration fee offset for FY 2026 or FY 2027, respectively.

IT Infrastructure for Submission Management

- FDA will continue to enhance IT infrastructure to support the process for the review of device applications, including maintaining and improving the Customer Collaboration Portal and developing electronic submission templates for Original PMA and Panel-Track Supplements, De Novo requests, Pre-submissions, and IDEs.

Training

- FDA will continue to evaluate and improve training for new and existing reviewers, and training efforts will be closely coordinated with the QMOE Program to provide more targeted and personalized training to staff.

Time Reporting

- FDA will continue to perform complete time reporting such that data from time reporting can be used to conduct workload analysis and capacity planning.

Process Improvements

- Interactive Review: FDA will continue to incorporate an interactive review process.

- Deficiency Letters: FDA will update the 2017 guidance, "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions; Guidance for Industry and FDA Staff" to clarify what constitutes a statement of the basis for the deficiency. FDA will provide a statement for the basis of a deficiency 75/80/85/90/95% of the time for FY23/24/25/26/27 respectively. Performance will be determined through annual audits conducted by the QMOE Program.

- Enhanced Use of Consensus Standards: FDA will use lessons learned from the implementation of the Accreditation Scheme for Conformity Assessment (ASCA) Pilot during MDUFA IV to transition from a pilot to a sustainable and expanded program.

- Third Party Review: FDA will continue to support the Third Party Review program, with the objective of eliminating routine re-review by FDA of Third Party reviews.

- Patient Science and Engagement: FDA will continue to engage patients and incorporate their perspectives into the regulatory process, and, where appropriate, it will leverage collaborations and partnerships with patients, healthcare providers, industry, and others to advance these actions.

- Real World Evidence: FDA will continue development of real world data (RWD) and real world evidence (RWE) methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and clearance/approval of new devices.

- Digital Health: FDA will continue to build its digital health expertise and continue working to streamline and align FDA review processes with software lifecycles for digital health products.

- Guidance Document Development: FDA will continue MDUFA IV commitments related to timely completion of draft guidance documents.

- International Harmonization: FDA will take action to advance international harmonization and convergence of regulatory requirements.

- Total Product Lifecycle (TPLC) Advisory Program Pilot (TAP Pilot): FDA will launch a voluntary pilot program to help spur more rapid development as well as more rapid and widespread patient access to safe, effective, and high-quality medical devices of public health importance. The pilot will begin with a "soft launch" of up to 15 products in one CDRH Office of Health Technology (OHT) in FY23, and it will expand to enroll up to 325 products across multiple OHTs by the end of MDUFA V. FDA will assess, using an independent third party (or parties) and provide a public report on the progress of the pilot during MDUFA V, including assessing the following quantitative and qualitative metrics:
    - The extent to which FDA is successful at engaging in a teleconference with the participant on requested topic(s) pertaining to the TAP device within 14 days of the request for 90% of requests for interaction.
    - The extent to which FDA is successful at providing written feedback on requested topic(s) pertaining to the TAP device within 40 days of the request for 90% of requests for written feedback.
    - Participant satisfaction with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA.
    - Participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized).
    - An overall assessment of the outcomes of the Pilot and opportunities for improvement.

  In addition, FDA will begin to track other measures of program success, including:
    - Time from granting of Breakthrough designation or request for inclusion in the Safer Technologies Program (STeP) to receipt of marketing submission;
    - Time from receipt of marketing submission to marketing authorization; and
    - Requests for additional information during submission review.

  FDA and Industry agreed to details regarding the scope of products eligible for enrollment in the pilot, including that it will only apply to products granted a Breakthrough Product designation (in FY 2023-2027) or request for inclusion in the Safer Technologies Program (STeP) (in FY 2026-2027). During discussion, FDA and Industry debated how to expand the potential scope of pilot participants if resources permitted. FDA proposed to maintain the pilot within designated OHTs, but expand the scope to other devices of public health importance. Industry's proposal, which the parties adopted, states that FDA may consider enrolling other Breakthrough and STePdevices from additional OHTs as resources permit.

Independent Assessments

- MDUFA Workforce Data Assessment: FDA will retain an independent contractor to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. This will include assessment of positions (filled/vacant) and MDUFA process full time equivalents (FTEs), including the subset funded by user fees.

- Independent Assessment of Review Process Management: FDA and Industry will participate in a targeted assessment of the MDUFA process. The assessment will include consultation with both FDA and Industry at the start of the assessment and prior to issuance of the final report. The assessment will cover topics specified in the Commitment Letter. During discussion, FDA and Industry debated whether to include proposed language from Industry that woud specify no independent assessor from the previous two MDUFA Independent Assessments could be used to conduct the MDUFA V assessment. Industry expressed the opinion that this would bring a fresh perspective to the assessment. FDA expressed concern that it was unclear whether this condition could be appropriately imposed as part of the contracting process and could ultimately delay implementation of the commitment. The parties agreed not to include the additional language.

Performance Reports

- FDA will report its progress toward meeting the Commitment Letter goals on a quarterly and annual basis. During discussion, FDA inquired about Industry's goals for the commitment to report annually on "[t]he return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA V." Industry provided its perspective that this would be a qualitative report in which FDA would provide its perspective on actions taken to drive enhanced program efficiency—for instance, digital transformation, eSTAR, etc. Industry noted that they were not looking to overload FDA with this requirement, but that having this type of information to share annually with their members would be beneficial.

Laboratory Developed Tests

- In email exchanges prior to the meeting, FDA and ACLA discussed the inclusion of language related to laboratory developed tests (LDTs). This was in follow-up to discussion of LDTs during the February 22 and February 24 meetings, and ACLA's proposal on March 1 to include the following language in the MDUFA V Commitment Letter: "The assumptions underlying the MDUFA V framework and associated performance goals in this Commitment Letter include that FDA does not intend to seek to regulate LDTs as medical devices more broadly than currently during the MDUFA V period. ACLA's position is that LDTs are not medical devices subject to FDA's jurisdiction. In the event that FDA attempts to more broadly regulate LDTs as medical devices, a new framework with relevant performance goals and fee structure must be established with the input and agreement of relevant Industry representatives prior to implementation of any new regulation of LDTs. To the extent that laboratories choose to compy with device regulations in advance of that framework being established, FDA will treat LDTs no less favorably than the devices to which MDUFA V

performance goals apply."

- FDA stated, in explaining its counterproposal, that it did not support including most of the statement in the commitment letter because it is not a commitment and not the factual basis for a commitment. Also, the Agency would not want the statement to be misunderstood to be a commitment about future actions the Secretary will or will not take. In addition, FDA explained that to model projections during MDUFA negotiations, the Agency makes certain assumptions about the types and volume of device submissions will be received. Since there were LDT-related submissions during MDUFA IV (the baseline period), the projections for MDUFA V presume receipt of LDT submissions over the next five years. Although FDA's projections do not presume a disproportionate increase in such submissions due to the Agency's practice of generally defaulting to the status quo in modeling projections, that is not relevant to the future plans of the Agency.

- FDA provided a counterproposal to add a revised version of language that was included in the MDUFA IV Commitment Letter regarding LDTs, and that it would reflect discussion of LDTs in meeting minutes.

- The parties ultimately agreed that the Commitment Letter will include the following language from FDA's counterproposal with respect to LDTs: "To the extent that laboratories make submissions regarding LDTs that are covered by the MDUFA V agreement, FDA will treat such LDT submissions no less favorably than other submissions to which MDUFA V performance goals apply."

Proposed Statutory Changes

- Total Revenue Amount and New Adjustments: To implement the proposed enhancements and goals for MDUFA V, new funding is proposed to be phased in over the course of MDUFA V. Most of the new funding is specified in the following total revenue amounts, which will be adjusted for inflation:
    - $312,606,000 for fiscal year (FY) 2023
    - $335,750,000 for FY 2024
    - $350,746,400 for FY 2025
    - $366,486,300 for FY 2026
    - $418,343,000 for FY 2027

  In addition, MDUFA V will provide for a performance improvement adjustment that, if applicable, will increase total fee collections. It is only potentially applicable in fiscal years 2025 through 2027.

- Base Fees For Premarket Applications/Submissions: To implement the proposed MDUFA V enhancements and goals, the draft recommendations will include the following proposed changes to the base fees for premarket applications:
    - $425,000 in FY 2023
    - $435,000 in FY 2024
    - $445,000 in FY 2025
    - $455,000 in FY 2026

- $470,000 in FY 2027

The base fees for various submission types are determined as a percentage of the fee for a premarket application. In MDUFA V, two changes to these percentages are proposed: the fee for a panel-track supplement would increase from 75% to 80% of the premarket application fee; and the fee for a premarket notification (510(k)) submission would increase from 3.4% to 4.5%.

- Base Fees For Establishment Registration:
  - $6,250 in FY 2023
  - $6,875 in FY 2024
  - $7,100 in FY 2025
  - $7,575 in FY 2026
  - $8,465 in FY 2027

- Inflation Adjustment: The inflation adjustment is proposed to be retained without modification, except for one technical change to the Consumer Price Index (CPI) to use the CPI for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index).

- Performance Improvement Adjustment: This proposed adjustment would allow FDA to collect fees in addition to the total revenue amount in fiscal years 2025, 2026 and 2027, if the Agency meets certain performance goals in fiscal years 2023, 2024, and 2025, and the performance goals are accordingly improved (from what they would otherwise be) for fiscal years 2025, 2026, and 2027. This adjustment would apply to registration fees. Base registration fees would be increased by different adjustment amounts, depending upon which performance goals are met, and in which year. There are adjustments for meeting (1) the Pre-submission written feedback goal, (2) the De Novo decision goal, and (3) the 510(k) and PMA decision goals, and the 510(k) and PMA shared outcome total time to decision goals. Dollar amounts for each adjustment are set forth in the statute. The sum of the applicable amounts for a fiscal year would be adjusted for inflation to calculate the total amount of the increase to base registration fees for a fiscal year. Under this provision, FDA may receive additional funding up to the following maximum amounts:
  - $15,396,600 for FY 2025
  - $44,135,700 for FY 2026
  - $56,244,000 for FY 2027

- Hiring Adjustment: This proposed new fee adjustment would provide for the reduction of registration fees in fiscal years 2025, 2026 and 2027 if specified hiring goals for fiscal years 2023, 2024 and 2025 are not met by a certain threshold. The amount of the hiring adjustment fee decrease would be the product of the number of hires by which the hiring goal was missed and one-quarter of the inflation-adjusted cost per full time equivalent (FTE). This adjustment would apply only to registration fees.

- Operating Reserve Adjustment: A new operating reserve adjustment is proposed that would provide for registration fees to be decreased if the amount of operating reserves of carryover user fees exceeds the "designated amount." The designated amount for a fiscal year is equal

to 13 weeks of operating reserves plus the one month of operating reserves required under current section 738(c)(5)(A). User fee funds in the carryover balance that are considered unappropriated or unearned are not included in the operating reserves.

In addition, during MDUFA V, FDA and Industry agreed that $118,000,000 of funds in the MDUFA IV carryover balance would be used to support the Third Party Review program and the Total Product Life Cycle Advisory Program Pilot. FDA and Industry agreed that this amount would be excluded when calculating the amount of operating reserves to determine if registration fees will be decreased. This exclusion would end after fiscal year 2026 so that any remaining portion of this $118,000,000 would be counted when determining whether the operating reserves exceed the designated amount for fiscal year 2027 and, if so, serve to reduce registration fees.

- Proposed Appropriations Trigger: The proposal is to update the appropriations trigger to $398,566,000 (which is 95 percent of the FY 2022 enacted level of budget authority appropriations for the Devices and Radiological Health program, rounded to the nearest thousand dollars) to provide assurance that device user fees will be additive to non-user fee appropriations.

[See next page regarding performance goals]

Meeting End Time: 3:05 pm EST

Performance Goals

Pre-submissions	FY23	FY24	FY25	FY26	FY27
High volume	75% of 4,300+	85% of 4,300+	90% of 4,300+	90% of 4,300+	90% of 4,300+
Low volume	90% if < 3,585	90% if < 4,060			
Performance with Add-on			90% of 4,700+	90% of 4,800+	90%

+ During the years in which add-on payments are not applied, the Pre-submission goal will be capped at 4,300 submissions, except for Pre-submissions associated with Breakthrough or STeP-designated products. If add-on payments are applied in FY25-26, the Pre-submission goal will be capped at 4,700 or 4,800 submissions respectively, except for Pre-submissions associated with Breakthrough or STeP-designated products. Any other Pre-submissions above the cap will receive feedback as resources permit. In all years, for any Pre-submissions under the cap for which FDA does not meet the 70 day goal, FDA commits to communicating with the sponsor about a timeline for providing written feedback.

510(k) TTD*	FY23	FY24	FY25	FY26	FY27
Base	128	124	112	112	112
Performance with Add-on	--	--	--	108	108

PMA TTD*	FY23	FY24	FY25	FY26	FY27
Base	290	290	285	285	285
Performance with Add-on	--	--	--	275	270

* If the FDA Decision Day goals and the FDA-Industry Total Time to Decision goals for 510(k) and PMA are met for submissions in FY23, then FDA would apply add-on payments in FY26. Likewise, if goals are met for submissions in FY24, then FDA would apply add-on payments in FY27. The FDA Decision Day Goal for 510(k) means that FDA will issue a MDUFA decision within 90 FDA Days for 95% of 510(k) submissions. The FDA Decision Day Goal for PMA means that FDA will issue a MDUFA decision within 180 FDA Days for 90% of Original PMAs, Product Development Protocols, Panel-Track Supplements, and Premarket Report Applications.

De Novo^	FY23	FY24	FY25	FY26	FY27
Base	70%	70%	70%	70%	70%
Performance with Add-on	--	--	--	80%	90%

^ The FDA Decision Day Goal for De Novo means that FDA will issue a MDUFA decision within 150 FDA Days for the specified percentage of De Novo Requests.