

# MDUFA PERFORMANCE GOALS AND PROCEDURES, FISCAL YEARS 2023 THROUGH 2027

<b>General</b> .....	1
<b>I. Shared Outcome Goals</b> .....	1
<b>A. PMA</b> .....	1
<b>B. 510(k)</b> .....	2
<b>II. Review Performance Goals - Fiscal Years 2023 Through 2027 As Applied to MDUFA Cohorts</b> .....	2
<b>A. Pre-Submissions</b> .....	2
<b>B. Original PMAs, Product Development Protocols, Panel-Track Supplements, and Premarket Reports</b> .....	5
<b>C. 180-Day PMA Supplements</b> .....	7
<b>D. Real-Time PMA Supplements</b> .....	7
<b>E. De Novo Requests</b> .....	7
<b>F. 510(k) Submissions</b> .....	8
<b>G. CLIA Waiver by Application</b> .....	9
<b>H. Original Biologics Licensing Applications (BLAs)</b> .....	10
<b>I. BLA Efficacy Supplements</b> .....	10
<b>J. Original BLA and BLA Efficacy Supplement Resubmissions</b> .....	10
<b>K. BLA Manufacturing Supplements Requiring Prior Approval</b> .....	10
<b>III. Opportunity for Performance Improvements</b> .....	11
<b>A. PMA and 510(k): Decision Goals and Shared Outcome Total Time to Decision Goals</b> .....	11
<b>B. De Novo Requests</b> .....	11
<b>C. Pre-Submissions</b> .....	12
<b>IV. Infrastructure</b> .....	12
<b>A. Quality Management</b> .....	12
<b>B. Financial Transparency and Hiring</b> .....	13
<b>1. Financial Transparency</b> .....	13
<b>2. Carryover Balance</b> .....	13
<b>3. Hiring Goals</b> .....	14
<b>4. Fee Adjustment Related to Hiring</b> .....	15
<b>C. IT Infrastructure for Submission Management</b> .....	15
<b>D. Training</b> .....	16
<b>E. Time Reporting</b> .....	16
<b>V. Process Improvements</b> .....	16
<b>A. Interactive Review</b> .....	16
<b>B. Deficiency Letters</b> .....	16
<b>C. Enhanced Use of Consensus Standards</b> .....	17
<b>D. Third Party Review</b> .....	18
<b>E. Patient Science and Engagement</b> .....	19
<b>F. Real World Evidence (RWE)</b> .....	20

G.	Digital Health.....	22
H.	Guidance Document Development .....	22
I.	International Harmonization.....	23
J.	Total Product Life Cycle (TPLC) Advisory Program .....	23
VI.	Independent Assessments .....	27
A.	Independent Assessment of MDUFA Workforce Metrics .....	27
B.	Independent Assessment of Review Process Management .....	27
VII.	Performance Reports.....	28
VIII.	Definitions and Explanations of Terms .....	31
A.	Applicant .....	31
B.	eSTAR (electronic Submission Template And Resource) .....	32
C.	FDA Days.....	32
D.	MDUFA Decisions .....	32
E.	Pre-Submission .....	33
F.	Substantive Interaction.....	34
G.	Total Time to Decision.....	34
H.	Application Types.....	35
I.	BLA-related Definitions .....	36

DRAFT

# **MDUFA PERFORMANCE GOALS AND PROCEDURES, FISCAL YEARS 2023 THROUGH 2027**

## **General**

The performance goals and procedures agreed to by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (“FDA” or “the Agency”) for the medical device user fee program in the Medical Device User Fee Amendments of 2022, are summarized below.

FDA and the industry are committed to protecting and promoting public health by providing timely access to safe and effective medical devices. Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices. Both FDA and the industry are committed to the spirit and intent of the goals described in this letter.

### **I. Shared Outcome Goals**

The program and initiatives outlined in this document are predicated on significant interaction between the Agency and applicants. FDA and representatives of the industry agree that the process improvements outlined in this letter, when implemented by all parties as intended, should reduce the average Total Time to Decision for premarket approval applications (PMAs) and premarket notification (510(k)) submissions, provided that the total funding of the device review program adheres to the assumptions underlying this agreement. FDA and applicants share the responsibility for achieving this objective of reducing the average Total Time to Decision, while maintaining standards for safety and effectiveness. Success of this program will require the cooperation and dedicated efforts of FDA and applicants to reduce their respective portions of the Total Time to Decision.

FDA will be reporting Total Time to Decision performance as described in Section VII. FDA and industry will participate in the independent assessment of progress toward this outcome, as described in Section VI below. As appropriate, key findings and recommendations from this assessment will be implemented by FDA.

#### **A. PMA**

**PMA Shared Outcome Total Time to Decision goal:** FDA will report on an annual basis the average Total Time to Decision as defined in Section VIII.G for the three most recent closed receipt cohorts. The following PMA Shared Outcome Total Time to Decision goals are subject to adjustment per Section III below:

For Original PMA and Panel Track Supplement submissions received in Fiscal Years (FY) 2023 through 2024, the average shared outcome Total Time to Decision goal for FDA and industry is 290 calendar days.

For Original PMA and Panel Track Supplement submissions received in FYs 2025 through 2027, the average shared outcome Total Time to Decision goal for FDA and industry is 285 calendar days.

**B. 510(k)**

**510(k) Shared Outcome Total Time to Decision goal:** FDA will report on an annual basis the average Total Time to Decision as defined in Section VIII.G for the most recent closed receipt cohort. The following 510(k) Shared Outcome Total Time to Decision goals are subject to adjustment per Section III below:

For 510(k) submissions received in FY 2023, the average Total Time to Decision goal for FDA and industry is 128 calendar days.

For 510(k) submissions received in FY 2024, the average Total Time to Decision goal for FDA and industry is 124 calendar days.

For 510(k) submissions received in FY 2025, the average Total Time to Decision goal for FDA and industry is 112 calendar days.

For 510(k) submissions received in FY 2026, the average Total Time to Decision goal for FDA and industry is 112 calendar days.

For 510(k) submissions received in FY 2027, the average Total Time to Decision goal for FDA and industry is 112 calendar days.

**II. Review Performance Goals - Fiscal Years 2023 Through 2027 As Applied to MDUFA Cohorts**

The overall objective of the review performance goals stated herein is to assure more timely access to safe and effective medical devices.

**A. Pre-Submissions**

FDA will continue the Pre-Submission program as described in the guidance on “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” with process improvements and performance goals as noted in this section.

For all Pre-Submissions in which the applicant requests a meeting or teleconference, the applicant will provide a minimum of three proposed meeting dates in the initial submission.

Within 15 calendar days of receipt of a Pre-Submission, FDA will communicate with the applicant regarding whether the application has been accepted and, if applicable, regarding scheduling of the meeting or teleconference. Acceptance will be determined based on the definition of Pre-Submission in Section VIII.E below and an acceptance checklist in published guidance. This communication consists of a written communication that a) identifies the reviewer assigned to the submission, b) acknowledges acceptance/rejection of the submission, and c) if the submission included a request for a meeting or teleconference and is accepted, either confirms one of the applicant's requested meeting dates or provides two alternative dates prior to day 75 from receipt of accepted submission. A determination that the request does not qualify as a Pre-Submission will require the concurrence of the appropriate management or designee and the reason for this determination will be provided to the applicant in the above written communication. FDA intends to reach agreement with the applicant regarding a meeting date within 30 days from receipt of accepted submission. For all requests for meetings or teleconferences that do not have such a meeting or teleconference scheduled by 30 days from receipt of an accepted submission, a FDA manager will contact the applicant to resolve scheduling issues by the 40<sup>th</sup> day.

**Pre-Submission Written Feedback goal:** FDA will provide written feedback that addresses the issues raised in the Pre-Submission request within 70 calendar days of receipt date or five calendar days prior to a scheduled meeting, whichever comes sooner, for:

In FY 2023, 90% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is 3585 or more, up to 4300 submissions.

In FY 2024, 90% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Submissions in the MDUFA Cohort if the MDUFA Cohort is 4060 or more, up to 4300 submissions.

In FY 2025-2027, 90% of Pre-Submissions in the MDUFA Cohort up to 4300 submissions.

These Pre-Submission Written Feedback goals are subject to adjustment per Section III below.

The MDUFA Cohort will only include Pre-Submissions (as defined in Section VIII.E below) for devices that are accepted for review up to a maximum number of accepted submissions subject to the goal. Pre-Submissions will be accepted in accordance with the Pre-Submission acceptance checklist described in FDA's guidance "Requests for

Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.”. In addition, the following types of requests for feedback available to Breakthrough-designated products and/or products included in the Safer Technologies Program (STeP) are considered accepted for review upon receipt:

- Sprint discussions;
- Requests for review of a data development plan; and
- Requests for review of a clinical protocol agreement.

The MDUFA Cohort will not include Pre-Submissions that are withdrawn at request of applicant or closed due to lack of applicant response.

For any Pre-Submissions in the MDUFA Cohort for which FDA does not meet the Pre-Submission Written Feedback goal, FDA will communicate with the applicant in a timely manner regarding a timeline for providing written feedback.

After the Pre-Submission MDUFA Cohort reaches the maximum number of submissions subject to the goal in a fiscal year, FDA still intends to provide timely feedback for Pre-Submissions for Breakthrough-designated products and products included in the Safer Technologies Program (STeP). After the Pre-Submission MDUFA Cohort reaches the maximum number of submissions subject to the goal, FDA intends to provide feedback for other Pre-Submissions as resources permit, but not to the detriment of meeting quantitative review timelines and statutory obligations.

Written feedback provided to the applicant will include: written responses to the applicant’s questions; FDA’s suggestions for additional topics for the meeting or teleconference, if applicable; or, a combination of both. If all of the applicant’s questions are addressed through written responses to the applicant’s satisfaction, FDA and the applicant can agree that a meeting or teleconference is no longer necessary, and the written responses will be considered the final written feedback to the Pre-Submission.

Applicants will be responsible for developing draft minutes for a Pre-Submission meeting or teleconference, and providing the draft minutes to FDA within 15 calendar days of the meeting. At the beginning and end of each meeting, the applicant will affirmatively state that they will draft minutes and provide them to FDA within 15 calendar days. The minutes will summarize the meeting discussions and include agreements and any action items. FDA will provide any edits to the draft minutes to the applicant via email within a timely manner. These minutes will become final 15 calendar days after the applicant receives FDA’s edits, unless the applicant indicates that there is a disagreement with how a significant issue or action item has been documented. In this case, within a timely manner, the applicant and FDA will conduct a teleconference to discuss that issue with FDA. At the conclusion of that teleconference, within 15 days FDA will finalize the minutes either to reflect the resolution of the issue or note that this issue remains a point of disagreement.

FDA intends that feedback the Agency provides in a Pre-Submission will not change, provided the information submitted in a future IDE or marketing application is consistent with that provided in the Pre-Submission and documented in the Pre-Submission, and that the data in the future submission, changes in the science, or changes in the standards of care do not raise any important new issues materially affecting safety or effectiveness. The minutes described above will serve as the record of the Agency's Pre-Submission feedback. Modifications to FDA's feedback will be limited to situations in which FDA concludes that the feedback does not adequately address important new issues materially relevant to a determination of safety and/or effectiveness or substantial equivalence. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

By March 31, 2024, the Agency will issue draft guidance to update the guidance on "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. FDA will provide an opportunity for the public to comment on the updated guidance. No later than 18 months after the close of the public comment period, the Agency will issue a final guidance. FDA will implement this guidance once final.

**B. Original PMAs, Product Development Protocols, Panel-Track Supplements, and Premarket Reports**

The performance goals in this section apply to all Original PMAs, Product Development Protocols (PDPs), Panel-Track Supplements, and Premarket Reports.

FDA will communicate with the applicant regarding whether the application has been accepted for filing review within 15 calendar days of receipt of the application. This communication consists of a written communication that a) identifies the reviewer assigned to the submission, and b) acknowledges acceptance/rejection of the submission based upon the review of the submission against objective acceptance criteria outlined in a published guidance document and consistent with the statute and its implementing regulations.

If the application is not accepted for filing review, FDA will notify the applicant of those items necessary for the application to be considered accepted for filing review.

For those applications that are accepted for filing review, FDA will communicate the filing status within 45 calendar days of receipt of the application.

For those applications that are not filed, FDA will communicate to the applicant the specific reasons for rejection and the information necessary for filing.

If the application is filed, FDA will communicate with the applicant through a Substantive Interaction within 90 calendar days of the filing date of the application for 95% of submissions.

When FDA issues a major deficiency letter, that letter will be based upon a complete review of the application and will include all deficiencies. Deficiency letters will include a statement of the basis for the deficiencies, as provided in Section V.B below.

Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a determination of safety and effectiveness. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues materially relevant to a determination of safety or effectiveness. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs. Issues related to post-approval studies, if applicable, and revisions to draft labeling will typically be addressed through interactive review once major deficiencies have been adequately addressed.

**PMA decision goal:** For Original PMAs, PDPs, Panel-Track Supplements, and Premarket Reports that do not require Advisory Committee input, FDA will issue a MDUFA decision within 180 FDA Days for 90% of submissions. This PMA decision goal is relevant for purposes of Section III below.

For submissions that require Advisory Committee input, FDA will issue a MDUFA decision within 320 FDA Days for 90% of submissions. FDA will issue a MDUFA decision within 60 days of the Advisory Committee recommendation, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. The Office Director shall review each request for Advisory Committee input for appropriateness and need for this input.

If in any one fiscal year, the number of submissions that require Advisory Committee input is less than 10, then it is acceptable to combine such submissions with the submissions for the following year(s) in order to form a cohort of 10 or more submissions, upon which the combined years' submissions will be subject to the performance goal. If the number of submissions that require Advisory Committee input is less than 10 for FY 2027, it is acceptable to combine such submissions in the prior year(s) to form a cohort of 10 or more submissions: in such cases, FDA will be held to the FY 2027 performance goal for the combined years' submissions.

To facilitate an efficient review prior to the Substantive Interaction, and to incentivize submission of a complete application, submission of an unsolicited major amendment prior to the Substantive Interaction extends the FDA Day review clock by the number of FDA Days that have elapsed. Submission of an unsolicited major amendment after the Substantive Interaction extends the FDA Day goal by the number of FDA Days equal to

75% of the difference between the filing date and the date of receipt of the amendment. Requests from FDA that a submission be made will not be considered unsolicited.

For all PMA submissions that do not reach a MDUFA decision by 20 days after the applicable FDA Day goal, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application preventing FDA from reaching a decision. The information provided will reflect appropriate management input and approval and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks. Issues should be resolved through interactive review. If all of the outstanding issues are adequately presented through written correspondence, FDA and the applicant can agree that a meeting or teleconference is not necessary.

For PMA submissions that receive a MDUFA decision of Approvable, FDA will issue a decision within 60 days of the sponsor's response to the Approvable letter, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.

In addition, information about submissions that miss the FDA Day goal will be provided as part of FDA's Performance Reports, as described in Section VII.

### **C. 180-Day PMA Supplements**

FDA will communicate with the applicant through a Substantive Interaction within 90 calendar days of receipt of 95% of submissions.

FDA will issue a MDUFA decision within 180 FDA Days for 95% of submissions.

### **D. Real-Time PMA Supplements**

FDA will issue a MDUFA decision within 90 FDA Days for 95% of submissions.

### **E. De Novo Requests**

**De Novo decision goal:** FDA will issue a MDUFA decision within 150 FDA Days for 70% of De Novo requests. This De Novo decision goal is subject to adjustment per Section III below.

Deficiencies identified will be based upon a complete review of the submission and will include all deficiencies. Deficiency letters will include a statement of the basis for the deficiencies, as provided in Section V.B below. Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a classification determination. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues

materially relevant to a classification determination. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs. Issues related to revisions to draft labeling will typically be addressed through interactive review once major deficiencies have been adequately addressed.

At the applicant's request and as resources permit, but not to the detriment of meeting the quantitative review timelines, if a final decision has not been rendered within 180 FDA days, FDA will discuss with the applicant all outstanding issues with the submission preventing FDA from reaching a decision. This discussion will reflect appropriate management input and approval and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.

#### **F. 510(k) Submissions**

FDA will communicate with the applicant regarding whether the submission has been accepted for review within 15 calendar days of receipt of the submission. For those submissions that are not accepted for review, FDA will notify the applicant of those items necessary for the submission to be considered accepted.

FDA will provide written communication that a) identifies the reviewer assigned to the submission, and b) acknowledges acceptance/rejection of the submission based upon the review of the submission against objective acceptance criteria outlined in a published guidance document. This communication represents a preliminary review of the submission and is not indicative of deficiencies that may be identified later in the review cycle.

For 510(k) submissions received under the eSTAR program, a submission that passes the initial technical screening will be considered accepted for review as of the date the submission was received.

FDA will communicate with the applicant through a Substantive Interaction within 60 calendar days of receipt of the submission for 95% of submissions.

Deficiencies identified in a Substantive Interaction, such as a telephone/email hold or Additional Information Letter, will be based upon a complete review of the submission and will include all deficiencies. Deficiency letters will include a statement of the basis for the deficiencies, as provided in section V.B below. Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a determination of substantial equivalence. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues materially relevant to a determination of substantial equivalence. Such a

determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

**510(k) decision goal:** FDA will issue a MDUFA decision for 95% of 510(k) submissions within 90 FDA Days. This 510(k) decision goal is relevant for purposes of Section III below.

For all 510(k) submissions that do not reach a MDUFA decision within 100 FDA Days, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application preventing FDA from reaching a decision. The information provided will reflect appropriate management input and approval and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks. Issues should be resolved through interactive review. If all of the outstanding issues are adequately presented through written correspondence, FDA and the applicant can agree that a meeting or teleconference is not necessary.

In addition, information about submissions that miss the 510(k) decision goal will be provided as part of FDA's Performance Reports, as described in Section VII.

#### **G. CLIA Waiver by Application**

FDA will engage in a Substantive Interaction with the applicant within 90 days for 90% of the applications.

Pre-Submission review timeframes in Section II.A apply to Pre-Submissions for CLIA Waiver by Application and Dual submission 510(k)/CLIA Waiver applications.

Industry will inform FDA that it plans to submit a dual submission (510(k) and CLIA Waiver application) during the Pre-Submission process. FDA will issue a decision for 90% of dual submission applications within 180 FDA days.

For "CLIA Waiver by application" submissions FDA will issue a MDUFA decision for 90% of the applications that do not require Advisory Committee input within 150 FDA days.

For "CLIA Waiver by application" submissions FDA will issue a MDUFA decision for 90% of the applications that require Advisory Committee input within 320 FDA days.

If in any one fiscal year, the number of submissions in any CLIA Waiver by Application category is less than 10, then it is acceptable to combine such submissions with the submissions for the following year(s) in order to form a cohort of 10 or more submissions, upon which the combined years' submissions will be subject to the performance goal.

For all CLIA waiver by application submissions and dual submissions that do not reach a decision by 20 days after the applicable FDA Day goal, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application preventing FDA from reaching a decision. The information provided will reflect appropriate management input and approval, and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks. Issues should be resolved through interactive review. If all of the outstanding issues are adequately presented through written correspondence, FDA and the applicant can agree that a meeting or teleconference is not necessary.

In addition, information about submissions that miss the FDA Day goal will be provided as part of FDA's Performance Reports, as described in Section VII.

#### **H. Original Biologics Licensing Applications (BLAs)**

FDA will review and act on standard original BLA submissions within 10 months of receipt for 90% of submissions.

FDA will review and act on priority original BLA submissions within 6 months of receipt for 90% of submissions.

#### **I. BLA Efficacy Supplements**

FDA will review and act on standard BLA efficacy supplement submissions within 10 months of receipt for 90% of submissions.

FDA will review and act on priority BLA efficacy supplement submissions within 6 months of receipt for 90% of submissions.

#### **J. Original BLA and BLA Efficacy Supplement Resubmissions**

FDA will review and act on Class 1 original BLA and BLA efficacy supplement resubmissions within 2 months of receipt for 90% of submissions.

FDA will review and act on Class 2 original BLA and BLA efficacy supplement resubmissions within 6 months of receipt for 90% of submissions.

#### **K. BLA Manufacturing Supplements Requiring Prior Approval**

FDA will review and act on BLA manufacturing supplements requiring prior approval within 4 months of receipt for 90% of submissions.

### **III. Opportunity for Performance Improvements**

MDUFA V will provide for increases in fee revenue above the annual total revenue amount to support performance improvements in FY 2025, FY 2026, and/or FY 2027, as detailed below. If such fee revenue adjustments are not made, the performance goals in Section II apply.

For the purpose of fee revenue adjustments, performance of all goals in this section, except for the Pre-Submission Written Feedback goal, will be determined based on data available as of 18 months following the close of the fiscal year at issue. Thus, for a FY 2023 goal, the performance will be determined based on data available as of March 31, 2025. For a FY 2024 goal, the performance will be determined based on data available as of March 31, 2026. For the Pre-Submission Written Feedback goal, performance will be determined based on data available as of 6 months following the close of the fiscal year at issue. Thus, for example, for the Pre-Submission Written Feedback goal for FY 2023, performance will be determined based on data available as of March 31, 2024.

#### **A. PMA and 510(k): Decision Goals and Shared Outcome Total Time to Decision Goals**

If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met for FY 2023, and fee revenue above the annual total revenue amount is provided in FY 2026 and FY 2027 to support performance improvements, the 510(k) Shared Outcome Total Time to Decision goal will be adjusted to 108 days for FY 2026 and FY 2027 and the PMA Shared Outcome Total Time to Decision goal will be adjusted to 275 days for FY 2026 and FY 2027.

If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met in FY 2024, and fee revenues above the annual total revenue amount are provided in FY 2027 to support performance improvements, the 510(k) Shared Outcome Total Time to Decision goal will be adjusted to 108 days and the PMA Shared Outcome Total Time to Decision goal will be adjusted to 270 days for FY 2027.

#### **B. De Novo Requests**

If the De Novo decision goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided in FY 2026 and FY 2027 to support performance improvements, the goal will be adjusted to 80% of De Novo requests receiving a MDUFA decision within 150 FDA days for FY 2026 and 2027.

If the De Novo decision goal is met for FY 2024, and fee revenue above the annual total revenue amount is provided in FY 2027 to support performance improvements, the goal

will be adjusted to 90% of De Novo requests receiving a MDUFA decision within 150 FDA days in FY 2027.

### **C. Pre-Submissions**

If the Pre-Submission Written Feedback goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided to support performance improvements, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Submissions in FYs 2025, 2026 and 2027.

If the Pre-Submission Written Feedback goal is met for FY 2024, and fee revenue above the annual total revenue amount is provided to support performance improvements, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Submissions in FY 2026 and FY 2027.

If the Pre-Submission Written Feedback goal is met for FY 2025, and fee revenue above the annual total revenue amount is provided to support performance improvements, the goal will not be subject to a maximum number of submissions in FY 2027.

The goal for percent of Pre-Submissions in the MDUFA Cohort receiving timely feedback, as described in Section II.A, will remain at 90% for FYs 2025, 2026, and 2027.

## **IV. Infrastructure**

### **A. Quality Management**

The CDRH Quality Management and Organizational Excellence (QMOE) Program is comprised of a team of certified quality management staff who report to the Center Director. This QMOE staff are focused on meeting customers' needs by improving consistency, efficiency, timeliness, and effectiveness of operations. The QMOE Program establishes and leads the CDRH Quality Management System (QMS) activities, facilitates process improvements, independently audits CDRH processes and activities, and assesses the effectiveness of actions taken to prevent potential (risk management) and resolve existing issues (nonconformity management).

At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan with the QMOE Program. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's nonconformity management process. FDA will continue to expand the scope of its annual audits as it implements and builds up its auditing capability, as resources permit. At a minimum, FDA audits in the following areas will be completed: Pre-Submissions and Third Party Review Program.

As part of these ongoing audits, high-performing premarket review best practices utilized in one Office of Health Technology (OHT) will be identified and shared accordingly with other OHTs to improve efficiencies and effectiveness.

At least once per year, FDA will report on the results of the audits, best practices identified and shared across OHTs, and the actions taken in response to nonconformities associated with the nonconformity management process.

## **B. Financial Transparency and Hiring**

### **1. Financial Transparency**

FDA will publish a MDUFA 5-year financial plan no later than the end of the 2nd quarter of FY 2023. The financial plan will include the Agency's annual hiring targets. No later than the end of the 2nd quarter of each subsequent fiscal year, FDA will publish updates to the 5-year plan as of the end of the prior fiscal year. The annual updates will include information concerning:

- The number of new MDUFA V hires by Office;
- The number of new MDUFA V hires made from outside the Center, as well as the number of new MDUFA V hires made from current Center employees (if any);
- The number of unfilled new MDUFA V hires;
- The changes in the personnel compensation and benefit costs for the process for the review of medical device applications that exceed the amounts provided by the personnel compensation and benefit costs portion of the inflation adjustment;
- An accounting of appropriated user fee funds included in the operating reserves at the end of each fiscal year, as well as the carryover balance of user fee funds that are considered unappropriated or unearned and therefore not included in the operating reserves; and
- An accounting of the amount excluded from the designated amount within the operating reserves, which is intended to support the Third Party Review program and the Total Product Life Cycle Advisory Program Pilot.

### **2. Carryover Balance**

MDUFA V will provide for FDA to decrease registration fees if the Agency has more than 13 weeks of operating reserves in the carryover balance. In addition, during MDUFA V FDA will use funds in the carryover balance to support the Third Party Review program and the Total Product Life Cycle Advisory Program Pilot. The amount of carryover balance funds intended to support these programs will be excluded when calculating the amount of operating reserves to determine if registration fees will be decreased. The current statutory one-month reserve will also be excluded when calculating the amount of operating reserves to determine if registration fees will be decreased. User fee funds in the carryover balance that are considered unappropriated or unearned are not included in the operating reserves.

No less than annually, FDA and industry will work together to seek alignment on how best to utilize available funds in the carryover balance to improve the process for the review of device applications – e.g., performance on submission types with performance goals and/or quality management programs. FDA and industry will use, as input for the discussion, workload information, performance objectives, and ongoing reported performance.

### **3. Hiring Goals**

Enhancements to the medical device review program require that FDA recruit, hire and retain sufficient numbers and types of technical, scientific, and other program experts to support the process for the review of device applications. MDUFA V provides significant new resources to FDA to support these activities.

To help ensure that FDA accomplishes hiring in accordance with the assumptions underlying the agreement, FDA will establish annual hiring goals for each year of MDUFA V.

The minimum hiring goals for FY 2023-2025 are:

<i>FY 2023:</i>	144 hires
<i>FY 2024:</i>	42 hires
<i>FY 2025:</i>	24 hires

As described in Section III, the MDUFA V agreement provides for enhancements to the shared outcome total time to decision goals and to specified review performance goals, provided that specified goals were met in prior years. These enhanced goals will be applicable in FY 2025 (for the Pre-Submission Written Feedback goal) and FY 2026-2027 (for the Pre-Submission Written Feedback goal, the PMA Shared Outcome Total Time to Decision goal, the 510(k) Shared Outcome Total Time to Decision goal, and the De Novo Decision goal).

FDA and Industry have agreed that, if performance improvement adjustments are triggered for each year per Section III, the Agency will increase hiring to support the enhanced goals.

#### *FY 2025*

In FY 2025, if performance improvement adjustments are made to the Pre-Submission Written Feedback goal per Section III, FDA will increase the hiring goal by 59 hires to a total of 83 hires. As part of the process for establishing the user fee rates for FY 2025, FDA will also calculate the hiring goal for that year and include the goal in the associated *Federal Register* fee-setting notice.

## *FY 2026 and FY 2027*

In FY 2026 and FY 2027, the number of hires will depend on (1) which performance improvement adjustments are triggered for that year, and (2) whether the hiring goal was increased the prior year. For FY 2026 and FY 2027, as part of the process for establishing the user fee rates for that year, FDA will also calculate the hiring goal for that year and include the goal in the associated *Federal Register* fee-setting notice.

### *Pre-hires*

For purposes of determining whether the hiring goal is met for FY 2023, FDA will include “pre-hires” that are made in FY 2022 for MDUFA V positions. In addition, for subsequent fiscal years, if FDA exceeds the hiring goal, the additional hires made above the goal will be counted towards the following fiscal year goal.

#### **4. Fee Adjustment Related to Hiring**

For FY 2023, if the hiring goal is missed by more than 15% at the end of the fiscal year (i.e., if fewer than 123 hires are made in FY 2023, including FY 2022 pre-hires), unused fees that were projected to support these hires for FY 2023 will be used to decrease registration fees for FY 2025.

For FY 2024 or FY 2025, if the hiring goal is missed by more than 10% at the end of the fiscal year (i.e., if fewer than 38 hires are made in FY 2024), unused fees that were projected to support these positions for the applicable fiscal year will be used to decrease registration fees for FY 2026 and FY 2027, respectively.

The amount of the hiring adjustment fee decrease will 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).

For the purpose of calculating progress toward meeting these hiring goals, a hire is defined as someone who has been confirmed as on board by the date indicated in a full-time position. Hires may be recruited from outside the FDA, or, in some cases, a hire can also be a current FDA employee who is changing positions within the agency.

#### **C. IT Infrastructure for Submission Management**

FDA will continue to enhance IT infrastructure to support the process for the review of device applications.

FDA will maintain and improve on the Customer Collaboration Portal, including the submission progress tracking system that provides near real-time submission status. By the end of MDUFA V, the progress tracking system will include 510(k), Original PMA and Panel-Track Supplements, De Novo, Pre-Submissions, and IDEs.

FDA will continue to develop electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. Templates for Original PMA and Panel-Track Supplements, De Novo, Pre-Submissions, and IDEs will be completed and made available for voluntary use by the end of MDUFA V.

#### **D. Training**

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

#### **E. 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.

#### **V. Process Improvements**

##### **A. Interactive Review**

The Agency will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and applicants. As described in the 2014 guidance document, “Types of Communication During the Review of Medical Devices Submissions,” both FDA and industry believe that an interactive review process for premarket medical device submissions should help facilitate timely completion of the review based on accurate and complete information. Interactive review is intended to facilitate the efficient and timely review and evaluation by FDA of premarket submissions and is expected to support reductions in total time to decision. The interactive review process contemplates increased informal interaction between FDA and applicants, including the exchange of scientific and regulatory information.

##### **B. Deficiency Letters**

By January 1, 2023, the Agency 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 and continue alignment with the following:

- Deficiency letters should include a statement of the basis for the deficiencies (e.g., a specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). In the instance

when the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific issue and the information to support its position.

- Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a marketing authorization decision (e.g., 510(k) clearance, PMA approval, and de novo classification).

FDA will train staff and managers on the updated guidance and work to make improvements (including incorporating best practices), as appropriate, to address findings from audits and consistent with the guidance.

FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859-1:1999 (“Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection”). FDA will review each fiscal year’s audit results with industry no later than the first quarterly meeting of the following fiscal year.

### **C. Enhanced Use of Consensus Standards**

The voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot is intended to enhance product reviewers' and device manufacturers' confidence in medical device testing when manufacturers rely on testing completed by ASCA-accredited testing laboratories. This should generally decrease the need for the FDA to request additional information regarding testing methodologies when a premarket submission includes ASCA testing. ASCA also incorporates existing international conformity assessment standards and practices where practical.

FDA will use lessons learned from implementation of the ASCA Pilot Program during MDUFA IV to transition from a pilot to a sustainable and expanded program. Specifically, the Agency will:

1. By the end of FY 2023, FDA will complete the pilot. In Q2 of FY 2024, FDA will provide a report on the performance of the ASCA Pilot Program (to replace the report specified in the MDUFA IV Commitment Letter, Commitment IV.D.8.a). In the report, FDA will provide at least the following information:
  - a. Adequacy of the standards selected to support confidence by FDA and industry in the methods used and results reported by ASCA-accredited testing laboratories;

- b. Testing laboratory participation in the training and ASCA program, and areas where any nonconformities were observed;
  - c. Number of submissions containing the ASCA Summary Report;
  - d. Summary Report acceptance rate by FDA reviewers; and
  - e. Summary of commonly cited deficiencies regarding the Summary Report.
2. FDA will train staff and supervisors so that specific deficiencies are relevant to the requirements of the Summary Report.
  3. FDA will continue to provide adequate training to testing laboratories and reviewers to accurately execute the ASCA process.
  4. FDA will report annually on the progress of the ASCA program.
  5. FDA will work with stakeholders for further input on programmatic improvements and/or consideration for expansion.

#### **D. Third Party Review**

The Agency will continue to support the Third Party Review program, with the objective of eliminating routine re-review by FDA of Third Party reviews through continuation of the following activities:

1. Provide training for Third Parties seeking accreditation by FDA. This training shall include the opportunity for Third Parties to have access to redacted review memos and other information as appropriate.
2. When FDA's expectations for a particular device type change, FDA will maintain a process to convey this information to the Third Parties and to industry.
3. Audit and provide tailored re-training to accredited Third Parties based on the results of audits.
4. Publish performance of individual accredited Third Parties with at least five completed submissions on FDA's website (e.g., rate of NSE, average number of holds, average time to SE).

FDA will consider the factors described in the guidance, "510(k) Third Party Review Program," in determining device type eligibility for the Third Party Review program.

Consistent with that guidance, some device types that rely on clinical data to demonstrate substantial equivalence may be eligible for Third Party Review.

## **E. Patient Science and Engagement**

The Agency will take the following actions to continue engaging patients and incorporating their perspectives in the regulatory process. Where appropriate, the Agency will leverage collaborations and partnerships with patients, healthcare providers, industry, and others to advance these actions.

1. Expand clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing applicant-proposed use of voluntary patient preference information (PPI), voluntary patient reported outcomes (PROs), and/or patient generated health data (PGHD). These staff will provide submission review and early consultation/advice to industry during study planning.
2. Issue a draft guidance providing best practices on incorporating into premarket studies clinical outcome assessments including their use as primary or co-primary endpoints. A clinical outcome assessment (COA) describes or reflects how a person feels, functions, or survives and can be reported by a health care provider or a non-clinical observer (such as a parent), through performance of an activity or task, or by the patient.
3. Support the use of innovative technologies to capture patient input and reduce patient burden to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention.
4. By the end of FY 2024, hold a public meeting to explore ways to use patient-generated health data to help advance remote clinical trial data collection and support clinical outcome assessments.
5. FDA will undertake the following activities to improve the regulatory predictability and impact of patient science:
  - a. Develop case examples of modified or adapted PRO instruments to make efficient use of existing validated PRO instruments which may be improved or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.
  - b. Strengthen efforts to expand staff understanding of Patient Science and Engagement (PSE) topics, and consistent evaluation in submissions through training curriculum and internal infrastructure to improve

consistency (e.g., Focal Point Program).

- c. Update FDA’s existing guidance, “Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling,” with pragmatic insights and to address common questions for those interested in the voluntary use of PPI in regulatory submissions.
  - d. Explore opportunities to improve patient science tools for medical devices and advance health equity through targeted incorporation of diverse patient perspectives and integration of data from diverse patients.
  - e. Identify high impact opportunities to incorporate patient perspectives.
6. Facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules on device trials, real-world data, device development tools, and regulatory frameworks. FDA will also make these educational modules publicly available, as appropriate.
  7. The existing dispute resolution process should be used in the event of disagreement between the applicant and the Agency on the need for PPI, PRO and/or other tools to capture PGHD.

**F. Real World Evidence (RWE)**

The Agency will use user fee revenue for the continued development of Real-World Data (RWD) and RWE methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and new clearance/approval of new devices, and clarify related reporting requirements.

1. FDA will update the 2017 guidance document Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices to provide more clarity on:
  - a. Least burdensome general expectations on what is needed to demonstrate the “Fit-for-Purpose of RWD” for premarket regulatory purposes, including expanded indications for use and new clearance/approval of new devices;
  - b. More information, including generalized examples, on previously used and accepted methodologies; and
  - c. Best practices for RWE review.

2. FDA will continue to advance CDRH's RWD/RWE Training program for FDA review teams including the medical review staff. Topics will include best practices for RWE review and when to engage with CDRH RWE subject matter experts.
3. FDA will provide transparent program development updates and financial accounting of User Fee revenue specifically intended for the activities in this section.
  - a. FDA will update stakeholders on the RWE program activities at two or more open public meetings during the course of MDUFA V.
  - b. FDA hiring of internal experts to support the review of RWD/RWE-related submissions will be tracked.
  - c. If any portion of the user fee funding is distributed to the National Evaluation System for health Technology (NEST), the funding should be used to transparently:
    - i. Support the development of RWD resources to facilitate appropriate access for research studies;
    - ii. Convene experts to develop best practices and, advance innovative methodology approaches with respect to RWE development and analysis;
    - iii. Include, on the organization's governing board, no fewer than 4 representatives of the trade associations that participated in the MDUFA V negotiations (AdvaMed, MDMA, MITA, and ACLA), with each association appointing an individual to serve. Industry representation on the governing board, if applicable, will make up at least 25% of the governing board membership at all times, and shall be selected by the industry associations. The representative from each trade association may be part of the staff of the association or appointed from a member company. If any of the trade associations elects not to participate on the governing board or for any additional seats allocated to industry, the participating trade associations will determine how to fill any vacant Industry positions.
  - d. By the end of FY 2023, FDA will publish a document requesting public comment on how FDA should use any portion of the user fee funding that may be distributed to any external organization(s) other than NEST to support premarket RWE.

- e. If any portion of the user fee funding is distributed to an external organization(s) other than NEST, the funding will be accounted for in FDA's quarterly MDUFA report.

## **G. Digital Health**

The Agency 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. Specifically, the Agency will:

1. Continue to develop software and digital health technical expertise to provide assistance for premarket submissions that include software, interoperable devices, or otherwise incorporate digital health technologies, such as artificial intelligence or machine learning (AI/ML), Virtual, Mixed, and Augmented Reality (VR/MR/AR) and wearables.
2. Strengthen efforts to expand staff understanding of digital health topics and enhance consistent evaluation in submissions through training and internal infrastructure (e.g., Focal Point Program).
3. Continue to participate in international harmonization efforts related to digital health, including work on developing software and other digital health convergence efforts.
4. Finalize the draft guidance, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period.
5. Publish draft guidance describing a process to evaluate a predetermined change control plan for digital health devices.

## **H. Guidance Document Development**

FDA will apply user fee revenues to ensure timely completion of Draft Guidance documents. The Agency will strive to finalize, withdraw, reopen the comment period, or issue a new draft guidance for 80% of draft guidance documents within 3 years of the close of the comment periods as resources permit. The Agency will strive to finalize, withdraw, reopen the comment period, or issue a new draft guidance for 100% of draft guidance documents within 5 years of the close of the comment periods as resources permit. The Agency will continue to develop guidance documents and improve the development process as resources permit, but not to the detriment of meeting quantitative review timelines and statutory obligations.

## **I. International Harmonization**

FDA is committed to improving the efficiency of the global regulatory systems for medical devices through international harmonization and convergence of regulatory requirements. The Agency will take the following actions to advance such international harmonization. Specifically, the Agency will:

1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.
2. Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies and practices, as needed and consistent with applicable disclosure law and policy.
3. Commencing in FY 2023, assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents and make this information publicly available to enhance clarity and transparency.
4. Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision making.
5. Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.
6. By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described above.
7. Commencing with FY 2024, publish an annual assessment of the international harmonization activities described the strategic plan above, including the progress assessment described in subparagraph 3 above.

## **J. Total Product Life Cycle (TPLC) Advisory Program**

FDA will establish a pilot of the Total Product Life Cycle (TPLC) Advisory Program (TAP Pilot) during the course of MDUFA V.

1. Vision: The long-term vision for a successful TPLC Advisory Program (TAP) is to help spur more rapid development as well as more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance. A mature TAP will also help ensure the sustained success of the Breakthrough devices program.
2. TAP Pilot Objective: The TAP Pilot is intended to demonstrate the feasibility and benefits of process improvements to FDA's early interactions with participants and FDA's facilitation of interactions between participants and stakeholders that support the vision for TAP. Through the TAP Pilot, the FDA will provide the following types of strategic engagement for innovative devices of public health importance:
  - Improving participants' experiences with FDA by providing for more timely premarket interactions;
  - Enhancing the experience of all participants throughout the device development and review process, including FDA staff;
  - Facilitating improved strategic decision-making during product development, including earlier identification, assessment, and mitigation of product-development risk;
  - Facilitating regular, solutions-focused engagement between FDA review teams, participants, and other stakeholders such as patients, providers, and payers, beginning early in device development; and
  - Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process
3. Goals: To achieve the above TAP Pilot objective, FDA will:
  - a. Begin and support a TAP Pilot, scoped to include the following:
    - In FY 2023, enroll up to 15 products in a "soft launch" in one Office of Health Technology (OHT); selection of the OHT will include consideration of the OHT's historical number of granted Breakthrough designations, workload, and available staffing and expertise;
    - In FY 2024, continue to support products enrolled in the previous fiscal year and expand to enroll up to 45 additional products in at least two OHTs (i.e., up to 60 total products enrolled through FY 2024);

- In FY 2025, continue to support products enrolled in previous fiscal years and expand to enroll up to 65 additional products in at least four OHTs (i.e., up to 125 total products enrolled through FY 2025); and
  - In FY 2026 – FY 2027, continue to support products enrolled in previous fiscal years and expand to enroll up to 100 additional products each fiscal year within existing OHTs or expand to additional OHTs, depending on lessons learned from FY 2023 – FY 2025 experience (i.e., up to 225 total products enrolled through FY 2026 and up to 325 total products enrolled through FY 2027).
  - For FY 2024 – FY 2027, in addition to the considerations above, selection of the OHTs will include consideration of experience from prior years and input from industry and other stakeholders.
- b. Implement and track appropriate qualitative and quantitative success metrics.
  - c. Regularly review TAP pilot progress with industry, share feedback, and assess the impact of the TAP Pilot and opportunities for improvement.
  - d. Publish an assessment of the TAP Pilot on the FDA web site no later than January 30, 2026.

For purposes of the annual performance report and corrective action report, the goals of the TAP pilot are set forth in Section V.J.3 above.

The survey and quantitative metrics described below, as well as any other success measures, are for informational purposes and are neither review time nor performance enhancement goals.

4. Enrollment. FDA intends to enroll participants in the pilot using the following criteria:
  - a. Participation in the pilot will be voluntary.
  - b. For FY 2023 – FY 2025, products will be those with a granted Breakthrough designation. For FY 2026 – FY 2027, products will be those with a granted Breakthrough designation or request for inclusion in the Safer Technologies Program (STeP).
  - c. Participants have not submitted a Pre-Submission about the product after granted Breakthrough designation or request for inclusion in STeP.
  - d. Products will be early in their product development process (e.g., have not yet initiated a pivotal study) at time of pilot enrollment.

- e. Each participant will have a maximum of one product enrolled in the pilot per fiscal year.
- f. Participants will be enrolled on first-come, first-served basis.

FDA will inform potential participants of the TAP Pilot as part of the Breakthrough designation process or request for inclusion in STeP process.

If spaces remain available in a participating OHT or if resources permit, FDA may consider enrolling devices from additional OHT(s).

- 5. TAP Pilot Assessment. FDA will conduct an assessment of the TAP Pilot using an independent third party (or parties) to assess the TAP pilot. This assessment will include a participant survey and quantitative and qualitative success metrics, starting in FY 2024, that include but are not limited to:
  - a. 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.
  - b. 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.
  - c. Participant satisfaction with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA.
  - d. Participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized).
  - e. An overall assessment of the outcomes of the Pilot and opportunities for improvement.
- 6. Other Measures. FDA will begin to track other measures of program success, which will include:
  - 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.

## **VI. Independent Assessments**

### **A. Independent Assessment of MDUFA Workforce Metrics**

FDA will retain a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting 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 FTEs, including the subset funded by user fees, for each applicable FDA Center and Office.

The report will include the contractor's findings from the assessment and recommendations for improved methodologies to represent MDUFA FTE resources, including the subset funded by user fees. The assessment will be published on FDA's website by March 31, 2025.

### **B. Independent Assessment of Review Process Management**

FDA and the industry will participate in a targeted assessment of the process for the review of device applications. 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 shall be conducted under contract to FDA by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope described below within the budget provided under this user fee agreement.

The contractor will:

1. Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V;
2. Assess the alignment of resource needs with the training and expertise of hires;
3. Identify and share best practices across OHTs in OPEQ;
4. Assess the effectiveness of program areas targeted for improvement under this agreement, including the following:
  - a. Implementation and impact of changes to the guidance "Developing and Responding to the Deficiencies in Accordance with the Least Burdensome Provisions,"
  - b. Implementation and impact of changes to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program,"

- c. Third Party Review program (continued reduction of routine re-review by FDA of Third Party reviews),
- d. Digital Health program,
- e. Patient Science and Engagement program,
- f. Real World Evidence program, and
- g. International Harmonization.

5. Assess other key areas identified by FDA and industry as resources permit.

FDA will award the contract no later than March 31, 2025. However, the contractor would not begin the audit of Pre-Submissions before October 1, 2025. The contractor will publish comprehensive findings and recommendations within 1 year, after reviews with FDA and industry and opportunities to provide feedback for the contractor's consideration prior to finalizing the final report. For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.

FDA will incorporate findings and recommendations, as appropriate, into its management of the process for the review of device applications. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.

## **VII. Performance Reports**

The Agency will report its progress toward meeting the goals described in this letter, as follows. If, throughout the course of MDUFA V, the Agency and Industry agree that a different format or different metrics would be more useful, the reporting will be modified accordingly as per the agreement of both FDA and Industry.

1. Quarterly reporting at the CDRH OHT level/CBER Center level (in recognition of the significantly smaller number of submissions reviewed at CBER):
  - 1.1. For 510(k) submissions that do not go through a Third Party, reporting will include:
    - i. Average and quintiles of the number of calendar days to Substantive Interaction
    - ii. Average, and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision
    - iii. Average number of review cycles
    - iv. Rate of submissions not accepted for review
  - 1.2. For PMA submissions, reporting will include:

- i. Average and quintiles of the number of calendar days to Substantive Interaction for Original PMA, Panel-Track PMA Supplement, and Premarket Report Submissions
    - ii. Average and quintiles of the of FDA Days, Industry Days, and Total Days to a MDUFA decision
    - iii. Rate of applications not accepted for filing review, and rate of applications not filed
  - 1.3. For De Novo requests, reporting will include:
    - i. Average, and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision
    - ii. Average number of review cycles
    - iii. Rate of submissions not accepted for review
  - 1.4. For Pre-Submissions, reporting will include:
    - i. Number of Pre-Submissions in the MDUFA cohort
    - ii. Rate of submissions not accepted for review
    - iii. Average and quintiles of the number of calendar days from submission to written feedback
    - iv. Number of Pre-Submissions that require a meeting
    - v. Percent of submissions with meetings for which industry provided minutes within 15 days
  - 1.5. For IDE applications, reporting will include:
    - i. Number of original IDEs received
    - ii. Average number of amendments prior to approval or conditional approval of the IDE
  - 1.6. In FY 2023, for marketing submissions for In Vitro Diagnostics, FDA will report on the status of submissions received in FY 2020-2021 that remain under review as a result of being paused while the Agency focused on COVID-19-related submissions.
2. CDRH will report quarterly, and CBER will report annually, the following data at the Center level:
  - 2.1. Rate of NSE decisions for 510(k) submissions
  - 2.2. Rate of withdrawals for 510(k), De Novo, and PMA submissions
  - 2.3. Rate of Not Approvable decisions for PMA submissions
  - 2.4. Rate of Denial decisions for De Novo requests
  - 2.5. Key product areas or other issues that FDA identifies as noteworthy because of a potential effect on performance, including significant rates of Additional Information requests
  - 2.6. Specific topic or product area as it relates to performance goals, agreed upon at the previous meeting
  - 2.7. Number of submissions that missed the goals and the total number of elapsed calendar days broken down into FDA days and industry days
  - 2.8. Newly released draft and final guidance documents, and status of other priority guidance documents
  - 2.9. Agency level summary of fee collections

- 2.10. Independent assessment implementation plan status
  - 2.11. Results of independent assessment and subsequent periodic audits and progress toward implementation of the recommendations and any corrective action
  - 2.12. Number of fee waivers or reductions granted by type of submission
3. The Agency will report quarterly the following data for the MDUFA program:
    - 3.1. Progress towards meeting annual hiring goals
    - 3.2. Per Section V.F.3.e, if any portion of the user fee funding intended for real world evidence activities is distributed to an external organization(s) other than NEST, information regarding use of the user fee funding
4. In addition, the Agency will provide the following information on an annual basis:
    - 4.1. Review time devoted to direct review of applications
    - 4.2. The number of Premarket Report Submissions received
    - 4.3. Summary information on training courses available to CDRH and CBER employees, including new reviewers, regarding device review and the percentage of applicable staff that have successfully completed each such course. CDRH will provide information concerning any revisions to the new reviewer training program curriculum.
    - 4.4. Performance on the shared outcome goal for average Total Time to Decision
    - 4.5. For 510(k) submissions, reporting will include:
      - i. Number of submissions reviewed by a Third Party
      - ii. Number of Special Submissions
      - iii. Number of Traditional Submissions
      - iv. Average and number of days to Accept/Refuse to Accept
      - v. Number of Abbreviated Submissions
    - 4.6. For 510(k) submissions that go through a Third Party, reporting will include:
      - i. Time from FDA receipt of Third Party report to FDA decision at the 90% percentile
      - ii. Rate of NSE
      - iii. Average number of holds
      - iv. Average time to SE
    - 4.7. For PMA submissions, reporting will include the number of the following types of PMA submissions received:
      - i. Original PMAs
      - ii. Priority PMAs
      - iii. Premarket Reports
      - iv. Panel-Track PMA Supplement
      - v. PMA Modules
      - vi. 180-Day PMA Supplements
      - vii. Real-Time PMA Supplements
      - viii. Number of submissions FDA classifies as unsolicited major, solicited major, and minor amendments
    - 4.8. For De Novo requests, reporting will include:

- i. Number of submissions received
- ii. Average and number of days to Accept/Refuse to Accept
- 4.9. For CLIA waiver applications, reporting will include:
  - i. Number of CLIA waiver applications received
  - ii. Average and quintiles of the number of calendar days to Substantive Interaction
  - iii. Average and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision and a discussion of any trends in the data
- 4.10. Report on the ASCA program
- 4.11. Data regarding the reviewer to manager ratio
- 4.12. Report on QMOE program
- 4.13. Summary of QMOE audits, including annual audit of Deficiency Letters under Section V.B above
- 4.14. Summary of primary cost drivers that contribute to change in personnel compensation and benefits costs (e.g., cost of living adjustments and increases in agency benefits contributions, if applicable)
- 4.15. The return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA V.

FDA will report annual and quarterly data on performance within goals for 510(k), De Novo, and PMA MDUFA decisions for devices identified as LDTs by the submitter compared to all non-LDT IVD devices. The following elements will be reported:

- Number and percentage of LDT 510(k)s and non-LDT IVD 510(k)s completed within 90 FDA days
- Number and percentage of LDT De Novo requests and non-LDT IVD De Novo requests completed within 150 FDA days
- Number and percentage of LDT PMAs and non-LDT IVD PMAs completed within 180 FDA days

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.

## **VIII. Definitions and Explanations of Terms**

### **A. Applicant**

Applicant means a person who makes any of the following submissions to FDA:

- an application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C Act);
- a premarket notification under section 510(k) of the FD&C Act;
- an application for investigational device exemption under section 520(g) of the FD&C Act;

- a Pre-Submission;
- a De Novo classification request (De Novo request) under section 513(f)(2) of the FD&C Act;
- a CLIA Waiver by application.

## **B. eSTAR (electronic Submission Template And Resource)**

An electronic submission template built within a structured dynamic PDF that guides a user through construction of an eSubmission. eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of 510(k) submissions as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

## **C. FDA Days**

FDA Days are those calendar days when a submission is considered to be under review at the Agency for submissions that have been accepted (510(k) or De Novo request), filed (PMA) or submitted (CLIA Waiver by application). FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted (510(k) or De Novo request) or filed (PMA).

## **D. MDUFA Decisions**

Original PMAs, Product Development Protocols, Panel-Track Supplements, and Premarket Report Applications: Decisions are approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial.

180-Day PMA Supplements: Decisions for 180-Day PMA Supplements are approval, approvable, and not approvable.

Real-Time PMA Supplements: Decisions for Real-Time PMA supplements are approval, approvable, and not approvable.

510(k)s: Decisions for 510(k)s are substantially equivalent (SE) or not substantially equivalent (NSE).

De Novo Requests: Decisions for De Novo requests are grant, withdrawal, and decline.

CLIA Waiver by Application Submissions: Decisions for CLIA Waiver by Application Submissions are approval, withdrawal, and denial.

Submissions placed on Application Integrity Hold will be removed from the MDUFA cohort.

## **E. Pre-Submission**

A Pre-Submission includes a formal written request from an applicant for feedback from FDA that is provided in the form of a formal written response or, if the manufacturer chooses, formal written feedback followed by a meeting or teleconference in which any additional feedback or clarifications are documented in meeting minutes.

A Pre-Submission provides the opportunity for an applicant to obtain FDA feedback prior to intended submission of an investigational device exemption or marketing application. The request must include specific questions regarding review issues relevant to a planned investigational device exemption (IDE), CLIA Waiver by Application, Accessory Classification Request, or marketing application (e.g., questions regarding pre-clinical testing protocols or data requirements; design and performance of clinical studies and acceptance criteria). A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or submission preparation.

The following forms of FDA feedback to applicants are not considered Pre-Submissions.

- Interactions requested by either the applicant or FDA during the review of a marketing application (i.e., following submission of a marketing application, but prior to reaching an FDA Decision).
- TPLC Advisory Program Pilot interactions.
- General information requests initiated through the Division of Industry and Consumer Assistance (DICE).
- General questions regarding FDA policy or procedures.
- Meetings or teleconferences that are intended to be informational only, including, but not limited to, those intended to educate the review team on new device(s) with significant differences in technology from currently available devices, or to update FDA about ongoing or future product development, without a request for FDA feedback on specific questions related to a planned submission.
- Requests for clarification on technical guidance documents, especially where contact is recommended by FDA in the guidance document. However, the following requests will generally need to be submitted as a Pre-Submission in order to ensure appropriate input from multiple reviewers and management: recommendations for device types not specifically addressed in the guidance document; recommendations for nonclinical or clinical studies not addressed in the guidance document; requests regarding use of alternative means to address recommendations specified in a guidance document.

- Phone calls or email messages to reviewers that can be readily answered based on a reviewer's experience and knowledge and do not require the involvement of a broader number of FDA staff beyond the routine involvement of the reviewer's supervisor and more experienced mentors.

## **F. Substantive Interaction**

Substantive Interaction is an email, letter, teleconference, video conference, or other form of communication such as a request for Additional Information or Major Deficiency letters by FDA notifying the applicant of substantive deficiencies identified in initial submission review, or a communication stating that FDA has not identified any deficiencies in the initial submission review and any further minor deficiencies will be communicated through interactive review. An approval or clearance letter issued prior to the Substantive Interaction goal date will qualify as a Substantive Interaction.

If substantive issues warranting issuance of an Additional Information or Major Deficiency letter are not identified, interactive review should be used to resolve any minor issues and facilitate an FDA decision. In addition, interactive review will be used, where, in FDA's estimation, it leads to a more efficient review process during the initial review cycle (i.e., prior to a Substantive Interaction) to resolve minor issues such as revisions to administrative items (e.g., 510(k) Summary/Statement, Indications for Use statement, environmental impact assessment, financial disclosure statements); a more detailed device description; omitted engineering drawings; revisions to labeling; or clarification regarding nonclinical or clinical study methods or data.

Minor issues may still be included in an Additional Information or Major Deficiency letter where related to the resolution of the substantive issues (e.g., modification of the proposed Indications for Use may lead to revisions in labeling and administrative items), or if they were still unresolved following interactive review attempts. Both interactive review and Substantive Interactions will occur on the review clock except upon the issuance of an Additional Information or Major Deficiency Letter which stops the review clock.

## **G. Total Time to Decision**

Total Time to Decision is the number of calendar days from the date of receipt of an accepted (with respect to 510(k)s) or filed (with respect to Original PMAs and Panel Track Supplements) submission to a MDUFA decision.

For the purpose of calculating and reporting on 510(k) shared outcome Total Time to Decision goals in section II, the average Total Time to Decision for 510(k) submissions is calculated as the average of Total Times to Decision for 510(k) submissions within a 99% closed cohort, with the following provisions:

In FY 2023, the cohort excludes submissions with any one hold greater than 180-days and excluding the highest 5% of Total Time to Decision on the remaining cohort.

In FY 2024-2027, the cohort excludes the highest 2% and lowest 2% of values and includes all 510(k)s with a MDUFA decision.

If the number of submissions in any MDUFA V receipt cohort exceeds the number of submissions in the FY 2021 or FY 2022 receipt cohort (whichever is higher) by 5% or more, a 1% increase in the trim will be applied to the highest values.

A cohort for a FY is closed when 99% of the MDUFA cohort has reached a MDUFA decision. For the purpose of determining whether improved performance and fee revenue adjustments in Section III are applicable, the 510(k) Shared Outcome Total Time to Decision goal is calculated in the same manner except that the calculation is conducted based on data available as of 18 months following the close of the fiscal year to which the goal applies, and the cohort does not need to be 99% closed. See Section III.

For the purpose of calculating and reporting on PMA shared outcome Total Time to Decision goals in Section II, the average Total Time to Decision for PMAs is calculated as the three-year rolling average of the annual Total Times to Decision for Original PMAs and Panel Track supplements (for example, for FY 2024, the average PMA Total Time to Decision would be the average of FY 2022 through FY 2024) within a closed cohort, excluding the highest 5% and the lowest 5% of values. A cohort for a FY is closed when 95% of the MDUFA V cohort has reached a MDUFA decision. For the purpose of determining whether increased performance and fee revenue adjustments in Section III are applicable, the PMA shared outcome Total Time to Decision goal is calculated in the same manner except that the calculation is conducted based on data available as of 18 months following the close of the fiscal year to which the goal applies and the cohort does not need to be 99% closed.

## **H. Application Types**

**Original PMA** means an application for an approval of a device submitted under section 515(c) of the FD&C Act. It does not include a supplement to such an application after it has been approved or a Premarket Report.

**Premarket Report** means a report submitted under section 515(c)(2) of the FD&C Act seeking premarket approval for a class III reprocessed single use device.

**Panel-Track Supplement** means a supplement to an approved Original PMA or Premarket Report that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

**180-Day PMA Supplement** means a supplement to an approved Original PMA or Premarket Report that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

**Real-Time PMA Supplement** means a supplement to an approved Original PMA or Premarket Report that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

**De Novo Classification Request (De Novo Request)** means a request made under section 513(f)(2) of the FD&C Act with respect to the classification of a device.

**Premarket Notification (510(k)) Submission** means a report submitted under section 510(k) of the FD&C Act.

## **I. BLA-related Definitions**

**Review and act on** – the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

**Class 1 resubmitted applications** – applications resubmitted after a complete response letter that includes the following items only (or combinations of these items):

- (a) Final printed labeling
- (b) Draft labeling
- (c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
- (d) Stability updates to support provisional or final dating periods
- (e) Commitments to perform Phase 4 studies, including proposals for such studies
- (f) Assay validation data
- (g) Final release testing on the last 1-2 lots used to support approval
- (h) A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class 1 category)
- (i) Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
- (j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry

**Class 2 resubmitted applications** – resubmissions that include any other items, including any item that would require presentation to an advisory committee.