Performance Report to Congress

Medical Device User Fee Amendments

FY 2022

Executive Summary

On August 18, 2017, the President signed into law the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52). FDARA amended the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products. FDARA reauthorized and expanded the Medical Device User Fee Amendments (MDUFA) for 5 additional years (i.e., fiscal year (FY) 2018 through FY 2022) (referred to as "MDUFA IV").

This report presents preliminary data on the progress of the U.S. Food and Drug Administration (FDA) in meeting FY 2022 MDUFA IV goals and updated data on FDA's progress in meeting FY 2021 and FY 2020 MDUFA IV goals.

This report also addresses additional performance data (including for MDUFA IV performance enhancement goals) that were required by FDARA and that FDA was directed to provide in connection with the Consolidated Appropriations Act, 2017 (Public Law 115-31).

All data presented in this report are as of September 30, 2022.

A. Preliminary FY 2022 Performance

1. Review Goals

FDA received FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 16 review goals, one review goal was sufficiently complete to determine the outcome and was met, five review goals were sufficiently complete to determine the outcome and were missed, and ten review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts, including the two shared outcome goals, are not yet sufficiently complete to determine the outcome). For the remaining 9 (of the 25) review goals, there are no submissions for the respective MDUFA cohort.

2. Performance Enhancement Goals

FDA had 19 performance enhancement goals due in FY 2022, all of which were completed on time. Two additional performance enhancement goals are awaiting a dependency that has yet to be completed.

B. Updated FY 2021 Performance

1. Review Goals

FDA received enough FY 2021 submissions to calculate performance results for 13 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, six review goals were sufficiently complete to determine the outcome and were missed, and three review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts, including the two shared outcome goals, are not yet sufficiently complete to determine the outcome). For the remaining 12 (of the 25) review goals, there are no reportable performance metrics because there was an insufficient number of received submissions for the respective MDUFA cohort or there were no submissions.

C. Updated FY 2020 Performance

1. Review Goals

FDA received enough FY 2020 submissions to calculate performance results for 15 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 15 review goals, nine review goals were sufficiently complete to determine the outcome and were met, four review goals were sufficiently complete to determine the outcome and was missed, and two review goal are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohort is not yet sufficiently complete to determine the outcome). These pending goals will be included in a future report upon closure of the review cohort.

Table of Contents

I. Introduction 1

A. Performance Presented in This Report 1

1. MDUFA Review Goals 1

2. MDUFA Performance Enhancement Goals 3

3. Additional Performance Data 4

B. Submission Types Included in This Report 4

II. MDUFA IV Review-Time Goals and Commitments 7

A. Review Goals with Specific Target Percentages 7

B. Shared Outcome Goals 9

III. MDUFA IV Review Goal Performance 10

A. Summary of Review Goal Performance 10

B. Review Goals with Specific Target Percentages 10

1. FY 2022 Preliminary Performance Data 12

2. FY 2021 Updated Performance Data 15

3. FY 2020 Updated Performance Data 18

4. FY 2019 Updated Performance Data 18

C. Shared Outcome Goals (FY 2018 Through FY 2022) 19

IV. MDUFA Review Workloads: FY 2017 Through FY 2022 20

Appendix A: Definitions of Key Terms 1

Appendix B: Performance Information for De Novo, Section 513(g), and Section 522 Postmarket Device Surveillance Plan Submissions 1

Appendix C: Additional Information from FDARA's Section 903 Requirement ... 1

A. Number of Premarket Applications Filed and Reports Submitted 1

B. Number of Expedited Development and Priority Review Designations 4

Appendix D: Analysis of the Use of Funds 1

A. Analysis of the Use of Funds 1

1. Differences Between Aggregate Numbers 1

2. Performance Enhancement Goals..... 5

3. Common Causes and Trends Impacting the Ability to Meet Goals..... 16

Appendix E: FY 2022 Corrective Action Report 1

A. Executive Summary 2

B. MDUFA Review Goals 5

1. FY 2022 Review Goal Performance 6

2. FY 2021 Review Goal Performance (Updated) 8

3. FY 2020 Review Goal Performance (Updated) 11

C. MDUFA Performance Enhancement Goals 14

1. Program and Process Implementation 14

Appendix F: Rationale for MDUFA Program Changes 1

A. Changes in the Number of Full Time Equivalents (FTEs) Hired as Agreed Upon in the MDUFA IV Commitment Letter and Number of FTEs Funded by Budget Authority at FDA by Division Within CDRH, CBER, ORA, and the Office of the Commissioner (OC) 1

1. Changes in the Number of FTEs Hired as Agreed Upon in the MDUFA IV Commitment Letter..... 2

2. Changes in the Number of FTEs Funded by Budget Authority at FDA by Division Within CDRH, CBER, ORA, and OC..... 3

B. Changes in the Fee Revenue Amounts and Costs for the Process for the Review of Devices..... 5

C. Number of Employees for Whom Time Reporting Is Required 6

Acronym List

3PRO	Third Party Review Organizations
ASCA	Accreditation Scheme for Conformity Assessment
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CLIA	Clinical Laboratory Improvement Amendments
EUA	Emergency Authorization Equipment
FDA	U.S. Food and Drug Administration
FDARA	FDA Reauthorization Act of 2017
FTE	Full Time Equivalent
FY	Fiscal Year (October 1 to September 30)
GMP	Good Manufacturing Practice
IDE	Investigational Device Exemption
IMDRF	International Medical Device Regulators Forum
IVD	In vitro Diagnostics
MDUFA	Medical Device User Fee Amendments
NEST	National Evaluation System for health Technology
NSE	Not Substantially Equivalent
OC	Office of the Commissioner
OHTs	Offices of Health Technology
OIR	Office of In Vitro Diagnostics and Radiological Health
OP	Office of Policy
OPEQ	Office of Product Evaluation and Quality
OST	Office of Strategic Partnership and Technology Innovation

ORA	Office of Regulatory Affairs
PDP	Product Development Protocol
PMA	Premarket Approval Application
PPE	Personal Protective Equipment
PRO	Patient Reported Outcome
RTA	Refuse to Accept
RWE	Real World Evidence
SE	Substantially Equivalent
SI	Substantive Interaction
TL	Test Laboratories
TTD	Total Time to Decision

I. Introduction

On August 18, 2017, the President signed into law the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which included the reauthorization and expansion of the Medical Device User Fee Amendments (MDUFA) for 5 additional years (fiscal year (FY) 2018 through FY 2022) (referred to as "MDUFA IV"). MDUFA IV authorizes the U.S. Food and Drug Administration (FDA or the Agency) to collect user fees for the review of medical device premarket applications, reports, and other submissions and for establishment registrations. In return, FDA committed to meet certain review goals (including shared outcome goals) and performance enhancement goals.[1]

Some of the notable changes to MDUFA IV include the addition of more rigorous outcome goals shared by both industry and FDA, new review goals for Pre-Submissions and De Novo classification requests, and a number of new performance enhancement goals. Additional information on the history of MDUFA I, MDUFA II, and MDUFA III can be found on FDA's website.[2]

A. Performance Presented in This Report

1. MDUFA Review Goals

For this report, MDUFA review goals include review goals with specific target percentages (e.g., 90 percent), a Pre-Submission written feedback goal, and shared outcome goals. In any given year, FDA's review goal performance includes reviews of submissions pending from previous fiscal years and submissions received during the current fiscal year.

This report presents preliminary review goal performance for the FY 2022 MDUFA IV cohort submissions. This report also includes updated review goal performance information for FY 2020 and FY 2021 MDUFA IV cohort submissions.

The following information refers to all FDA review goal performance presented in this report.

- Unless otherwise noted, all performance data are as of September 30, 2022.
- Unless otherwise noted, review goal performance is based on FDA's combined performance on MDUFA submissions reviewed in the Center for Devices and Radiological Health (CDRH) and/or the Center for Biologics Evaluation and Research (CBER), depending on submission type. This is different from MDUFA

[1] www.fda.gov/media/102699/download.

[2] www.fda.gov/about-fda/user-fee-performance-reports/mdufa-performance-reports.

Quarterly Performance Reports located on FDA's website,[3] in which performance is reported separately for each Center. Details of which Center reviews each submission type are outlined in Appendix A of this report.

- With the exception of shared outcome goals and the Pre-Submission written feedback goal, only review goals with specific target percentages (e.g., 90 percent) are presented in this report.

- Review goal performance data are based on a fiscal year receipt cohort. Until all submissions in a cohort receive a final decision or are sufficiently complete for FDA to determine whether the review goal has been met, a preliminary performance assessment is provided for that cohort. The MDUFA cohort performance for each submission type is therefore subject to change until that cohort is closed.

- Submissions that were closed without a MDUFA decision are not included in the MDUFA cohort and, therefore, are not included in the data used to measure MDUFA performance. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without an FDA MDUFA decision, please refer to the Review Workload tables in this report. MDUFA decisions for each submission type are outlined in Appendix A of this report.

- The Original Premarket Approval Applications (PMAs), Product Development Protocols (PDPs), Panel-Track PMA Supplements, and Premarket Reports performance includes PMAs that have been filed for devices granted a breakthrough designation (previously referred to as "priority review" or "expedited").

- Biologics License Applications (BLAs) have many application categories: Priority Original, Standard Original, Priority Efficacy Supplements, Standard Efficacy Supplements, Manufacturing Supplements Requiring Prior Approval, Class I Original BLA and BLA Efficacy Supplement Resubmissions, and Class II Original BLA and BLA Efficacy Supplement Resubmissions.

- "FDA days" refers to the calendar days in which a submission is under review by FDA. FDA days begin on FDA's date of receipt of the Refuse to Accept (RTA)-acceptable submission or of the amendment to the submission that enables the submission to be accepted or filed.

- "Review-time goals" are defined as the time period identified by the number of calendar days or FDA days for when individual submissions are to have an interaction or be acted on. An "on-time" (or "within goal") "review" indicates that an action was completed within the number of days specified by the review-time

[3] www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports.

goal.

- Review-time goals range from 60 days to 320 days. To meet MDUFA review goals with specific target percentages, FDA must meet the various review-time goals.

- Performance for review goals with specific target percentages is based on the number of submissions reviewed on time (i.e., completed within the goal) and overdue (i.e., acted on past the review goal or pending past the review goal) and is presented as the within goal performance percentage.

- The "within goal performance percentage" refers to the percent of reviews where FDA met a review-time goal for a given type of submission. FDA's within goal performance percentage for a given type of submission is used to determine whether FDA met or exceeded the MDUFA review goals.

- When determining FDA's performance for review goals with specific target percentages, calculated percentages are rounded to the nearest whole number up to 99 percent. Percentages above 99 percent, but below 100 percent, are always rounded down to 99 percent.

- "Filing status" refers to whether the review team has decided that the application is administratively and scientifically complete and contains adequate content, presentation, and organization of information.

- Preliminary review goal performance for FY 2022 submissions is shown as the percentage of submissions completed within goal as of September 30, 2022, excluding any submissions that have not yet reached their due date. The highest possible percent of reviews that may be completed within goal is shown as the highest possible review goal performance.

- Review goal performance presented in this report for Premarket Notifications (or 510(k)s) includes CDRH's Third Party 510(k)s. Information on the CDRH 510(k) review goal performance without Third Party 510(k)s can be found in the MDUFA IV Quarterly Performance Reports located on FDA's website.[4]

2. MDUFA Performance Enhancement Goals

For this report, "performance enhancement goals" are defined as any non-review goal identified in the letters[5] described in section 201(b) of MDUFA IV for the applicable

[4] www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports.

[5] https://www.fda.gov/files/about%20fda/published/MDUFA---Performance-Goals-and-Procedures--Fiscal-Years-2018-Through-2022.pdf

fiscal year. Performance information on the FY 2022 performance enhancement goals is located in Appendices D and E of this report.

3. Additional Performance Data

On May 5, 2017, the Consolidated Appropriations Act, 2017 (Public Law 115-31), was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year ending September 30, 2017. Senate Report 114-259 directed FDA to provide performance information related to medical devices—specifically, the extent to which the Agency's responses meet statutory time frames and total numbers for De Novo classification requests under section 513(f)(2) (De Novo classification) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for requests for information about classification under section 513(g), and for postmarket device surveillance plan submissions under section 522 of the FD&C Act (also known as a "section 522 plan"). These data are contained in Appendix B of this report.

As stated earlier, on August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products. FDARA requires "additional information" (section 903, beginning in FY 2018), a "rationale for MDUFA program changes" (section 903, beginning in FY 2020), and specified analyses of the use of funds (section 904, beginning in FY 2018) in the annual performance reports of each of the human medical product user fee programs. FDARA also requires FDA to publicly issue a corrective action report that either (1) confirms that the Agency's commitment letter goals were met and makes recommendations for improvements or (2) identifies which commitment letter goals were not met in MDUFA IV for the applicable fiscal year (section 904). This information is contained in Appendices C, D, E, and F of this report.

B. Submission Types Included in This Report

The following submission types are included in the MDUFA performance data tables in this report:

- **Original PMA** - An application providing scientific and medical data to demonstrate a reasonable assurance that a Class III medical device is safe and effective for its intended use.
- **PDP** - A PDP allows an applicant to reach an early agreement with FDA as to what will be done to demonstrate the safety and effectiveness of a new device. Early interaction in the development cycle of a device allows an applicant to address the concerns of FDA before expensive and time-consuming resources are expended. A PDP that has been declared completed by FDA is considered to have an approved PMA.

- **Panel-Track PMA Supplement** - A supplemental application to an approved PMA or premarket report that requests approval of a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

- **Premarket Report for Reprocessed Single Use Devices** - A type of premarket application required for high-risk devices originally approved for a single use (that is, use on a single patient during a single procedure) that a manufacturer has reprocessed for an additional use. Reprocessors of certain single use devices are required to submit premarket reports instead of PMAs.
- **180-Day PMA Supplement** - A supplemental application to an approved PMA or premarket report that requests approval of a significant change in aspects of a device, such as its design, specifications, or labeling, when demonstration of a reasonable assurance of safety and effectiveness either does not require new clinical data or requires only limited clinical data.
- **Real-Time PMA Supplement** - A supplement to an approved PMA or premarket report that requests approval of 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** - The De Novo classification process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process. Devices that are classified into Class I or Class II through a De Novo classification request may be marketed and used as predicates for future premarket notification (i.e., 510(k)) submissions.
- **Premarket Notification (510(k))** - A premarket submission made to FDA to demonstrate that a device to be marketed is substantially equivalent to a legally marketed predicate device that is not subject to the PMA review process. Applicants must compare their proposed device to one or more similar legally marketed devices and support their substantial equivalence claim. [6]
- **Clinical Laboratory Improvement Amendments (CLIA) Waiver** - A categorization issued by FDA allowing certain laboratory tests to be performed by laboratories with a CLIA Certificate of Waiver
- **CLIA Waiver by Application** - A submission providing data to demonstrate

[6] For more information on 510(k)s, see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

that a laboratory test is simple and has an insignificant risk of erroneous results.

- **Dual 510(k) and CLIA Waiver by Application** - A single premarket submission seeking both 510(k) clearance and CLIA waiver. Generally, to support 510(k) clearance and CLIA waiver, such submissions demonstrate that a laboratory test is substantially equivalent to a legally marketed device, as appropriate, and is simple and has an insignificant risk of erroneous results.
- **Pre-Submission** - 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, a meeting or teleconference in which the feedback is documented in meeting minutes. A "Pre-Submission meeting" is a meeting or teleconference in which FDA provides its substantive feedback on the Pre-Submission. A Pre-Submission provides the opportunity for an applicant to obtain FDA's feedback prior to an intended submission of an Investigational Device Exemption (IDE) or marketing application. The request should include specific questions regarding review issues relevant to a planned IDE or marketing application.

- **BLA** - An application submitted when an applicant wishes to obtain licensure of a biological product. A "priority BLA" is a BLA for a product that would, if approved, involve a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. A "non-priority BLA" is considered a "standard BLA."[7]

- **BLA Supplement** - A supplemental application to an approved BLA requesting approval of a change to a licensed biological product. When the change has the substantial potential to adversely affect the safety or effectiveness of the product, FDA's approval is required prior to product distribution. A supplement to an approved application proposing to make one or more changes to a product, its manufacturing, or its labeling that necessitates the submission of data from significant clinical studies is considered an "Efficacy Supplement."

- **BLA Resubmission and BLA Efficacy Supplement Resubmission** - A resubmission used to respond to a letter from FDA indicating that the information was deficient. For Class I resubmissions, the new information may include matters related to product labeling, safety updates, and other minor clarifying information. For Class II resubmissions, the new information could warrant presentation to an advisory committee or a re-inspection of the manufacturer's device establishment.

[7] For more information on BLAs, see www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

II. MDUFA IV Review-Time Goals and Commitments

For this report, MDUFA IV review goals include review goals with specific target percentages, Pre-Submission written feedback goals, and shared outcome goals. The tables below summarize the review goal commitments agreed to in MDUFA IV for FY 2018 through FY 2022.

A. Review Goals with Specific Target Percentages

The tables below summarize the 23 review goals agreed to in MDUFA IV that have specific target percentages. Review goals with specific target percentages are defined by both a "review-time goal" (i.e., the time period, identified by the number of calendar days or FDA days for when individual submissions are to have an interaction or be acted on) and "commitment target" (i.e., the target percentage of submissions required to meet the review-time goal), both of which are summarized below for all relevant submission types and for each fiscal year from FY 2018 through FY 2022.

The following table also summarizes the review goal for Pre-Submission written feedback. The commitment target for this goal, which is included for ease of reference, is defined by the number of submissions, not percentage of submissions, that meet the review-time goal.

Review-Time Goals and Commitment Targets

Submission Type	Review-Time Goal	Commitment Target				
		FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision with No Advisory Committee Input	180 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee Input	320 FDA days	90%	90%	90%	90%	90%
180-Day PMA Supplements						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision	180 FDA days	95%	95%	95%	95%	95%
Real-Time PMA Supplements						
Decision	90 FDA days	95%	95%	95%	95%	95%

Review-Time Goals and Commitment Targets (continued)

Submission Type	Review-Time Goal	Commitment Target				
		FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novo Classification Requests						
Decision	150 FDA days	50%	55%	60%	65%	70%
510(k) Premarket Notifications						
Substantive Interaction	60 calendar days	95%	95%	95%	95%	95%
Decision	90 FDA days	95%	95%	95%	95%	95%
CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	90%	90%	90%	90%	90%
Decision with No Advisory Committee Input	150 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee Input	320 FDA days	90%	90%	90%	90%	90%
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	90%	90%	90%	90%	90%
Decision with No Advisory Committee Input	180 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee Input	320 FDA days	90%	90%	90%	90%	90%
Pre-Submissions						
Provide Written Feedback*	70 calendar days or 5 days prior to the meeting, whichever comes sooner	1,530	1,645	1,765	1,880	1,950
BLAs						
Priority Original BLAs	6 calendar months	90%	90%	90%	90%	90%
Standard Original BLAs	10 calendar months	90%	90%	90%	90%	90%
BLA Manufacturing Supplements Requiring Prior Approval	4 calendar months	90%	90%	90%	90%	90%
Priority BLA Efficacy Supplements	6 calendar months	90%	90%	90%	90%	90%
Standard BLA Efficacy Supplements	10 calendar months	90%	90%	90%	90%	90%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	2 calendar months	90%	90%	90%	90%	90%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	6 calendar months	90%	90%	90%	90%	90%

*This goal is defined by the number, not percentage, of submissions that meet the review-time goal.

B. Shared Outcome Goals

The table below summarizes the review goals related to the shared outcomes agreed to in MDUFA IV for relevant submission types and for each fiscal year from FY 2018 through FY 2022. Shared outcome goals represent a commitment by both FDA and applicants; these goals are reported as the average total time to decision (TTD) within a closed cohort and are based on the methodology prescribed in the MDUFA IV commitment letter.

MDUFA IV's Shared Outcome Goals

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs and Panel-Track PMA Supplements					
Total TTD Goal (Days)	320	315	310	300	290
510(k) Premarket Notifications					
Total TTD Goal (Days)	124	120	116	112	108

III. MDUFA IV Review Goal Performance

A. Summary of Review Goal Performance

For this report, MDUFA IV review goals include review goals with specific target percentages, Pre-Submission written feedback goals, and shared outcome goals. The tables below summarize FDA's MDUFA IV review goal performance in FY 2020, FY 2021, and FY 2022. FDA will continue to report on review goal performance until it can determine if it has met or missed each goal for which it has received sufficient submissions to determine the goal performance.

Each fiscal year, FDA has the following 25 MDUFA IV review goals: 23 review goals with specific target percentages (including one Pre-Submission written feedback goal) and two shared outcome goals. Preliminary and updated performance data through September 30, 2022, including completed and pending reviews, indicate that FDA has sufficient data to calculate performance results on 15 FY 2020 goals, 13 FY 2021 goals, and 16 FY 2022 goals. FDA met (or has the potential to meet) 11 of the 15 FY 2020 review goals, seven of the 13 FY 2021 review goals, and 11 of the 16 FY 2022 review goals. FDA's response to the unprecedented COVID-19 public health emergency has impacted its MDUFA performance, resulting in four missed FY 2020 review goals, six missed FY 2021 review goals, and five missed FY 2022 review goals.

B. Review Goals with Specific Target Percentages

The following tables provide FDA's preliminary performance data on the 23 review goals with specific target percentages for submissions in the relevant fiscal year MDUFA Cohort [A]. This table includes FDA's performance on the Pre-Submission written feedback goal. The "Pre-Submission written feedback goal," which is included for ease of reference, is defined by the number of submissions, not a specific target percentage. Additional detail on FDA's review goal performance can be found in the MDUFA IV Quarterly Performance Reports posted on FDA's website.[8]

Additional information about the performance provided in the below tables is as follows:

- *MDUFA Cohort [A]* = the number of submissions Completed Within Goal [B], Completed Overdue [C], Pending Within Goal [D], and Pending Overdue [E] ([A] = [B]+[C]+[D]+[E]).

[8] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452535.htm.

- *Completed Within Goal [B]* = the number of submissions with a MDUFA action as of September 30, 2022, that met the MDUFA goal.

- *Completed Overdue [C]* = the number of submissions with a MDUFA action as of September 30, 2022, that did not meet the MDUFA goal.

- *Pending Within Goal [D]* = the number of submissions without a MDUFA action that were still within the goal as of September 30, 2022.

- *Pending Overdue [E]* = the number of submissions without a MDUFA action that were past the goal as of September 30, 2022.

- *Review Goal [F]* = the "commitment target" as defined in the previous section of this report, which is the target percentage of the relevant fiscal year MDUFA cohort submissions that are required to meet the review-time goal.

- *Current Review Goal Performance [G]* = the percentage of actions that FDA completed within the review-time goal. When calculating [G], the numerator is the number Completed Within Goal [B]. The denominator is the MDUFA Cohort [A] minus all submissions Pending Within Goal [D]. Therefore, Current Review Goal Performance [G] = [B] / ([A] - [D]). When the fiscal year cohort was sufficiently complete to determine the outcome, this column indicates whether FDA met ("(MET)" in the tables below) or missed ("(MISSED)" in the tables below) the goal.

- *Highest Possible Review Goal Performance [H]* = the scenario when all pending submissions within the goal are completed within that goal. [H] is calculated by adding all submissions Pending Within Goal [D] to those already Completed Within Goal [B] divided by the MDUFA Cohort [A]. Therefore, Highest Possible Review Goal Performance [H] = ([B] + [D]) / [A].

- For certain submissions, the MDUFA IV commitment letter states it is acceptable to combine a MDUFA cohort of less than 10 submissions (from any one fiscal year) with the MDUFA cohort of other fiscal year(s) to form a combined cohort of 10 or more submissions and calculate a combined performance. Applicable submissions include PMA submissions that require Advisory Committee input and CLIA Waiver by Application submissions (including "Dual 510(k) and CLIA Waiver by Applications"). If performance has been calculated in this way, the table will include data from the combined cohort (used to calculate performance results), followed by data from the single fiscal year (in parentheses). Performance for applicable review goals will not be calculated if, after combining with other fiscal year cohort(s), a combined cohort does not include at least 10 submissions.

1. FY 2022 Preliminary Performance Data

FDA had a sufficiently complete MDUFA cohort to determine the outcome for six of the 23 review goals with specific target percentages. For the remaining 17 goals, the MDFUA cohort was insufficiently complete to determine the outcome (eight goals), FDA did not receive any submissions (seven goals), or the received MDUFA cohort was insufficient (in single or combined years) to calculate performance results (two goals).

For goals for which FDA received a sufficient MDUFA cohort to calculate performance results and had at least one "Completed" submission, the table below includes both a calculated "Current Review Goal Performance" (column [G]) and "Highest Possible Review Goal Performance" (column [H]). The review goals for which the MDUFA cohort was sufficiently complete to determine the outcome (as well as whether the goal was met or missed) are shown in **bold** text.

In summary, as of September 30, 2022, FDA had met one review goal with a specific target percentage and missed five. Specifically, FDA missed the 180-Day PMA Supplements – Substantive Interaction, 510(k) Premarket Notifications - Substantive Interaction, 510(k) Premarket Notifications – Decision, Dual 510(k) and CLIA waiver – Substantive Interaction (FY 2022 data combined with FY 2021 data), and Dual 510(k) and CLIA waiver – Decision (FY 2022 data combined with FY 2021 data) review goals.

FY 2022 Preliminary Performance Data

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports								
Substantive Interaction	37	24	1	11	1	95%	92%	95%
Decision with No Advisory Committee Input	37	8	0	28	1	90%	89%	97%
Decision with Advisory Committee Input[§]	2 (0)	1 (0)	0 (0)	1 (0)	0 (0)	90%	‡	‡
180-Day PMA Supplements								
Substantive Interaction	150	84	18	44	4	95%	79% **(MISSED)**	85%
Decision	150	44	2	102	2	95%	92%	97%
Real-Time PMA Supplements								
Decision	270	199	3	64	4	95%	97%	97%
De Novo								

Decision	60	10	0	46	4	70%	71%	93%
510(k) Premarket Notifications								
Substantive Interaction	3,122	2,393	268	420	41	95%	89% **(MISSED)**	90%
Decision	3,165	1,580	59	1,406	120	95%	90% **(MISSED)**	94%
CLIA Waiver by Applications**								
Substantive Interaction‡	5 (1)	0 (0)	3 (0)	1 (1)	0 (0)	90%	‡	‡
Decision with No Advisory Committee Input‡	5 (1)	1 (0)	1 (0)	1 (1)	2 (0)	90%	‡	‡
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications§								
Substantive Interaction	13 (9)	0 (0)	6 (2)	3 (3)	4 (4)	90%	**0% (MISSED)**	23%
Decision with No Advisory Committee Input	13 (9)	1 (0)	1 (0)	7 (7)	4 (2)	90%	**17% (MISSED)**	62%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,362	1,859	503	556	83	1950	N/A	N/A
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	1	0	0	1	0	90%	0%	100%
BLA Manufacturing Supplements Requiring Prior Approval	48	39	0	9	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	0	90%	*	*
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2	2	0	0	0	90%	**100% (MET)**	100%

* No submissions were received in FY 2022; therefore, no performance can be reported.

Third Party 510(k)s have a Decision but do not have a Substantive Interaction. As such, both Third Party and non-Third Party 510(k)s are included in the Decision data, but only non-Third Party 510(k)s are included in the Substantive Interaction data.

‡ Per an agreement in the MDUFA IV commitment letter, the MDUFA cohort from this fiscal year was combined with the cohort from the prior fiscal year because the cohort for the prior fiscal year was insufficient (< 10) to calculate performance results. However, the combined cohort was also insufficient (< 10) to calculate performance results.
§ The performance shown is from a combined MDUFA cohort of FY 2021 and FY 2022 submissions.
** The performance shown is from a combined MDUFA cohort of FY 2020, FY 2021, and FY 2022 submissions.

2. FY 2021 Updated Performance Data

FDA had a sufficiently complete MDUFA cohort to determine the outcome for 10 of the 23 review goals with specific target percentages. For the remaining 13 goals, the MDFUA cohort was insufficiently complete to determine the outcome (one goal), FDA did not receive any submissions (seven goals), or the received MDUFA cohort was insufficient (in single or combined years) to calculate performance results (five goals).

For goals for which FDA received a sufficient MDUFA cohort to calculate performance results and had at least one "Completed" submission, the table below includes both a calculated "Current Review Goal Performance" (column [G]) and "Highest Possible Review Goal Performance" (column [H]). The review goals for which the MDUFA cohort was sufficiently complete to determine the outcome (as well as whether the goal was met or missed) are shown in **bold** text in the table below.

In summary, as of September 30, 2022, FDA had met four review goals with a specific target percentage and missed six. Specifically, FDA met the Real Time PMA – Decision, Pre-Submissions – Provide Written Feedback, Standard Original BLAs and BLA Manufacturing Supplements Requiring Prior Approval review goals and missed the (1) Original PMA, PDPs, Panel Track PMA Supplements and Pre-Market Reports - Substantive Interaction; (2) Original PMA, PDPs, Panel Track PMA Supplements and Pre-Market Reports - Decision with No Advisory Committee Input; (3) 180-Day PMA Supplements – Substantive Interaction; (4) 180-Day PMA Supplements – Decision; (5) 510(k) Premarket Notifications - Substantive Interaction; and (6) 510(k) Premarket Notifications – Decision review goals.

FY 2021 Updated Performance Data

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports								
Substantive Interaction	72	57	15	0	0	95%	79% **(MISSED)**	79%
Decision with No Advisory Committee Input	70	42	11	10	7	90%	70% **(MISSED)**	74%
Decision with Advisory Committee Input	2	1	0	1	0	90%	**	**
180-Day PMA Supplements								
Substantive Interaction	184	151	32	0	1	95%	82% **(MISSED)**	82%
Decision	184	155	19	8	2	95%	88% **(MISSED)**	89%
Real-Time PMA Supplements								
Decision	285	274	11	0	0	95%	96% **(MET)**	96%
De Novo Classification Requests								
Decision	56	28	12	13	3	65%	65%	73%
510(k) Premarket Notifications								
Substantive Interaction	3,739	3,260	456	7	16	95%	87% **(MISSED)**	87%
Decision	3,522	2,881	313	255	73	95%	88% **(MISSED)**	89%
CLIA Waiver by Applications #§								
Substantive Interaction#	4 (3)	0 (0)	3 (3)	0 (0)	0 (0)	90%	‡	‡
Decision with No Advisory Committee Input	4 (3)	1 (1)	1 (0)	0 (0)	2 (2)	90%	‡	‡
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*

* No submissions were received in FY 2021; therefore, no performance can be reported.

Third Party 510(k)s have a Decision but do not have a Substantive Interaction. As such, both Third Party and non-Third Party 510(k)s are included in the Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.

‡ Per an agreement in the MDUFA IV commitment letter, the MDUFA cohort from this fiscal year was combined with the cohort from the prior fiscal year because the cohort for the prior fiscal year was insufficient (< 10) to calculate performance results. However, the combined cohort was also insufficient (< 10) to calculate performance results. Therefore, performance will be calculated in a future fiscal year if a combined cohort of 10 or more submissions is achieved.

One CLIA Waiver was denied before Substantive Interaction.

§ The performance shown is from a combined MDUFA cohort of FY 2020 and FY 2021 submissions.

** The MDUFA cohort for this fiscal year was insufficient (<10) to calculate performance results. Therefore, per an agreement in the MDUFA IV commitment letter, performance will be calculated in a future fiscal year if a combined cohort of 10 or more submissions is achieved.

FY 2021 Updated Performance Data (continued)

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	4	0	4	0	0	90%	‡	‡
Decision with No Advisory Committee Input	4	1	1	0	2	90%	‡	‡
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,555	2,039	516	N/A	N/A	1880	2039 **(MET)**	2039
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	2	2	0	0	0	90%	100% **(MET)**	100%
BLA Manufacturing Supplements Requiring Prior Approval	52	52	0	0	0	90%	100% **(MET)**	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	0	90%	*	*
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	0	90%	*	*

* No submissions were received in FY 2021; therefore, no performance can be reported.

Third Party 510(k)s have a Decision but do not have a Substantive Interaction. As such, both Third Party and non-Third Party 510(k)s are included in the Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.

‡ The MDUFA cohort for this fiscal year was insufficient (< 10) to calculate performance results. Therefore, per an agreement in the MDUFA IV commitment letter, performance will be calculated in a future fiscal year if a combined cohort of 10 or more submissions is achieved.

3. *FY 2020 Updated Performance Data*

By September 30, 2022, FDA had a sufficiently complete MDUFA cohort to determine the outcome for the five remaining review goals with specific target percentages from the FY 2020 cohort. In summary, FDA met four of the review goals (Original PMA, PDP, Panel Track PMA Supplements, and Premarket Reports – Decision with Advisory Committee Input, 180-Day Supplements – Decision, De Novo Classification Requests – Decision, and 510(k) Premarket Notifications - Decisions).

FY 2020 Updated Performance Data

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports								
Decision with No Advisory Committee Input	72	64	4	3	1	90%	94%	93%
Decision with Advisory Committee Input*	11 (4)	10 (4)	1 (0)	0 (0)	0 (0)	90%	91% **(MET)**	91%
180-Day PMA Supplements								
Decision	172	164	4	3	1	95%	97% **(MET)**	97%
De Novo Classification Requests								
Decision	64	40	21	0	3	60%	63% **(MET)**	63%
510(k) Premarket Notifications								
Decision	3,243	3,083	136	15	9	95%	96% **(MET)**	96%

* Per an agreement in the MDUFA IV commitment letter, the MDUFA cohort from this fiscal year was combined with the cohort from a prior fiscal year because the prior fiscal year cohort was insufficient (< 10) to calculate performance results. Now that a combined cohort of 10 or more submissions has been achieved, performance can be calculated. The performance shown is from a combined MDUFA cohort of FY 2018, FY 2019, and FY 2020 submissions.

4. *FY 2019 Updated Performance Data*

By September 30, 2022, FDA had a sufficiently complete MDUFA cohort to determine the outcome for the one remaining review goal with specific target percentages from the FY 2019 cohort. In summary, FDA met this goal (Original PMA, PDP, Panel Track PMA Supplements, and Premarket Reports – Decision with No Advisory Committee Input).

FY 2019 Updated Performance Data

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports								
Decision with No Advisory Committee Input	56	51	5	0	0	90%	91% **(MET)**	91%

C. Shared Outcome Goals (FY 2018 Through FY 2022)

FDA has two shared outcome goals each fiscal year, one for Original PMAs and Panel-Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort based on the methodology prescribed in the MDUFA IV commitment letter. A PMA cohort is considered closed when 95 percent of applications have reached a decision. A 510(k) cohort is considered closed when 99 percent of accepted submissions have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER.

FDA's performance in the MDUFA IV shared outcome goals (as well as whether the goal was met or missed) as of September 30, 2022, is shown in **bold** text in the table below. The FY 2020 510(k) cohort met the decision threshold to calculate the average TTD, and FDA missed the goal. The FY 2021 and FY 2022 510(k) cohorts and the FY 2020, FY 2021, and FY 2022 PMA cohorts have not met the decision threshold to calculate the average TTD. FDA will report the average TTD for these goals in future reports once these cohorts have met the decision threshold.

MDUFA IV's Shared Outcome Goals

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs and Panel-Track PMA Supplements					
TTD Goal (Days)	320	315	310	300	290
TTD Performance (Days)	**272 (MET)**	**267 (MET)**	*	*	*
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
TTD Performance (Days)	**123 (MET)**	**128 (MISSED)**	**139 (MISSED)**	*	*

* As of September 30, 2022, the fiscal year cohort had not met the decision threshold to calculate performance results.

IV. MDUFA Review Workloads: FY 2017 Through FY 2022

The table below compares review workloads for submission types with MDUFA review goals for FY 2022 and a 5-year average (FY 2017 through FY 2021).

- The review workload reflects the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee). Details of which administrative requirements apply to which submission type are outlined in Appendix A.

- Five-year averages and comparisons are calculated only for submission types that had MDUFA review goals in the entire 5-year period. Review workload is reported as "N/A" for years when a submission type did not have MDUFA review goals.

- Review workload numbers may differ from the MDUFA cohort numbers presented in other tables because submissions closed without MDUFA decisions are not included in the MDUFA cohort.

The review workload in FY 2022 was calculated for 13 of the 15 submission types that had data available to calculate a 5-year average. The other two submission types were new to MDUFA IV and did not have the 5-year historical data. Four of the 13 submission types did not receive any submissions for FY 2022. Original PMAs and Panel-Track Supplements had a notable workload decrease in FY 2022 compared to the 5-year average.

Review Workload by Submission Type

Submission Type	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	5-Year Average (FY 2017 to FY 2021)	FY 2022 Compared to 5-Year Average
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	70	77	59	80	79	46	73	-37%
180-Day PMA Supplements	276	196	196	184	195	153	209	-27%
Real-Time PMA Supplements	338	341	375	358	287	274	340	-19%
510(k) Premarket Notifications	4,098	3,591	3,776	3,830	4,092	3885	3877	0%
De Novo Classification Requests	n/a	56	62	69	63	80	*	*
CLIA Waiver by Applications	7	4	9	1	3	1	5	-80%
Dual 510(k) and CLIA Waiver by Applications	6	11	6	6	4	9	7	+29%
Pre-Submissions‡	n/a	2783	3253	3383	3170	3177	*	*
BLAs								
Priority Original BLAs	1	0	0	0	0	0	0	0%
Standard Original BLAs	5	14	4	0	2	1	5	-80%
BLA Manufacturing Supplements Requiring Prior Approval	38	94	54	92	52	48	66	-27%
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0	0%
Standard BLA Efficacy Supplements	1	1	8	2	0	0	2	-100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	17	0	0	0	4	-100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	40	7	0	1	0	2	10	-80%

* No 5-year average is available due to a lack of MDUFA review goals in some years.
‡ This does not include Pre-Submissions resubmitted after being closed without feedback due to a reallocation of resources for COVID-19 activities.

Appendix A: Definitions of Key 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 FD&C Act;
- a premarket notification under section 510(k) of the FD&C Act;
- a De Novo classification request under section 513(f)(2) of the FD&C Act;
- a Pre-Submission;
- a CLIA waiver by application;
- a Dual 510(k) and CLIA waiver by application; or
- a BLA or supplement to a BLA under the Public Health Service Act.

B. Electronic Copy (eCopy): An electronic copy is an exact duplicate of a submission, created and submitted on a CD, DVD, or in another electronic media format that FDA has agreed to accept, accompanied by a copy of the signed cover letter and the complete original paper submission. An electronic copy is not considered to be an "electronic submission," although it is considered to be a type of submission in electronic format.

C. FDA Days: FDA days are the calendar days in which a submission is considered to be under review at the Agency for submissions that have been accepted (510(k) or De Novo classification request) or filed (PMA) or submitted (CLIA Waiver by Application). FDA days begin on FDA's date of receipt of the Third Party or RTA-acceptable non-Third Party submission or of the amendment to the submission that enables the submission to be accepted (510(k) or De Novo classification request) or filed (PMA).

D. MDUFA Decisions: MDUFA decisions for each MDUFA submission type are as follows:

Submission Type	MDUFA Decisions
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	• Approval • Approvable • Approvable pending good manufacturing practice (GMP) inspection • Not Approvable • Withdrawal (including Deletions) • Denial
180-Day PMA Supplements	• Approval • Approvable • Approvable pending GMP inspection • Not Approvable

Submission Type	MDUFA Decisions
Real-Time PMA Supplements	• Approval • Approvable • Not Approvable
510(k)s	• Substantially Equivalent (SE) • Not Substantially Equivalent (NSE)
De Novo Classification Requests	• Grant • Withdrawal (including Deletions) • Decline
CLIA Waiver by Applications	• Approval • Withdrawal (including Deletions) • Denial
Dual 510(k) and CLIA Waiver by Applications	• SE/Approval • SE/Withdrawal • SE/Denial • Withdrawal (including Deletions) • NSE/Denial
Pre-Submissions	• Email Reply • Email Feedback Sent Before Meeting
BLAs and Biologics License Supplements (BLSs)	• Complete response • Approval • Denial

BLAs have many application categories: Priority Original, Standard Original, Priority Efficacy Supplements, Standard Efficacy Supplements, Manufacturing Supplements Requiring Prior Approval, Class I Original BLA and BLA Efficacy Supplement Resubmissions, and Class II Original BLA and BLA Efficacy Supplement Resubmissions. Submissions placed on Application Integrity Program 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, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission meeting is a meeting or teleconference in which FDA provides its substantive feedback on the Pre-Submission. A Pre-Submission provides the opportunity for an applicant to obtain FDA's feedback prior to an intended submission of an IDE or marketing application. The request should include specific questions regarding review issues relevant to a planned IDE or marketing application (e.g., questions regarding pre-clinical and clinical testing protocols or data requirements). A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. Certain forms of FDA's feedback to applicants, such as the following, are not considered Pre-Submissions because they represent information that can be readily addressed by the FDA review team or are another type of submission:

- General information requests initiated through the Division of Industry and Consumer Education

- General questions regarding FDA's 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's feedback on specific questions related to a planned submission

- Requests for clarification on technical guidance documents, especially when contact is recommended by FDA in the guidance document. However, the following requests should generally be submitted as a Pre-Submission to ensure appropriate input from multiple reviewers and management: consultation on device types not specifically addressed in the guidance document; clarification of nonclinical or clinical studies not addressed in the guidance document; and requests regarding use of an alternative means to address recommendations specified in the 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.

- Interactions requested by either the applicant or FDA during the review of a marketing application (i.e., following the submission of a marketing application, but prior to FDA reaching a decision).

F. Review Workload: The review workload reflects the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee). Details of which administrative requirements apply to which submission type are as follows:

Submission Type	Applicable Administrative Requirements
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	eCopy, User Fee
180-Day PMA Supplements	eCopy, User Fee
Real-Time PMA Supplements	eCopy, User Fee
510(k)s (non-Third Party)	eCopy, User Fee
510(k)s (Third Party)	eCopy

Submission Type	Applicable Administrative Requirements
De Novo Classification Requests	eCopy, User Fee
CLIA Waiver by Applications	None
Dual 510(k) and CLIA Waiver by Applications	eCopy, User Fee
Pre-Submissions	eCopy
Priority Original BLAs	eCopy, User Fee
Standard Original BLAs	eCopy, User Fee
BLA Manufacturing Supplements Requiring Prior Approval	eCopy
Priority BLA Efficacy Supplements	eCopy, User Fee
Standard BLA Efficacy Supplements	eCopy, User Fee
Class I Original BLA and BLA Efficacy Supplement Resubmissions	eCopy
Class II Original BLA and BLA Efficacy Supplement Resubmissions	eCopy

G. Reviewing Center: Review goal performance data in this report are based on FDA's combined performance on MDUFA submissions reviewed in CDRH and/or CBER, depending on submission type. Details of which Center reviews which submission type are as follows:

Submission Type	Reviewing Center(s)
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	CDRH and CBER
180-Day PMA Supplements	CDRH and CBER
Real-Time PMA Supplements	CDRH and CBER
510(k)s	CDRH and CBER
De Novo Classification Requests	CDRH and CBER
CLIA Waiver by Applications	CDRH only
Dual 510(k) and CLIA Waiver by Applications	CDRH only

Submission Type	Reviewing Center(s)
Pre-Submissions	CDRH and CBER
BLAs and BLSs	CBER only

H. Substantive Interaction: Substantive Interaction is an email, letter, teleconference, video conference, fax, or other form of communication, such as a request for Additional Information or a Major Deficiency letter, by FDA notifying the applicant of substantive deficiencies identified in the initial submission review, or a communication stating that FDA has not identified any deficiencies in the initial submission review and that any further minor deficiencies will be communicated through interactive review. An approval or clearance letter issued on or 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 a decision by FDA. In addition, interactive review will be used where, in FDA's estimation, it will lead 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., a modification of the proposed Indications for Use may lead to revisions in labeling and administrative items) or if these minor issues 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 that stops the review clock.

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 I resubmitted applications – Applications resubmitted after a complete response letter that includes only the following items (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 one or two lots used to support approval
(h) A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class I category)
(i) Other minor clarifying information (determined by the Agency as fitting the Class I 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 II resubmitted applications – Resubmissions that include any other items, including any item that would require presentation to an advisory committee.

Appendix B: Performance Information for De Novo, Section 513(g), and Section 522 Postmarket Device Surveillance Plan Submissions

On May 5, 2017, the Consolidated Appropriations Act, 2017 (Public Law 115-31), was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year ending September 30, 2017. Senate Report 114-259 directed FDA to provide performance information related to medical devices including the extent to which the Agency's responses have met statutory time frames. Specifically, FDA was directed to report (1) the number of De Novo classification requests under section 513(f)(2) of the FD&C Act for which FDA met the statutory requirement and the total number of De Novo classification requests submitted; (2) the total number of requests for classification under section 513(g) and the number that met the statutory requirement; and (3) the number of orders for postmarket device surveillance under a section 522 plan for which FDA responded within 60 days.

The table below provides the requested information in the three categories and includes the percentage of submissions for which FDA met its statutory timelines. This is followed by additional information about each of the three submission types. The number of De Novo classification requests received includes those that passed eCopy and user fee requirements. Note that the 120-day timeline specified in section 513(f)(2) of the FD&C Act, against which the performance data in this Appendix is calculated, is different from the MDUFA IV performance goal for De Novo requests, which is based on a timeline of 150 FDA days. The number of 513(g) submissions received are those that passed user fee requirements.

As of September 30, 2022, only FY 2018 and FY 2019 had closed cohorts. For these cohorts, FDA met the statutory timelines for issuing a final decision on a De Novo classification request 21 to 34 percent of the time. Fiscal years 2020 to 2022 are not currently closed. Therefore, these data may change. As of September 30, 2022, FDA had met the statutory timelines for issuing a final decision on a De Novo classification request for FYs 2020 to 2022, 18 to 50 percent of the time. For FY 2018 to FY 2022, FDA responded to 513(g) requests within the statutory time frame 16 to 36 percent of the time and met the statutory time frame for responding to a section 522 plan 38 to 86 percent of the time.

Performance Data for Submissions with Statutory Time Frames

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novo Classification Requests Under 513(f)(2)					
Number received that passed applicable administrative requirements	56	62	64	56	60
Number completed with a Granted, Declined, or Withdrawn decision	56	62	61	40	10
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory time frame of 120 days*	18	21	13	7	5
Percent that met the statutory time frame	32%	34%	21%	18%	50%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)					
Number received that passed applicable administrative requirements	115	132	151	133	149
Number to which FDA responded within the statutory time frame of 60 days	41	47	44	29	24
Percent that met the statutory time frame‡	36%	36%	29%	22%	16%
Postmarket Surveillance Plans					
Number received	13	11	28	29	13
Number of FDA responses within 60 days of receipt	5	6	21	25	8
Percent that met the statutory time frame	38%	55%	75%	86%	62%

* Other De Novo classification request final decisions include Jurisdiction Transferred.
This metric is defined as the number of De Novo classification requests with a Granted/Declined/Withdrawn decision within 120 FDA days, as a percentage of the sum of the number of De Novo classification requests with a Granted/Declined/Withdrawn decision plus the number of De Novo classification requests pending a decision longer than 120 FDA days as of the cutoff date.
‡ These data are defined as the number of 513(g)s with a final decision within 60 FDA days, as a percentage of the sum of the number of 513(g)s pending a decision for longer than 60 FDA days as of the cutoff date.

Appendix C: Additional Information from FDARA's Section 903 Requirement

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products. Section 903 of FDARA requires "additional information" in the annual performance reports of each of the human medical product user fee programs. Specifically, section 903(b)(2) of FDARA requires the MDUFA annual performance report to include the following (for CDRH only and starting in FY 2018):

(I) The number of premarket applications filed under section 515 per fiscal year for each review division;

(II) The number of reports submitted under section 510(k) per fiscal year for each review division; and

(III) The number of expedited development and priority review designations under section 515C per fiscal year.

The information below fulfills these requirements.

A. Number of Premarket Applications Filed and Reports Submitted

The table below addresses the requirements of section 738A(a)(1)(A)(ii) of the FD&C Act as added by section 903(b)(2) of FDARA. Specifically, the table provides "the number of premarket applications filed under section 515 per fiscal year for each review division" and "the number of reports submitted under section 510(k) per fiscal year for each review division," referred to in the table as the "MDUFA Cohort."

Relevant information about the MDUFA cohort numbers provided below is as follows:

- "Premarket applications filed under section 515" are defined as submissions reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2022. This definition is consistent with the interpretation of identical statutory language in section 904 of FDARA and is addressed in other sections of this report.

- "Reports submitted under section 510(k)" are defined as submissions reviewed as Premarket Notifications (510(k)s) (including those reviewed as Third Party 510(k) submissions) that had received a MDUFA decision or were pending a

MDUFA decision as of September 30, 2022. This definition is consistent with the interpretation of identical statutory language in section 904 of FDARA and is addressed in other sections of this report.

- In performance reports for FY 2018 and FY 2019, "each review division" was defined as each of the divisions within CDRH's Office of Device Evaluation and Office of In Vitro Diagnostics and Radiological Health (OIR). In performance reports for FY 2020 and later, "each review division" is defined as each of the Offices of Health Technology (OHTs) within CDRH's Office of Product Evaluation and Quality (OPEQ). OPEQ and OHTs were established as part of CDRH's 2019 reorganization, which was completed on September 30, 2019. For this report, the OHTs within OPEQ are roughly equivalent to the "review divisions" that existed (and were reported on) in FY 2018 through FY 2019. This definition is also consistent with the interpretation of similar statutory language in other parts of section 903 of FDARA and addressed in other sections of this report.

- Consistent with other parts of this report, the MDUFA cohort is based on a fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.

- Also consistent with other parts of this report, submissions that were closed without a MDUFA decision are not included in the MDUFA cohort and, therefore, are not included in the table below. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without a MDUFA decision, please refer to the review workload tables in other sections of this report.

- As stipulated in FDARA, the numbers below include only submissions reviewed by CDRH and do not include submissions reviewed by CBER. This is different from other parts of this report, where the MDUFA cohort includes submissions from both CDRH and CBER.

FY 2022 MDUFA Cohorts by CDRH's OHTs

Submission Type	MDUFA Cohort (CDRH only)	OHT1	OHT2	OHT3	OHT4	OHT5	OHT6	OHT7*	OHT8
Original PMA, PDP, Panel-Track PMA Supplements, and Premarket Reports									
Substantive Interaction	36	3	12	0	2	4	2	12	1
Decision with No Advisory Committee Input	36	3	12	0	2	4	2	12	1
Decision with Advisory Committee Input	0	0	0	0	0	0	0	0	0
180-Day PMA Supplements									
Substantive Interaction	143	19	51	14	10	18	3	27	1
Decision	143	19	51	14	10	18	3	27	1
Real-Time PMA Supplements									
Decision	261	24	121	27	6	30	8	45	0
510(k) Premarket Notifications									
Substantive Interaction	3087	422	315	372	613	217	524	203	421
Decision	3130	435	325	374	614	222	525	201	434

* This office is sometimes referred to as "OIR."
OHT7 was divided into OH7 and OHT8 during FY2022.

B. Number of Expedited Development and Priority Review Designations

The table below addresses the requirements of section 738A(a)(1)(A)(ii)(III) of the FD&C Act as added by section 903(b)(2) of FDARA. Specifically, the table provides "the number of expedited development and priority review designations under section 515C [actually 515B] per fiscal year," referred to in the table as the "Number of Breakthrough Device Designations."

Relevant information about the Breakthrough Device Designation numbers provided below is as follows:

- The number of breakthrough device designations represents the number of designation requests granted as of September 30, 2022, in the relevant fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.

- As stipulated in FDARA, the numbers below include only designation requests reviewed by CDRH and do not include those reviewed by CBER.

CDRH Breakthrough Device Designations

Cohort	Number of Breakthrough Device Designations
FY 2018	62
FY 2019	120
FY 2020	147
FY 2021	216
FY 2022	132*

*As of September 30, 2022, the FY 2022 cohort was 90 percent closed.

Appendix D: Analysis of the Use of Funds

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products. FDARA requires specified analyses of the use of funds in the annual performance reports of each of the human medical product user fee programs. These analyses are to include information such as differences between aggregate numbers of submissions and certain types of decisions, an analysis of performance goals, and a determination of causes affecting the ability to meet goals.

Section 904 of FDARA requires the issuance of corrective action reports. The required corrective action report is provided in Appendix E. The remaining required information is below.

A. Analysis of the Use of Funds

FDARA requires that the analysis of use of funds include information on (I) the differences between aggregate numbers of submissions and certain types of decisions, (II) an analysis of performance goals, and (III) a determination of causes affecting the ability to meet goals. These data are contained below.

1. Differences Between Aggregate Numbers

The following table addresses section 738A(a)(1)(A)(v)(I) of the FD&C Act as added by section 904(b)(1) of FDARA, pertaining to MDUFA, which requires FDA to include (beginning in FY 2018) data showing "[t]he difference between the aggregate number of premarket applications filed under section 515 and aggregate reports submitted under section 510(k) and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the Agency, accounting for –

(aa) the number of applications filed, and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the applicable fiscal year.

The table below provides the data required above for the applicable fiscal year as well as additional data necessary to interpret it. Relevant information about the data provided is as follows:

- *MDUFA Cohort [A]* = “aggregate number of premarket applications filed under section 515 and aggregate reports submitted under section 510(k).” The MDUFA Cohort [A] includes both Completed [B] and Pending [F] submissions ([A] = [B] + [F]). “Premarket applications filed under section 515” are defined as submissions reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2022. “Aggregate reports submitted under section 510(k)” are defined as submissions reviewed as Premarket Notifications (510(k)s) (including those reviewed as Third Party 510(k) submissions) that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2022. This definition is consistent with the interpretation of identical statutory language in section 903 of FDARA and is addressed in other sections of this report.

- Consistent with other parts of this report, the MDUFA cohort is based on a fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.

- Also consistent with other parts of this report, submissions that were closed without a MDUFA decision are not included in the MDUFA cohort and, therefore, are not included in the table below. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without a MDUFA decision, please refer to the review workload tables in other sections of this report.

- *Completed [B]* = the number of submissions with a MDUFA action as of September 30, 2022. Completed [B] includes both Completed Within Goal [C] and Completed Overdue [D] submissions ([B] = [C] + [D]).

- *Completed Within Goal [C]* = the number of Completed [B] submissions that had met the MDUFA goal as of September 30, 2022.

- *Completed Overdue [D]* = the number of Completed [B] submissions that had not met the MDUFA goal as of September 30, 2022.

- *Major deficiency letters, not approvable letters, denials [E]* = “aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the [A]gency” and represents the number of times Completed [B] submissions had this specific action (or equivalent) for each MDUFA goal. Specific actions relevant to each MDUFA goal and submission type are as follows:

Submission Type	Relevant Specific Action
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports	
Substantive Interaction	Major deficiency letter
Decision with No Advisory Committee Input	Not Approvable or Denial
Decision with Advisory Committee Input	Not Approvable or Denial
180-Day PMA Supplements	
Substantive Interaction	Major deficiency letter
Decision	Not Approvable or Denial
Real-Time PMA Supplements	
Decision	Not Approvable or Denial
510(k) Premarket Notifications	
Substantive Interaction	Additional Information Request
Decision	Not Substantially Equivalent

- *Pending [F]* = "(aa) the number of applications filed, and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year." Pending [F] includes both Pending Within Goal [G] and Pending Overdue [H] submissions ([F] = [G] + [H]).

- *Pending Within Goal [G]* = the number of Pending [F] submissions that had met the goal as of September 30, 2022.

- *Pending Overdue [H]* = the number of Pending [F] submissions that had not met the goal as of September 30, 2022.

- *Overdue (completed + pending) [I]* = "(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) of [MDUFA IV] for the applicable fiscal year" and represents the number of submissions that had not met the MDUFA goal as of September 30, 2022. Overdue [I] includes both Completed Overdue [D] and Pending Overdue [H] submissions ([I] = [D] + [H]).

FY 2022 Differences Between Aggregate Numbers **Submission Type**	**MDUFA cohort [A]**	**Completed [B]**	Completed Within Goal **[C]**	Completed Overdue **[D]**	"Major deficiency letters, not approvable letters, denials" **[E]**	**Pending [F]**	Pending Within Goal **[G]**	Pending Overdue **[H]**	Overdue (completed + pending) **[I]**
Original PMA, PDP, Panel-Track Supplements, and Premarket Reports									
Substantive Interaction	37	25	24	1	20	12	11	1	2
Decision with No Advisory Committee Input	37	8	8	0	0	29	28	1	1
Decision with Advisory Committee Input	0	0	0	0	*0*	0	0	0	0
180-Day PMA Supplements									
Substantive Interaction	150	102	84	18	*57*	48	44	4	22
Decision	150	46	44	2	*1*	104	102	2	4
Real-Time PMA Supplements									
Decision	270	*202*	199	3	*8*	68	64	4	7
510(k)									
Substantive Interaction*	3,122	2661	2,393	268	1,748	461	420	41	309
Decision*	3,165	1639	1,580	59	33	1526	1,406	120	179

* Third Party 510(k)s have a Decision but do not have a Substantive Interaction review phase. As such, both Third Party and non-Third Party 510(k)s are included in the Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.

2. Performance Enhancement Goals

The following table addresses section 738A(a)(1)(A)(v)(II) of the FD&C Act as added by section 904(b)(1) of FDARA, pertaining to MDUFA, which requires FDA to include relevant data to determine whether CDRH has met performance enhancement goals identified in the letters described in section 201(b) of MDUFA IV for the applicable fiscal year.

For this report, “performance enhancement goals” are defined as any non-review goal described in the MDUFA IV commitment letter with a specified goal date that falls within the applicable fiscal year. All goals that meet this definition for this fiscal year are summarized below.

In summary, FDA had 19 performance enhancement goals due in FY 2022, all of which were completed on time. Two additional performance enhancement goals are awaiting a dependency that has yet to be completed.

FY 2022 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Infrastructure				
Quality Management At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's Corrective and Preventive Action process.	9/30/2022	Y	9/30/2022	<u>FY 2022 Audit Schedule:</u> A data call for audits to be included in the FY 2022 Audit Schedule was sent to industry on 11/08/2021. There were no requests by industry for FY 2022. The FY 2022 schedule included the following audits that FDA committed to perform as part of MDUFA IV: • Withdrawals • Special 510(k) conversions • Interactive Review • Submission Issue Meetings In addition, the FY 2022 audit schedule included audits of CDRH's Quality Management System processes and the Accreditation Scheme for Conformity Assessment (ASCA) program. The Quality Management System audits included evaluating the effectiveness of the Corrective and Preventive Action process. Overall, 13 audits were conducted in FY 2022. <u>FY 2023 Audit Schedule:</u> A data call for audits to be included in the FY 2023 Audit Schedule was sent to industry on 6/2/2022. Industry provided the following topics: biocompatibility requests in Additional Information Letters, Special 510(k) conversions, and deficiencies.

Performance enhancement goals described in Section III ("Infrastructure") of the MDUFA IV commitment letter

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Infrastructure				
Quality Management Additional audits in the following areas will be completed by the end of FY 2022: Submission Issue Meetings, Interactive Review, Withdrawals and Special 510(k) conversions.	9/30/2022	Y	9/30/2022	All audits were completed by 9/30/22. No non-conformities were found for Submission Issue Meetings. One common non-conformity was found for Withdrawals, Special 510(k) conversions, and Interactive Review. An additional non-conformity was found for Interactive Review. OPEQ was notified of the non-conformities, is exploring the root causes, and will submit a corrective action plan within the specified time.
IT Infrastructure for Submission Management The Agency will update the Guidance "eCopy Program for Medical Device Submissions" to reflect the respective changes to the technical standards and specifications.	Awaiting Dependency *	Awaiting Dependency		As described in the FY 2021 MDUFA annual performance report, FDA published the final guidance document "Providing Regulatory Submissions for Medical Devices in Electronic Format – Submissions Under Section 745A(b) of the FD&C Act" on 7/15/2020 (www.fda.gov/media/131064/download). This guidance document provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions, solely in electronic format, for medical devices. It also states that FDA plans to implement the guidance document on the use of electronic submission templates with individual guidance documents specifying the formats for specific submissions and the corresponding timetables for implementation. The first draft individual guidance document "Electronic Submission Template for Medical Device 510(k) Submissions," which specifies the electronic format for 510(k) submissions, was issued on 9/29/2021. The corresponding final guidance document was issued on 9/22/2022 (www.fda.gov/media/152429/download). The final guidance document states that FDA will provide industry with "a transition period of a minimum of one year prior to the requirement that all 510(k) submissions be provided as electronic submissions." This transition period is a necessary prerequisite for updating the eCopy guidance document. The large number of submissions FDA expects to receive during the transition period will allow FDA to ensure the accuracy of technical standards and specifications for electronic submissions. In addition, the transition period will allow FDA to incorporate relevant learnings, updates, and changes in the eCopy guidance document.

Performance enhancement goals described in Section III ("Infrastructure") of the MDUFA IV commitment letter.
* "Target goal date" is not explicitly defined in the MDUFA IV commitment letter but is implied based on another commitment happening first.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Infrastructure				
Time Reporting FDA will implement complete time reporting by the end of MDUFA IV such that data from time reporting can be used to conduct workload analysis and capacity planning.	9/30/2022	M	3/15/2020	FDA went live with 100-percent time reporting for CDRH in March 2020 and has been using the data for workload analyses and capacity planning. Collected time reporting data were used to facilitate MDUFA V capacity planning analyses.
Fee Setting, Fee Collections, and Workload If the collections are in excess of the resources needed to meet performance goals given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and industry will work together to assess how best to utilize those resources to improve performance on submission types with performance goals and/or quality management programs, using, as input for the discussion: workload information, performance objectives and ongoing reported performance.	09/30/2022	Y	09/30/2022	As reported in the FY 2021 MDUFA financial report (see https://www.fda.gov/about-fda/user-fee-financial-reports/mdufa-financial-reports), FY 2021 total collections less unearned revenue equaled $262,220,545 in funding available for use compared to the inflation-adjusted statutory revenue target of $236,059,000. This increase resulted in an excess revenue of $26,161,545 for the year that could be utilized. Discussions on the use of this excess revenue occurred during FY 2022 as part of the MDUFA V negotiations.

Performance enhancement goals described in Section III (“Infrastructure”) of the MDUFA IV commitment letter.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
CLIA Waiver by Application FDA will provide a status report on completion and issuance of revisions to Section V of the Guidance on "Recommendations for CLIA Waiver Applications" to include appropriate use of comparable performance between a waived user and moderately complex laboratory user to demonstrate accuracy.	9/30/2022	Y	2/26/2020	The final guidance document "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," which includes recommendations for the appropriate use of comparable performance between a waived user and moderately complex laboratory user to demonstrate accuracy, was issued on 2/26/2020 (https://www.fda.gov/media/109582/download). A draft version of this guidance document was issued on 11/29/2018.
Enhanced Use of Consensus Standards FDA will provide an annual report on the progress of the ASCA program.	1/31/2022	Y	1/31/2022	FDA published the calendar year 2021 annual report on the progress of the ASCA program by January 2022 (https://www.fda.gov/media/155672/download).
Enhanced Use of Consensus Standards FDA, in consultation with stakeholders, will identify appropriate recognized consensus standards for consideration as part of the pilot as the specific focus for ASCA. a. By the end of FY 2022: FDA will have piloted, and provided a report on the viability of, an ASCA program which utilizes the schema identified in guidance to include utilization of 5 appropriate cross-cutting/horizontal and/or device-specific areas, at least one of which will be device-specific. b. Standards included as part of the ASCA Program will need to have well established endpoints/acceptance criteria built into the standard to allow effective tracking of TL competence.	9/30/2022	Y	9/30/22	As of September 30, 2022, ASCA features 94 standards/test methods; 45 standards are device/product specific from the IEC 60601 family (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=1&sortcolumn=st&ascapilotyn=on&pagenum=5). ASCA has granted ASCA recognition to five accreditation bodies and granted ASCA accreditation to 91 testing labs. In the MDUFA V commitment letter, FDA agreed that in Q2 of FY 2024 it 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). Therefore, as of September 30, 2022, FDA has not provided a report on the viability of the ASCA program.

‡ Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
Enhanced Use of Consensus Standards FDA will establish a publicly-accessible website listing TLs accredited by ASCA and the FDA-recognized consensus standard(s) for which they are accredited.	9/30/2022	Y	9/30/2022	ASCA's first public web page was published on 9/25/2020. Since then, the publicly accessible databases listing ASCA-recognized accreditation bodies and ASCA-accredited test labs have been published. In FY2022 stakeholder-specific web pages were published (directed at manufacturers, test labs, and accreditation bodies). Additionally, the online FDA Standards Recognition Database was enhanced to identify what recognized standards are in ASCA to assist stakeholders. These web pages and database can be accessed at the main ASCA web page(https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca).
Enhanced Use of Consensus Standards FDA will develop an internal IT system to track CA activities of the ASCA Program.	9/30/2022	Y	9/25/2020	An internal database was established that tracks accreditation body and test lab applications, audits, training, scopes, contacts, and communications. A tracking capability was built into the submission tracking database to identify submissions with ASCA testing.
Third Party Review FDA will strengthen the process for accreditation of Third Parties. a. FDA will 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.	9/30/2022	Y	9/30/2022	FDA provided training for Third Party Review Organizations (3PROs) seeking accreditation. Details of this training curriculum can be found on FDA's website (https://www.fda.gov/medical-devices/510k-third-party-review-program/training-curriculum-third-party-reviewers). Consistent with FDA's published plan to eliminate routine FDA re-review of third party 510(k) reviews (https://www.fda.gov/media/116168/download), FDA also created a publicly available library of redacted memos for selected devices with a high volume of third-party reviews (https://www.fda.gov/medical-devices/510k-third-party-review-program/review-memos-third-party-510k-reviewers).
Third Party Review FDA will strengthen the process for accreditation of Third Parties. b. When FDA's expectations for a particular device type change, FDA will have in place a process to convey this information to the Third Parties and to industry.	9/30/2022	Y	9/30/2022	FDA follows an established process to communicate to 3PROs and industry when expectations for a particular device type change. This process includes: • Sending a quarterly newsletter to highlight new information. • Recommending, as per the guidance document "510(k) Third Party Review Program" (https://www.fda.gov/media/85284/download), that 3PROs send in an early interaction request for the first review of a device in a product code if 6 months has passed since they have reviewed that product code to ensure they have current FDA thinking on related regulatory issues. • Monitoring the mailbox 3P510k@fda.hhs.gov daily, which allows 3PROs to reach out to FDA with any questions they have.

Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
Third Party Review FDA will implement a program to audit reviews conducted by accredited Third Parties. a. FDA will provide tailored re-training to accredited Third Parties based on the results of audits.	9/30/2022	Y	9/30/2022	The guidance document "510(k) Third Party Review Program" (https://www.fda.gov/media/85284/download) was drafted and published in 2020 which outlines the audit process. FDA created internal SOPs and Work Instructions for the audit process in FY18-FY21. Audits were conducted utilizing a risk-based approach by BIMO in August 2022 for the active 3P510k Review Organizations. The audits generally follow these documents: IMDRF MSAP Working Group N3 Final: 2016 (Edition 2) "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition" (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf) and IMDRF/GRRP WG/N40 Final: 2017 "Competence, Training, and Conduct Requirements for Regulatory Reviewers" (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf). FDA offers recurring meetings with the active 3PROs to answer questions/concerns, offer grading feedback, and provide ad hoc training as needed.
Third Party Review FDA will publish performance of individual accredited Third Parties with at least five completed submissions on the web (e.g., rate of NSE, average number of holds, average time to SE).	9/30/2022	Y	9/30/2022	Every quarter, FDA published a report on the performance of individual accredited Third Parties with at least five completed submissions (https://www.fda.gov/about-fda/cdrh-transparency/510k-third-party-performance-metrics-and-accreditation-status).
Patient Engagement and the Science of Patient Input FDA will undertake several activities to improve the regulatory predictability and impact of PROs, including: a. FDA will clarify to device review divisions that use of PROs is voluntary and may be one potential way of demonstrating safety or effectiveness (or elements of either or both, such as in a composite endpoint). Consistent with least burdensome principles, applicants may use alternative approaches.	9/30/2022	Y	9/30/2020	The final guidance document "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation," issued on 1/26/2022, emphasizes the use of patient-reported outcome (PRO) instruments is generally voluntary (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use). The voluntary use of PROs was also addressed in the report "Value and Use of Patient-Reported Outcomes (PROs) in Assessing Effects of Medical Devices" (https://www.fda.gov/media/109626/download). CDRH has undertaken multiple efforts to develop training designed for expanding its staff's understanding of PROs. As part of CDRH's commitment to build its capacity, the Patient Science and Engagement program developed a course for the Advanced Reviewer Certification Program (RCP) to introduce PROs, provide background on PRO development, and explain the evaluation of PROs in submissions. To supplement the training content offered through the advanced certification program, the engagement program staff also launched the Patient Science and Engagement curriculum in February 2018. The curriculum, intended for reviewers, medical officers,

				team leads, and biostatisticians, included clarification of the methods for developing and voluntary use of clinical outcome assessments and patient preference information across the Total Product Life Cycle of medical devices. Between 2018 and 2021, there were 785 enrollments in these curriculum courses, with 375 reviewers completing at least one course in the curriculum. All training reflects the least burdensome principles.

‡ Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
Patient Engagement & the Science of Patient Input b. FDA will modify the guidance to outline a flexible framework for PRO validation evidentiary thresholds. These thresholds may vary depending on the particular regulatory use of the PRO.	9/30/2022	Y	1/26/2022	The final guidance document "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation," which outlines a flexible framework for PRO validation evidentiary thresholds, was issued on 1/26/2022 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use).
Patient Engagement & the Science of Patient Input c. FDA will work on developing a model for "bridging studies" to make efficient use of existing validated PROs which may be improved or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.	9/30/2022	Y	9/30/2022	CDRH funded multiple studies to help inform the development of a model(s) for "bridging" studies and to evaluate whether existing PRO measures needed to be adapted for use in additional contexts of use. These studies are listed on CDRH's PRO website: https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/clinical-outcome-assessments-coas-medical-device-decision-making. The final guidance document "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation" also describes the benefits of and best practices for modifying or adapting (methodologic terminology for "bridging") existing PRO measures.

‡ Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
Real-World Evidence (RWE) If warranted based on the results of the pilot(s) described in (H)(1) above, FDA will revise its guidance on the use of RWE to reflect what has been learned from the pilots as to how RWE can be used to support: i. Expanded indications for use; and ii. New clearances/approvals. If supported by the pilot(s) described in (H)(1) above, the guidance will include discussion of how devices not currently subject to a registry can benefit from RWE.	Awaiting Dependency *	Awaiting Dependency		The Coordinating Center for the National Evaluation System for health Technology (NEST) implemented RWE pilots for at least two product codes, as described in section IV(H)(1) of the MDUFA IV commitment Letter. The MDUFA IV commitment Letter indicates that the following two reports describing the results from those pilots will be issued: • Publicly available report, issued by NEST (as described in section IV.(H)(2)(c) of the commitment letter). • Independent assessment, conducted by an independent third party (as described in section IV.(H)(2)(e) of the commitment letter). In NEST Forums, NESTcc publicly reported the results of 11 of the 21 Test-Cases. Recordings of the NESTcc's Test-Case reports can be found on NESTcc's website (https://nestcc.org/test-cases/). An independent third party, RAND Corporation, published an interim independent assessment report on 12/28/2021, covering 14 of the 21 Test-Cases to evaluate the strengths, limitations, and appropriate use of RWE for informing premarket decision-making (https://nestcc.org/independent-assessment-of-the-nestcc-test-cases-rand-interim-report/). The final independent assessment report was completed on 9/23/2022 but has not yet been published (as of September 30, 2022). Once finalized, it will be published on NESTcc's website. FDA intends to revise the guidance document "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" (https://www.fda.gov/media/99447/download) to incorporate relevant learnings from the RWE pilots after the final independent assessment report is published.
Real World Evidence (RWE) FDA will maintain on its website the list of eligible device procodes for which manufacturers are permitted to report malfunctions on a quarterly basis and in a summary MDR format.	9/30/2022	Y	9/30/2022	The Voluntary Malfunction Summary Reporting program was established in 2018 and permits participating manufacturers to report certain device malfunction medical device reports (MDRs) in summary form on a quarterly basis. The eligibility status of a given device product code for this program is listed in the CDRH Product Classification Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

‡ Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.
* "Target goal date" is not explicitly defined in the MDUFA IV commitment letter but is implied based on another commitment happening first.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Implementation‡				
Digital Health FDA will participate in international harmonization efforts related to digital health, including work on developing SaMD and other digital health convergence efforts through the International Medical Device Regulators Forum (IMDRF).	9/30/2022	Y	9/30/2022	FDA has participated in several international harmonization efforts related to digital health, including the following activities: • Creation and launch of an IMDRF technical document entitled "IMDRF's Machine Learning-enabled Medical Devices: Key Terms and Definitions" on 05/09/2022 (see https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions), which required a significant effort over 6 months involving seven international regulators. • Relaunch of the IMDRF SaMD working group to consider updates to related documents based on developments since these documents' original publication. • Identification and publication of, in October 2021,with the United Kingdom's Medicines and Healthcare products Regulatory Agency and Health Canada, 10 guiding principles that can inform the development of Good Machine Learning Practice "Good Machine Learning Practice for Medical Device Development: Guiding Principles" (see https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles). FDA continues to regularly bilaterally engage with a variety of international regulators, support outreach efforts, and participate in workshops to promote harmonized conformity assessment approaches around the globe.

‡ Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter describe these performance enhancement goals.

FY 2022 Performance Enhancement Goals (continued)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Assessments[§]				
Independent Assessment of Review Process Management FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. 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.	9/30/2022	Y	11/04/2021	The contractor issued a final report titled "MDUFA IV Independent Assessment-Final Report" on 9/30/2021 (see https://www.fda.gov/media/152594/download). As reported in the FY 2021 MDUFA annual performance report, the contractor found that for 10 of the 11 areas assessed, FDA met the commitments in the MDUFA IV commitment letter. The one commitment yet to be met as of the date of the FY 2021 MDUFA annual performance report was related to the issuance of the guidance document titled "Content of Premarket Submissions for Software Contained in a Medical Device". FDA subsequently addressed the contractor's sole recommendation in the final report by publishing the draft guidance document titled "Content of Premarket Submissions for Software Contained in a Medical Device" on 11/4/2021 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions). As described in Appendix F of the FY 2019 MDUFA annual performance report, FDA determined no corrective actions were necessary related to the commitment to issue this draft guidance.

[§] Section V ("Independent Assessment of Review Process Management") of the MDUFA IV commitment letter describes these performance enhancement goals.

3. Common Causes and Trends Impacting the Ability to Meet Goals

The following tables address section 738A(a)(1)(A)(v)(III) of the FD&C Act, as added by section 904(b)(1) of FDARA, which pertains to MDUFA and requires FDA to identify the most common causes and trends of external or other circumstances affecting the ability of CDRH, the Office of Regulatory Affairs (ORA), or FDA to meet the review time and performance enhancement goals identified in the letters described in section 201(b) of MDUFA IV.

A. FY 2022 GOALS

As indicated in other sections of this report, FDA received sufficient FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 16 review goals, one review goal was sufficiently complete to determine the outcome and was met, five review goals were sufficiently complete to determine the outcome and were missed, and 10 review goals are pending (i.e., FDA has the potential to meet each goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome).

In addition, FDA had 19 performance enhancement goals due in FY 2022, and two additional performance enhancement goals awaiting a dependency. As of September 30, 2022, all 19 performance enhancement goals due in FY 2022 were met; the two additional goals are awaiting a dependency that has yet to be completed.

With five missed review goals and ten still pending (of the 25 FY 2022 review goals), it is clear that, for the reasons described below, the COVID-19 pandemic has impacted the ability of CDRH, ORA, or FDA to meet all the goals.

From FY 2020 through FY 2022, FDA responded to the unprecedented COVID-19 public health emergency. In FY 2020, FY 2021, and FY 2022, FDA experienced a 31 percent, 20 percent, and 12 percent increase, respectively, in its total premarket submission volume compared to the pre-pandemic (FY 2019) work volumes. Since the beginning of the emergency, FDA has received over 8,500 medical device emergency use authorization (EUA) and pre-EUA submissions. FDA has authorized a 17-fold increase in medical device EUAs over those issued in all prior public health emergencies combined. FDA helped facilitate the development and availability of COVID-19 tests and collection kits, personal protective equipment (PPE) to help control the spread of the disease, and ventilators and other devices for treating COVID-19-related symptoms. Since the start of the emergency, FDA has issued EUAs or granted full marketing authorization to more than 2,600 medical devices for COVID-19. In addition, FDA conducted the timely review of more than 9 million medical device adverse event reports from FY 2020 through FY 2022 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19. Despite prioritizing COVID-19-related work, FDA still worked to meet many

MDUFA commitments. Meeting all MDUFA commitments remains FDA's goal, and the Agency is taking critical steps to improve its performance, when possible, relative to the FY 2022 cohort.

If, at the end of future fiscal years, the FY 2022 review goal cohorts are sufficiently closed and data indicate that FDA has missed additional FY 2022 goals, FDA will provide an update to the required information in future reports.

For a description of FY 2022 corrective efforts, see Appendix E.

Cause or Trend	Impact on FDA's Ability to Meet Goals
COVID-19 Public Health Emergency	See the text above for a description of how the COVID-19 public health emergency impacted FDA's ability to meet the five review goals missed in FY 2022. See Appendix E for a description of FDA's corrective efforts. FDA will provide additional information in future reports as necessary.

B. FY 2021 GOALS (UPDATED)

As indicated in other sections of this report and in the FY 2021 MDUFA performance report, FDA received sufficient FY 2021 submissions to calculate performance results for 13 of the 25 MDUFA IV review goals and had eight performance enhancement goals due in FY 2021.

As of September 30, 2022, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, six review goals were sufficiently complete to determine the outcome and were missed, and three review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome). Also as of September 30, 2022, eight (of the eight) performance enhancement goals were met.

With six missed review goals and three still pending (of the 25 FY 2021 review goals), it is clear that, for the reasons described below, the COVID-19 pandemic has impacted the ability of CDRH, ORA, or FDA to meet all the goals.

As noted in the FY 2022 goals subsection above, from FY 2020 through FY 2022, FDA responded to the unprecedented COVID-19 public health emergency. In FY 2020, FY 2021, and FY 2022, FDA experienced a 31 percent, 20 percent, and 12 percent increase, respectively, in its total premarket submission volume compared to the pre-pandemic (FY 2019) work volumes. Since the beginning of the emergency, FDA has received over 8,500 medical device EUA and pre-EUA submissions. FDA has authorized a 17-fold increase in medical device EUAs over those issued in all prior public health emergencies combined. FDA helped facilitate the development and availability of COVID-19 tests and collection kits, PPE to help control the spread of the disease, and ventilators and other devices for treating COVID-19-related symptoms. Since the start of the emergency, FDA has issued EUAs or granted full marketing

authorization to more than 2,600 medical devices for COVID-19. In addition, FDA conducted the timely review of more than 9 million medical device adverse event reports from FY 2020 through FY 2022 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19. Despite prioritizing COVID-19-related work, FDA still worked to meet many MDUFA commitments. Meeting all MDUFA commitments remains FDA's goal, and the Agency is taking critical steps to improve its performance, when possible, relative to the FY 2021 cohort.

If, at the end of future fiscal years, the FY 2021 review goal cohorts are sufficiently closed and data indicate that FDA has missed additional FY 2021 goals, FDA will provide an update to the required information in future reports.

For a description of FY 2021 corrective efforts, see Appendix E.

Cause or Trend	Impact on FDA's Ability to Meet Goals
COVID-19 Public Health Emergency	See the text above for a description of how the COVID-19 public health emergency impacted FDA's ability to meet six FY 2021 review goals missed in FY 2021. See Appendix E for a description of FDA's corrective efforts. FDA will provide additional information in future reports as necessary.

C. FY 2020 GOALS (UPDATED)

As indicated in other sections of this report and in both the FY 2021 and FY 2020 MDUVA performance reports, FDA received sufficient FY 2020 submissions to calculate performance results for 15 of the 25 MDUFA IV review goals and had 10 performance enhancement goals due in FY 2020.

As of September 30, 2022, for those 15 review goals, nine review goals were sufficiently complete to determine the outcome and were met, four review goals were sufficiently complete to determine the outcome and were missed, and two review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome). Also as of September 30, 2022, FDA completed all 10 performance enhancement goals, nine of which were completed on time.

With four missed goals but two still pending (of the 25 FY 2020 review goals), it is clear that, for the reasons described below, the COVID-19 pandemic has impacted the ability of CDRH, ORA, or FDA to meet all the goals.

As noted above, from FY 2020 through FY 2022, FDA responded to the unprecedented COVID-19 public health emergency. In FY 2020, FY 2021, and FY 2022, FDA experienced a 31 percent, 20 percent, and 12 percent increase, respectively, in its total premarket submission volume compared to the pre-pandemic (FY 2019) work volumes.

Since the beginning of the emergency, FDA has received over 8,500 medical device EUA and pre-EUA submissions. FDA has authorized a 17-fold increase in medical device EUAs over those issued in all prior public health emergencies combined. FDA helped facilitate the development and availability of COVID-19 tests and collection kits, PPE to help control the spread of the disease, and ventilators and other devices for treating COVID-19-related symptoms. Since the start of the emergency, FDA has issued EUAs or granted full marketing authorization to more than 2,600 medical devices for COVID-19. In addition, FDA conducted the timely review of more than 9 million medical device adverse event reports from FY 2020 through FY 2022 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19. Despite prioritizing COVID-19-related work, FDA still worked to meet many MDUFA commitments. Meeting all MDUFA commitments remains FDA's goal, and the Agency is taking critical steps to improve its performance, when possible, relative to the FY 2020 cohort.

For a summary of the types of circumstances and trends impacting FDA's ability to meet the one FY 2020 shared outcome goal missed in FY 2022 and a description of the FY 2022 corrective efforts, see Appendix E.

For a summary of the types of circumstances and trends impacting FDA's ability to meet the one FY 2020 performance enhancement goal missed in FY 2020 and a description of FY 2020 corrective efforts, see Appendix E of the FY 2020 MDUFA performance report.

Cause or Trend	Impact on FDA's Ability to Meet Goals
COVID-19 Public Health Emergency	See the text above for a description of how the COVID-19 public health emergency impacted FDA's ability to meet four FY 2020 review goals missed in FY 2020. See Appendix E for a description of FDA's corrective efforts. FDA will provide additional information in future reports as necessary.

Appendix E: FY 2022 Corrective Action Report

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products. Among the provisions of Title IX, section 904 of FDARA requires FDA to publicly issue a corrective action report that details FDA's progress in meeting the review and performance enhancement goals identified in MDUFA IV for the applicable fiscal year.

If the Secretary of Health and Human Services determines, based on the analysis presented in the MDUFA annual performance report, that each of the review and performance enhancement goals for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

If the Secretary determines, based on the analysis presented in the MDUFA annual report, that any review or performance enhancement goals for the applicable fiscal year were not met, the corrective action report shall include a justification, as applicable, for the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year. Such a description of corrective efforts is not required by statute for review time goals, but FDA is providing this information, regardless, in an effort to be complete. For review time goals (but not performance goals), the corrective action report shall also include a "description of the types of circumstances, in the aggregate, under which applications or reports submitted under section 515 or notifications submitted under section 510(k) missed review time goals but were approved during the first cycle review, as applicable."

This report satisfies this reporting requirement in section 738A(a)(2) of the FD&C Act as added by section 904(b)(2) of FDARA.

A. Executive Summary

FY 2022 Review Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Review Goals	FDA received enough FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 16 review goals, one review goal was sufficiently complete to determine the outcome and was met, ten review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome), and five review goals were sufficiently complete to determine the outcome and were missed, including the following: (1) Substantive Interaction for 180-Day PMA Supplements; (2) Substantive Interaction for 510(k) Premarket Notifications; (3) Decision for 510(k) Premarket Notifications; (4) Substantive Interaction for Dual 510(k) and CLIA Waiver by Application; and (5) Decision with No Advisory Committee Input for Dual 510(k) and CLIA Waiver by Applications. See the discussion on the impact of the COVID-19 public health emergency on FDA's workload in Appendix D and in the "Justification" section below. In FY 2022, FDA continued to prioritize the review of EUAs and other activities to respond to the COVID-19 pandemic. This shifting of resources significantly impacted FDA's ability to meet MDUFA review goals. As for the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review, submissions in the relevant cohorts are still pending so it is too soon to assess the missed review goals in aggregate. FDA will provide this information in subsequent corrective action reports, once all relevant FY 2022 cohorts are sufficiently complete.	FDA has missed five FY 2022 review goals. As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions has begun to lessen in FDA's in vitro diagnostic (IVD) and non-IVD offices, allowing FDA to reprioritize review efforts to MDUFA work. FDA has taken multiple steps to modernize its submission review, including to enhance the efficiency, consistency, and transparency of the review process for both industry and FDA, including the following improvements: <u>Process and programmatic improvements:</u> • Expansion of the Safety and Performance Based Pathway for the 510(k) program <u>Technology-based improvements:</u> • Creation of electronic templates for consistent 510(k) submissions (eSTAR)

FY 2021 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Review Goals	FDA received enough FY 2021 submissions to calculate performance results for 13 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, three review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome), and six review goals were sufficiently complete to determine the outcome and were missed, including the following: (1) Substantive Interaction for Original PMA, PDPs, Panel-Track PMA Supplements; (2) Decision with No Advisory Committee Input for Original PMA, PDPs, Panel-Track PMA Supplements; (3) Substantive Interaction for 180-Day PMA Supplements; (4) Decision for 180-Day PMA Supplements; (5) Substantive Interaction for 510(k) Premarket Notifications; and (6) Decision for 510(k) Premarket Notifications. See the discussion on the impact of the COVID-19 public health emergency on FDA's workload in Appendix D and in the "Justification" section below. In FY 2021, FDA continued to prioritize the review of EUAs and other activities to respond to the COVID-19 pandemic. This shifting of resources significantly impacted FDA's ability to meet MDUFA review goals. Additionally, of the 4,653 submissions within relevant FY 2021 PMA and 510(k) MDUFA cohorts, 94 510(k) submissions, one Panel-Track PMA Supplement, four 180-Day PMA Supplements, and 10 PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. With submissions still pending, it is too soon to completely determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. However, these circumstances include a delay of MDUFA work due to the COVID-19 pandemic and shifting of resources. Of the 94 510(k) submissions meeting these criteria, 51 are in the IVD office, and 43 are in the office responsible for review of PPE devices. For many of the submissions delayed due to the COVID-19 pandemic, FDA worked to resolve any deficiencies in the submission interactively with the sponsor rather than sending a deficiency letter.	FDA missed six FY 2021 review goals. As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions has begun to lessen in FDA's IVD and non-IVD offices, allowing FDA to reprioritize review efforts to MDUFA work. FDA has taken multiple steps to modernize its submission review, including to enhance the efficiency, consistency, and transparency of the review process for both industry and FDA, including the following improvements: <u>Process and programmatic improvements:</u> • Expansion of the Safety and Performance Based Pathway for the 510(k) program <u>Technology-based improvements:</u> • Creation of electronic templates for consistent 510(k) submissions (eSTAR)

FY 2020 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Review Goals	FDA received enough FY 2020 submissions to calculate performance results for 15 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 15 review goals, nine review goals were sufficiently complete to determine the outcome and were met, two review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome), and four review goals were sufficiently complete to determine the outcome and were missed—namely, (1) Substantive Interaction for 180-Day PMA Supplements; (2) Substantive Interaction for 510(k) Premarket Notifications; (3) Dual 510(k) and CLIA waiver by Application – Decision with no Advisory Committee Input; and (4) the 510(k) shared outcome goal for TTD. FDA and industry share two review goals, one of which was not met and one of which is still pending for the FY 2020 cohort. The shared TTD goal for 510(k) submissions for FY 2020 was 116 days. The actual FY 2020 performance was 139 days. See the discussion on the impact of the COVID-19 public health emergency on FDA's workload in Appendix D and in the "Justification" section below. In FY 2020, FDA prioritized the review of EUAs and other activities to respond to the COVID-19 pandemic. This shifting of resources significantly impacted FDA's ability to meet MDUFA review goals, including the shared TTD goal. During the pandemic, submitters took additional time to respond to requests for additional information for most submissions. As the TTD goal is shared between FDA and industry, FDA has identified areas to address the growing submission volumes and increase review efficiency. Of the 4,456 submissions within relevant FY 2020 PMA and 510(k) MDUFA cohorts, 17 510(k) submissions and four PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. For the 17 510(k) submissions, 14 of these submissions were IVD submissions and were delayed due to FDA's COVID-19 response. For the remaining three submissions, FDA determined that working with the applicant interactively would be the least burdensome way to resolve all deficiencies. Two of these three submissions were cleared 1 day after the 90-day goal. For the PMA Real-Time Supplements, all four submissions were approved with an average of 8 days past their 90-day goal. For these submissions, FDA determined that working with the applicant interactively (instead of sending a deficiency letter) would be the least burdensome way to resolve all deficiencies.	FDA missed three FY 2020 review goals, and FDA and industry missed one FY 2020 shared outcome goal (i.e., 510(k) TTD). As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions has begun to lessen in FDA's IVD and non-IVD offices, allowing FDA to reprioritize review efforts to MDUFA work. FDA has taken multiple steps to modernize its submission review, including to enhance the efficiency, consistency, and transparency of the review process for both industry and FDA, including the following improvements: <u>Process and programmatic improvements:</u> • Expansion of the Safety and Performance Based Pathway for the 510(k) program <u>Technology-based improvements:</u> • Creation of electronic templates for consistent 510(k) submissions (eSTAR)

FY 2022 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Program and Process Implementation	FDA had 19 performance enhancement goals due in FY 2022, all of which were completed on time. Two additional performance enhancement goals are awaiting a dependency that has yet to be completed.	FDA did not miss any FY 2022 performance enhancement goals. No corrective action is needed.

B. MDUFA Review Goals

The following section addresses section 738A(a)(2)(B)(i) through (iii) of the FD&C Act as added by section 904(b)(2) of FDARA, which requires that, if the Secretary determines that any review or performance enhancement goals for the applicable fiscal year were not met, FDA provide a justification for the determination of review goals missed and a description of the circumstances and any trends related to missed review goals, including "a description of the types of circumstances, in the aggregate, under which applications or reports submitted under section 515 or notifications submitted under section 510(k) missed review time goals but were approved during the first cycle review, as applicable." For this latter requirement, relevant information about what is provided below is as follows:

- "Applications or reports submitted under section 515" are defined as submissions reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2021. "Notifications submitted under section 510(k)" are defined as submissions reviewed as Premarket Notifications (510(k)s) (including those reviewed as Third Party 510(k) submissions) that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2021. These definitions are consistent with the interpretation of similar statutory language in section 903 and other parts of section 904 of FDARA and are addressed in other sections of this report.

- "Missed review time goals but were approved during the first cycle review" are submissions in a MDUFA cohort with a MDUFA decision that did not meet the MDUFA goal and did not include a request for Additional Information or a Major Deficiency letter.

This section includes all MDUFA review goals as they pertain to submissions in the FYs 2020, 2021, and 2022 cohorts.

1. FY 2022 Review Goal Performance

A. SUMMARY OF PERFORMANCE

FDA received enough FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 16 review goals, one review goal was sufficiently complete to determine the outcome and was met, 10 review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome), and five review goals were sufficiently complete to determine the outcome and were missed. The five missed goals were (1) Substantive Interaction for 180-Day PMA Supplements; (2) Substantive Interaction for 510(k) Premarket Notifications; (3) Decision for 510(k) Premarket Notifications; (4) Substantive Interaction for Dual 510(k) and CLIA Waiver by Application; and (5) Decision with No Advisory Committee Input for Dual 510(k) and CLIA Waiver by Application.

Additionally, with relevant submissions still pending, it is too soon to determine the number and types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. FDA will provide this information, in subsequent corrective action reports, once all relevant FY 2022 cohorts are sufficiently complete.

B. JUSTIFICATION

From FY 2020 through FY 2022, FDA responded to the unprecedented COVID-19 public health emergency. In FY 2020, FY 2021, and FY 2022, FDA experienced a 31 percent, 20 percent, and 12 percent increase, respectively, in its total premarket submission volume compared to the pre-pandemic (FY 2019) work volumes. Since the beginning of the emergency, FDA has received over 8,500 medical device EUA and pre-EUA submissions. FDA has authorized a 17-fold increase in medical device EUAs over those issued in all prior public health emergencies combined. FDA helped facilitate the development and availability of COVID-19 tests and collection kits, PPE to help control the spread of the disease, and ventilators and other devices for treating COVID-19-related symptoms. Since the start of the emergency, FDA has issued EUAs or granted full marketing authorization to more than 2,600 medical devices for COVID-19. In addition, FDA conducted the timely review of more than 9 million medical device adverse event reports from FY 2020 through FY 2022 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19. Despite prioritizing COVID-19-related work, FDA still worked to meet many MDUFA commitments. Meeting all MDUFA commitments remains FDA's goal, and the Agency is taking critical steps to improve its performance, when possible, relative to the FY 2022 cohort.

Because of this large increase in work volume and the need to respond to the public health emergency, FDA prioritized COVID-19 work over other work areas, including

work with MDUFA performance goals. This prioritization resulted in the missed performance goals as described above.

C. CORRECTIVE ACTIONS

FDA will continue to prioritize its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions for COVID-19-related products has begun to lessen in FDA's IVD and non-IVD offices. This reduction has allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels for non-IVD offices. FDA has begun to reduce the backlog of submissions with missed goals and has begun to reverse submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases. Submissions for non-IVD products under review continue to generally meet MDUFA goals. The IVD office has been hiring, and will continue to hire, additional staff and contractors to address the increased volume of work in the office.

Each of the roughly 3,500 510(k) submissions FDA receives each year is prepared by the individual submitter and may utilize a different format, a different layout, and contain a variety of content. Therefore, FDA reviewers have to orient themselves each time they begin a 510(k) review. This formatting inconsistency creates inefficiencies in the review process, which is exacerbated when the submission is disorganized, is incomplete, or contains many subsections and reports that are not linked. To help address this inefficiency, FDA published a final guidance document in July 2020 describing a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format;[1] FDA further published a final guidance on a 510(k)-specific electronic submission template[2] in September 2022. The currently available templates (one for non-IVD 510(k) and one for IVD 510(k)), referred to as "eSTAR," were piloted through the voluntary eSTAR Pilot Program launched in February 2020.[3]

eSTAR is a guided submission preparation tool that guides submitters through the process of preparing a comprehensive and organized 510(k), thereby supporting an increase in submission completeness and organization. Well-organized 510(k) submissions prepared using the eSTAR template have allowed for a more efficient review by FDA. Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. As of September 30, 2022, eSTAR is the only electronic submission template available to prepare a complete

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions.

[3] https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program.

510(k) electronic submission. The voluntary use of eSTAR is increasing, and FDA continues to develop and enhance this tool. Beginning on October 1, 2023, FDA will require all 510(k) submissions, unless exempted, to be submitted as electronic submissions.

In addition, in September 2019, FDA published a final guidance document on the Safety and Performance Based Pathway.[4] This pathway expands upon the Abbreviated 510(k) program and is an optional pathway for certain well-understood device types when a submitter demonstrates that a new device meets performance criteria identified by FDA in device-specific guidance documents to demonstrate that the device is as safe and effective as a legally marketed device. By identifying performance criteria for device types appropriate for the pathway and recommending test methodologies for those criteria when feasible, FDA has created a clear and transparent approach to demonstrating substantial equivalence for these device types.

FDA continues to expand on this pathway and published four additional final Safety and Performance Based Pathway guidance documents in FY 2022. As of September 30, 2022, nine final guidance documents and one draft guidance document for this pathway had been published.[5] FDA continues to identify additional device types that would be appropriate candidates for this program and to craft new guidance documents. FDA regularly encourages industry and other stakeholders to suggest additional devices for inclusion in this program and to submit evidence-based suggestions for the performance criteria.

2. FY 2021 Review Goal Performance (Updated)

A. SUMMARY OF PERFORMANCE

FDA received enough FY 2021 submissions to calculate performance results for 13 of the 25 MDUFA IV review goals. As of September 30, 2022, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, three review goals are pending (i.e., FDA has the potential to meet the goal, but the MDUFA cohorts are not yet sufficiently complete to determine the outcome), and six review goals were sufficiently complete to determine the outcome and were missed. The six goals missed were (1) Substantive Interaction for Original PMA, PDPs, Panel-Track PMA Supplements; (2) Decision with No Advisory Committee Input for Original PMA, PDPs, Panel-Track PMA Supplements; (3) Substantive Interaction for 180-Day PMA Supplements; (4) Decision for 180-Day PMA Supplements; (5) Substantive Interaction for 510(k) Premarket Notifications; and (6) Decision for 510(k) Premarket Notifications.

---

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

[5] See https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway.

Additionally, of the 4,653 submissions within relevant FY 2021 PMA and 510(k) MDUFA cohorts, 94 510(k) submissions, one Panel-Track PMA Supplement, four 180-Day PMA Supplements, and 10 PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. With submissions still pending, it is too soon to completely determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. However, these circumstances include a delay of MDUFA work due to the COVID-19 pandemic and shifting of resources. Of the 94 510(k) submissions meeting these criteria, 51 are in the IVD office and 43 are in the office responsible for PPE. For many of the submissions delayed due to the COVID-19 pandemic, FDA worked to resolve any deficiencies in the submission interactively with the sponsor rather than sending a deficiency letter.

B. JUSTIFICATION

As discussed above, the COVID-19 pandemic resulted in FDA shifting resources away from its MDUFA work to address the unprecedented volume of EUA submissions and other aspects of the response to COVID-19. This shifting of resources resulted in FDA missing performance goals as identified above.

C. CORRECTIVE ACTIONS

As noted above, FDA will continue to prioritize its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions for COVID-19-related products has begun to lessen in FDA's IVD and non-IVD offices. This reduction has allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels for non-IVD offices. FDA has begun to reduce the backlog of submissions with missed goals and has begun to reverse submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases. Submissions for non-IVD products under review continue to generally meet MDUFA goals. The IVD office has been hiring, and will continue to hire, additional staff and contractors to address the increased volume of work in the office.

Each of the roughly 3,500 510(k) submissions FDA receives each year is prepared by the individual submitter and may utilize a different format, a different layout, and contain a variety of content. Therefore, FDA reviewers have to orient themselves each time they begin a 510(k) review. This formatting inconsistency creates inefficiencies in the review process, which is exacerbated when the submission is disorganized, is incomplete, or contains many subsections and reports that are not linked. To help address this inefficiency, FDA published a final guidance document in July 2020 describing a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in

electronic format;[6] FDA further published a final guidance on a 510(k)-specific electronic submission template[7] in September 2022. The currently available templates (one for non-IVD 510(k) and one for IVD 510(k)), referred to as "eSTAR," were piloted through the voluntary eSTAR Pilot Program launched in February 2020.[8]

Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. As of September 30, 2022, eSTAR is the only electronic submission template available to prepare a complete 510(k) electronic submission. The voluntary use of eSTAR is increasing, and FDA continues to develop and enhance this tool. Beginning on October 1, 2023, FDA will require all 510(k) submissions, unless exempted, to be submitted as electronic submissions.

In addition, in September 2019, FDA published a final guidance document on the Safety and Performance Based Pathway.[9] This pathway expands upon the Abbreviated 510(k) program and is an optional pathway for certain well-understood device types when a submitter demonstrates that a new device meets performance criteria identified by FDA in device-specific guidance documents to demonstrate that the device is as safe and effective as a legally marketed device. By identifying performance criteria for device types appropriate for the pathway and recommending test methodologies for those criteria when feasible, FDA has created a clear and transparent approach to demonstrating substantial equivalence for these device types.

FDA continues to expand on this pathway and published four additional final Safety and Performance Based Pathway guidance documents in FY 2022. As of September 30, 2022, nine final guidance documents and one draft guidance document for this pathway had been published.[10] FDA continues to identify additional device types that would be appropriate candidates for this program and to craft new guidance documents. FDA regularly encourages industry and other stakeholders to suggest additional devices for inclusion in this program and to submit evidence-based suggestions for the performance criteria.

---

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions.

[8] https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program.

[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

[10] See https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway.

3. FY 2020 Review Goal Performance (Updated)

A. SUMMARY OF PERFORMANCE

By then end of FY 2022, FDA had a sufficient MDUFA cohort to calculate final FY 2020 performance for 16 of the 25 review goals (including the two shared goals). FDA has met nine of those 16 goals and missed four goals, including (1) Substantive Interaction for 180-Day PMA Supplements; (2) Substantive Interaction for 510(k) Premarket Notifications; (3) Dual CLIA – Decision with no Advisory Committee Input, and (4) the 510(k) shared outcome goal for TTD. The FY 2020 shared TTD review goal for 510(k)s was 116 days, which was 4 days less than for the FY 2019 cohort. The calculated TTD for the FY 2020 510(k) cohort was 139 days, an increase of 11 days from the FY 2019 cohort.

As indicated in other sections of this report, MDUFA review goal performance data are based on a fiscal year receipt cohort. Preliminary data indicate that FDA has the potential to meet the two remaining review goals (one review goal and one shared outcome goal). With submissions still pending, it is too soon to determine final performance for the full FY 2020 cohort of review goals. FDA will provide updated information in future reports on any missed goals.

Additionally, of the 4,456 submissions within relevant FY 2020 PMA and 510(k) MDUFA cohorts, 17 510(k) submissions and four PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. For the 17 510(k) submissions, 14 of these submissions were IVD submissions and were delayed due to FDA's COVID-19 response. For the remaining three 510(k) submissions, FDA determined that working with the applicant interactively would be the least burdensome way to resolve all deficiencies. Two of these three submissions were cleared 1 day after the 90-day goal. For the PMA Real-Time Supplements, all four submissions were approved with an average of 8 days past their 90-day goal. For these submissions, FDA determined that working with the applicant interactively (instead of sending a deficiency letter) would be the least burdensome way to resolve all deficiencies.

B. JUSTIFICATION

As discussed above, the COVID-19 pandemic resulted in FDA shifting resources away from its MDUFA work to address the unprecedented volume of EUA submissions and other aspects of the response to COVID-19. This shifting of resources resulted in FDA missing performance goals as identified above.

The TTD goal is a shared goal between FDA and industry wherein both parties share responsibility to achieve the goal. FDA's contribution to the TTD goal is measured by the time FDA took to review the submission and render a MDUFA decision. Industry's contribution to the TTD goal is measured by the time the 510(k) submitter took to respond to FDA's request for Additional Information when the submission is on hold

(i.e., is not under review by FDA). Both FDA and industry contributed to missing this shared outcome goal. In FY 2020, compared to FY 2019, FDA increased the number of days it took to review 510(k) submissions by 2.1 days. In addition, industry days increased by 9.1 days in FY 2020 compared to FY 2019. The combination of these factors led to missing the FY 2020 TTD goal. Factors that may have contributed to missing this goal include an increased size and complexity of medical device submissions, a lack of consistent formatting of submissions, and the COVID-19 public health emergency.

As discussed above, FDA prioritized its work related to the COVID-19 public health emergency, which significantly impacted the FY 2020 cohort. In addition, during the COVID-19 public health emergency, industry was granted additional time to respond to requests for additional information for most submissions. If submitters needed this additional time to respond, this additional time would contribute to the TTD for that submission. Submitters taking additional time to respond to FDA requests for Additional Information appears to have been caused by a variety of factors, including but not limited to global supply-chain issues, difficulty in scheduling non-clinical performance testing from third-party testing laboratories, and difficulty collecting clinical data at clinical sites.

C. CORRECTIVE ACTIONS

As noted above, FDA will continue to prioritize its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic has continued to evolve, the volume of new EUA submissions for COVID-19-related products has begun to lessen in FDA's IVD and non-IVD offices. This reduction has allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels for non-IVD offices. FDA has begun to reduce the backlog of submissions with missed goals and has begun to reverse submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases. Submissions for non-IVD products under review continue to generally meet MDUFA goals. The IVD office has been hiring, and will continue to hire, additional staff and contractors to address the increased volume of work in the office.

The TTD goal for 510(k)s decreases by 4 days each year of MDUFA IV, and both FDA and industry share responsibility to achieve the goal. As overall submission volumes increase, FDA continues to look for opportunities to streamline review processes to reduce the number of FDA days contributing to the TTD goal and to provide greater consistency and transparency to industry.

Each of the roughly 3,500 510(k) submissions FDA receives each year is prepared by the individual submitter and may utilize a different format, a different layout, and contain a variety of content. Therefore, FDA reviewers have to orient themselves each time they begin a 510(k) review. This formatting inconsistency creates inefficiencies in the review process, which is exacerbated when the submission is disorganized, is

incomplete, or contains many subsections and reports that are not linked. To help address this inefficiency, FDA published a final guidance document in July 2020 describing a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format;[11] FDA further published a final guidance on a 510(k)-specific electronic submission template[12] in September 2022. The currently available templates (one for non-IVD 510(k) and one for IVD 510(k)), referred to as "eSTAR," were piloted through the voluntary eSTAR Pilot Program launched in February 2020.[13]

Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. As of September 30, 2022 eSTAR is the only electronic submission template available to prepare a complete 510(k) electronic submission. The voluntary use of eSTAR is increasing, and FDA continues to develop and enhance this tool. Beginning on October 1, 2023, FDA will require all 510(k) submissions, unless exempted, to be submitted as electronic submissions.

In addition, in September 2019, FDA published a final guidance document on the Safety and Performance Based Pathway.[14] This pathway expands upon the Abbreviated 510(k) program and is an optional pathway for certain well-understood device types when a submitter demonstrates that a new device meets performance criteria identified by FDA in device-specific guidance documents to demonstrate that the device is as safe and effective as a legally marketed device. By identifying performance criteria for device types appropriate for the pathway and recommending test methodologies for those criteria when feasible, FDA has created a clear and transparent approach to demonstrating substantial equivalence for these device types.

FDA continues to expand on this pathway and published four additional final Safety and Performance Based Pathway guidance documents in FY 2022. As of September 30, 2022, nine final guidance documents and one draft guidance document for this pathway had been published.[15] FDA continues to identify additional device types that would be appropriate candidates for this program and to craft new guidance documents. FDA regularly encourages industry and other stakeholders to suggest additional devices for inclusion in this program and to submit evidence-based suggestions for the performance criteria.

---

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.

[12] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions.

[13] https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program.

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

[15] See https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway.

C. MDUFA Performance Enhancement Goals

The following section addresses section 738A(a)(2)(B)(i) and (iv) of the FD&C Act as added by section 904(b)(2) of FDARA, which requires FDA to provide a justification for missed performance enhancement goals and a description of the efforts FDA has put in place to improve the ability of the Agency to meet performance enhancement goals.

This section presents performance enhancement goals with required completion dates in FY 2022 that did not meet their specified goal. Consistent with other sections of this report, performance enhancement goals are defined as any non-review performance goal identified in the MDUFA IV commitment letter.

FDA had 19 performance enhancement goals due in FY 2022, all of which were completed on time. Two additional performance enhancement goals are awaiting a dependency that has yet to be completed.

1. Program and Process Implementation

A. SUMMARY OF PERFORMANCE

FDA had 19 performance enhancement goals due in FY 2022, all of which were completed on time. Two additional performance enhancement goals are awaiting a dependency that has yet to be completed.

B. JUSTIFICATION

FDA did not miss any FY 2022 performance enhancement goals. Therefore, no justification is needed.

C. FY 2021 CORRECTIVE ACTIONS

FDA did not miss any FY 2022 performance enhancement goals. Therefore, no corrective action is needed.

Appendix F: Rationale for MDUFA Program Changes

FDARA amended the FD&C Act to require the reporting of certain information relating to MDUFA program changes in the annual performance report. Specifically, section 903(b)(2) of FDARA added section 738A(a)(1)(A)(iv) of the FD&C Act, which requires the MDUFA annual performance report to include the following, starting in FY 2020:

(I) Data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and the number of full-time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) Data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of devices, including identifying drivers of such changes; and

(III) For each of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

The information below fulfills these requirements.

A. Changes in the Number of Full Time Equivalents (FTEs) Hired as Agreed Upon in the MDUFA IV Commitment Letter and Number of FTEs Funded by Budget Authority at FDA by Division Within CDRH, CBER, ORA, and the Office of the Commissioner (OC)

This section addresses the requirement in section 738A(a)(1)(A)(iv)(I) of the FD&C Act, as added by section 903(b)(2) of FDARA, to provide data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner.

1. Changes in the Number of FTEs Hired as Agreed Upon in the MDUFA IV Commitment Letter

The table below provides data to show changes in the number of FTEs hired, from FY 2021 to FY 2022, as agreed upon in the MDUFA IV commitment letter. Relevant information about the data provided is as follows:

- *Number of MDUFA IV Positions Filled* = the number of people hired under MDUFA IV. The MDUFA IV commitment letter states:

  > The Agency will apply user fee revenues to reduce the ratio of review staff to front line supervisors in the premarket review program to improve consistency. The Agency will also apply user fee revenues to enhance and supplement scientific review capacity by hiring device application reviewers as well as leveraging external experts needed to assist with the review of device applications (section III-B) and "to support the National Evaluation System for health Technology by … hiring FDA staff with expertise in the use of [Real World Evidence]" (section IV-H). However, the MDUFA IV commitment letter does not specify numerical hiring goals in terms of FTEs. Therefore, the Agency is providing data on the number of MDUFA IV positions filled through the end of the relevant fiscal year. Although some positions are filled from outside FDA, in some cases, a position can also be filled by a current FDA employee who is changing positions within the Agency. Numbers are provided cumulatively through the most recent fiscal year [B] and prior fiscal year [A].[1]

- *Change in Positions Filled (FY 2020) [C]* = the cumulative number of MDUFA IV positions filled through the most recent fiscal year minus the cumulative number of MDUFA IV positions filled through the prior fiscal year ([C] = [B] - [A]). This difference is equivalent to the number of MDUFA IV positions filled using MDUFA IV user fee revenues in the most recent fiscal year.

In summary, FDA filled all 217 MDUFA IV positions through the end of FY 2021, fulfilling its MDUFA IV hiring objectives.

[1] This table displays the *cumulative* number of MDUFA IV positions filled through the end of each fiscal year. Other user fee program reports may display the number of relevant positions filled in each fiscal year (non-cumulative).

MDUFA IV Positions Filled

Center	Number of MDUFA IV Positions Filled		Change in MDUFA IV Positions Filled (FY 2022) [C] ([B] – [A])
	Through FY 2021 [A]	Through FY 2022 [B]	
CDRH	213	213	0
CBER	4	4	0
ORA	0	0	0
OC	0	0	0
Total	**217**	**217**	0

2. *Changes in the Number of FTEs Funded by Budget Authority at FDA by Division Within CDRH, CBER, ORA, and OC*

The table below provides data to show the change from FY 2021 to FY 2022 in the number of FTEs funded by budget authority at FDA by each division within CDRH, CBER, ORA, and OC. All numbers in the table below have been rounded to the nearest tenths place. Relevant information about the data provided is as follows:

- *Number of MDUFA Program FTEs Funded by Budget Authority.* The table reflects the number of FTEs funded by budget authority for the MDUFA program. For this report, "budget authority" refers to FDA's non-user fee annual appropriations. The numbers in the table below reflect use of 2080 compensable hours to equate to one FTE and are provided for the most recent fiscal year [B] and the prior fiscal year [A].

- *Change in Number of MDUFA Program FTEs Funded by Budget Authority [C]* = the number of MDUFA program FTEs funded by budget authority in the most recent fiscal year minus the number of MDUFA program FTEs funded by budget authority in the prior fiscal year ([C] = [B] – [A]).

- To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," for CDRH, the information in the table is broken down to the offices within CDRH and the sub-offices within OPEQ. OPEQ, offices within OPEQ, the Office of Policy (OP), and the Office of Strategic Partnerships and Technology Innovation (OST) were established as part of CDRH's 2019 reorganization, which was completed on September 30, 2019. This approach to breakdown the divisions within CDRH is consistent with the interpretation of similar statutory language in other parts of section 903 of FDARA that are addressed in other sections of this report. For CBER, ORA, and OC, the information in the table is broken down to the office level.

In summary, FDA's MDUFA Process FTE funded by budget authority decreased from FY 2021 to FY 2022 due to the use of additional user fee funding from the MDUFA

carryover to support increased payroll costs. As reflected in the FY 2022 MDUFA financial report, the total MDUFA process FTEs increased from FY 2021 to FY 2022. This increase was attributed to an increased level of staff supporting MDUFA process activities, while new EUA submissions related to COVID-19 decreased.

MDUFA Program FTEs Funded by Budget Authority

Center & Office	Number of MDUFA Program FTEs Funded by Budget Authority**		Change in Number of MDUFA Program FTEs Funded by Budget Authority [C]
	FY 2021 [A]	FY 2022 [B]	
CDRH*			
OCD	9.9	7.9	-2.0
OPEQ			
OPEQ-OHT1	*36.7*	*25.7*	-11
OPEQ-OHT2	*43.2*	*29.1*	-14.1
OPEQ-OHT3	*40.4*	*33.3*	-7.0
OPEQ-OHT4	*30.1*	*20.6*	-9.5
OPEQ-OHT5	*27.7*	*21.1*	-6.6
OPEQ-OHT6	*30.6*	*21.9*	-8.7
OPEQ-OHT7	*43.0*	*63.6*	20.6
OPEQ-OHT8§§		*8.3*	8.3
OPEQ-OCEA	*52.6*	*47.6*	-5.0
OPEQ-ORP	*20.0*	*7.0*	-13.0
OPEQ-IO	*11.6*	*17.7*	6.1
OCE	36.6	21.6	-15.0
OM	34.5	29.0	-5.5
OP	6.4	5.8	-0.6
OSEL	22.9	14.1	-8.8
OST	25.5	24.5	-1.0
ODT***	2.0	1.3	-0.7
WCF	48.4	56.3	7.9
CBER			
OBE	1.3	1.0	-0.3
OBRR	38.4	32.0	-6.4
OCBQ	2.6	5.1	2.5
OTAT	4.5	4.2	-0.3
OVRR	0.2	0.0	-0.2
OCOD	2.3	1.4	-0.9
OD	5.8	3.2	-2.6
OM	4.4	3.4	-1.0
OIMT	0.4	0.3	0.1
WCF	4.8	4.7	-0.1

Center & Office	Number of MDUFA Program FTEs Funded by Budget Authority**		Change in Number of MDUFA Program FTEs Funded by Budget Authority [C]
	FY 2021 [A]	FY 2022 [B]	
OBPV††		0.2	
ORO‡‡		0.7	
ORA‡			
OMDRHO	26.3	32.0	5.7
WCF	2.3	2.5	0.2
OC§			
OC-IO	1.7	1.6	-0.1
OCC	12.0	14.0	2.0
OCS	4.4	4.3	-0.1
OCPP	12.4	11.7	-0.7
OEA	2.1	2.3	0.2
OHI	0.7	0.0	-0.7
OO	9.5	9.5	0.0
OPLIA	8.6	13.3	4.7
OSMP	0	0.0	0.0
WCF	4.4	4.5	0.1
OGPS	0.0	0.1	0.1

* The CDRH abbreviations are as follows: OCD=Office of the Center Director; OPEQ=Office of Product Evaluation and Quality; OHT=Office of Health Technology; OCEA=Office of Clinical Evidence & Analysis; ORP=Office of Regulatory Programs; IO=Immediate Office; OCE=Office of Communication and Education; OM=Office of Management; OP=Office of Policy; OSEL=Office of Science and Engineering Laboratories; OST=Office of Strategic Partnership and Technology Innovation; ODT=Office of Digital Transformation;; and WCF=Working Capital Fund (which is not an office).
^ This office is sometimes referred to as "OIR."
The CBER abbreviations are as follows: OBE=Office of Biostatistics and Epidemiology; OBRR=Office of Blood Research and Review; OCBQ=Office of Compliance and Biologics Quality; OTAT=Office of Tissues and Advanced Therapies; OVRR=Office of Vaccines Research and Review; OCOD=Office of Communication Outreach and Development; OD=Office of the Center Director; OM=Office of Management; OIMT=Office of Information Management and Technology; WCF=Working Capital Fund (which is not an office); OBPV=Office of Biostatistics and Pharmacovigilance; and ORO=Office of Regulatory Operations.
‡ The ORA abbreviations are as follows: OMDRHO=Office of Medical Devices and Radiological Health Operations and WCF=Working Capital Fund (which is not an office).
§ The OC abbreviations are as follows: OC-IO=Office of the Commissioner – Immediate Office; OCC=Office of Chief Counsel; OCS=Office of Chief Scientist; OCPP=Office of Clinical Policy and Programs; OEA=Office of External Affairs; OHI=Office of Health Informatics; OO=Office of Operations; OPLIA=Office of Policy, Legislation and International Affairs; OSMP=Office of Special Medical Programs; and WCF=Working Capital Fund (which is not an office).
**This table includes MDUFA program FTEs calculated through Working Capital Fund (WCF) assessments for certain centrally administered services provided to CDRH, CBER, ORA, and OC. Because many employees under OC and WCF do not report time, an average cost per OC WCF FTE was applied to derive the number of MDUFA program FTEs funded by budget authority.
†† A reorganization in CBER created this new office, it used to be part of OBE.
‡‡ A reorganization in CBER created this new office, it used to be part of OD.
§§ A reorganization in CDRH created this new office, which used to be part of OPEQ-OHT7.
*** This office was formerly called "OIMT."

B. Changes in the Fee Revenue Amounts and Costs for the Process for the Review of Devices

This section addresses the requirement in section 738A(a)(1)(A)(iv)(II) of the FD&C Act, as added by section 903(b)(2) of FDARA, to provide "data, analysis, and discussion of

the changes in the fee revenue amounts and costs for the process for the review of devices, including identifying drivers of such changes." Accordingly, the table below provides data for the MDUFA fee revenue amounts and process costs for FY 2021 and FY 2022, and the changes in these amounts from FY 2021 to FY 2022. Relevant information about the data provided is as follows:

- Fee Revenue Amounts represent FDA's net collection of medical device user fees.
- Review Process Cost represents FDA's total expenditure on the MDUFA program.
-
- Numbers are provided for both the most recent fiscal year [B] and prior fiscal year [A].
- *Change [C]* = shows fee revenue amounts or review process costs in the most recent fiscal year [B] minus fee revenue amounts or review process costs in the prior fiscal year [A] ([C] = [B] – [A]).

In summary, in FY 2022, FDA had net collections of $260 million in medical device user fees, which is a decrease of $8 million compared to FY 2021. This decrease can be attributed to a decrease in the number of new establishment registrations relative to FY 2021. FDA spent nearly $626 million in user fees and budget authority for the device review process in FY 2022, which is an increase of about $106 million compared to FY 2021. This increase was due to factors including an increase in FDA's level of staff effort towards MDUFA process-related activities, an increase in MDUFA-related payroll costs, and an increase in operating spending to expedite the implementation of the Digital Transformation initiative in support of MDUFA process activities. Detailed financial information for the MDUFA program can be found in the FY 2022 MDUFA financial report.

MDUFA Fee Revenues and Cost

Revenue/Cost	FY 2021 [A]	FY 2022 [B]	Change [C]
Fee Revenue Amounts (Net Collections) [1]	$268,753,004	$260,321,107	-$8,431,897
Review Process Cost	$519,469,345	$625,818,538	$106,349,193

[1] This includes unearned revenue.

C. Number of Employees for Whom Time Reporting Is Required

This section addresses the requirement in section 738A(a)(1)(A)(iv)(III) of the FD&C Act, as added by section 903(b)(2) of FDARA, to provide,

for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

Relevant information about the time reporting numbers provided in the table below is as follows:

- The numbers in the table represent the number of employees who were required to report their time and the number of employees who were not required to report their time as of September 30, 2022.

- These data reflect time reporting across all employees in each entity, rather than only those engaged in MDUFA program activities.

FY 2022 Time Reporting Requirements

	Number of Employees	
Center	Time Reporting Required	Time Reporting Not Required
CDRH	1,981	29
CBER	1,232	5
ORA	4,422	280
OC	55	2,632
Total	7,690	2,946

.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management. For information on obtaining additional copies, please contact:

Office of Planning, Evaluation, and Risk Management
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: 301-796-4850
E-mail: OPERM_ADMIN_Team@fda.hhs.gov

This report is available on FDA's home page at https://www.fda.gov/