Performance Report to Congress

Medical Device User Fee Amendments

FY 2023

Executive Summary

The fourth reauthorization of the Medical Device User Fee Amendments (MDUFA) program occurred on September 30, 2022, when the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180),[1] of which Division F is titled the FDA User Fee Reauthorization Act of 2022 (FUFRA). FUFRA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize the MDUFA program for an additional 5 years. This iteration of the MDUFA program is referred to as "MDUFA V" and is effective from fiscal year (FY) 2023 through FY 2027.

This report presents preliminary data on the progress of the U.S. Food and Drug Administration (FDA or Agency) in meeting FY 2023 MDUFA V goals and updated data on FDA's progress in meeting FY 2020, FY 2021, and FY 2022 MDUFA IV goals.

This report also addresses additional performance data (including for MDUFA performance-enhancement goals) that are required to be provided by section 738A(a)(1)-(2) of the FD&C Act and in connection with the Consolidated Appropriations Act, 2017 (Public Law 115-31).

All data presented in this report are as of September 30, 2023.

A. Preliminary FY 2023 Performance Results

1. Review Goals

FDA received FY 2023 submissions to calculate performance results for 16 of the 25 MDUFA V review goals. As of September 30, 2023, for those 16 review goals, two review goals were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 review goals (including the two shared outcome 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). For the remaining nine (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 (for three goals) or there were no submissions (for six goals)

[1] https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf.

2. Performance-Enhancement Goals

FDA had 16 performance-enhancement goals due in FY 2023, all of which were completed on time, except for one. Two additional goals due at the end of MDUFA V were met ahead of schedule.

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Acronym List

ASCA	Accreditation Scheme for Conformity Assessment
BA	Budget Authority
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CLIA	Clinical Laboratory Improvement Amendments
eSTAR	electronic Submission Template And Resource
EUA	Emergency Use Authorization
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)
IDE	Investigational Device Exemption
IMDRF	International Medical Device Regulators Forum
IVD	In Vitro Diagnostic
MDUFA	Medical Device User Fee Amendments
NEST	National Evaluation System for health Technology
NSE	Not Substantially Equivalent
OC	Office of the Commissioner
OHT	Office of Health Technology
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
PPE	Personal Protective Equipment
SE	Substantially Equivalent
TTD	Total Time to Decision

I. Introduction

On September 30, 2022, the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180), of which Division F is titled the FDA User Fee Reauthorization Act of 2022 (FUFRA). FUFRA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize the MDUFA program for an additional 5 years. This iteration of the MDUFA program is referred to as "MDUFA V". MDUFA V authorizes the U.S. Food and Drug Administration (FDA or 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 from MDUFA IV to MDUFA V include modified outcome goals shared by both industry and FDA, modified review goals for Pre-Submissions and De Novo classification requests, opportunities for performance improvement adjustments, and a wide array of performance-enhancement goals. Additional information on the history of MDUFA I, MDUFA II, MDUFA III, and MDUFA IV can be found on FDA's website.[2]

A. Performance Information 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) 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 information for the FY 2023 MDUFA V cohort submissions. This report also includes updated review goal performance information for the fiscal year (FY) 2020, FY 2021, and FY 2022 MDUFA IV cohort submissions.

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

- Unless otherwise noted, all performance data are as of September 30, 2023.

[1] https://www.fda.gov/media/158308/download?attachment.

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

- 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 the submission type. This combined performance is different from the performance reported on the MDUFA 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 C of 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 are therefore 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 C 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 considered to be under review at the Agency for submissions that have been accepted (i.e., 510(k) or De Novo request), filed (i.e., PMA), or submitted (i.e., CLIA Waiver by application). FDA days begin on the date of receipt of the submission or of the

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

amendment to the submission that enables the submission to be accepted (i.e., 510(k) or De Novo request) or filed (i.e., PMA).

- "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 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.

- The preliminary review goal performance results for FY 2023 submissions is shown as the percentage of submissions completed within the goal as of September 30, 2023, excluding any submissions that have not yet reached their due date. The highest possible percent of reviews that may be completed within the goal is shown as the highest possible review goal performance result.

- Review goal performance results 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 V Quarterly Performance Reports located on FDA's website.[4]

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

2. MDUFA Performance-Enhancement Goals

For this report, "performance-enhancement goals" are defined as any non-review goal identified in the letters described in section 2001(b) of MDUFA V for the applicable fiscal year (i.e., the MDUFA V commitment letter).[5] Performance information on the FY 2023 performance-enhancement goals is located in Appendices E and F of this report.

3. Additional Performance Data

The fourth reauthorization of the MDUFA program occurred on September 30, 2022, when the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, (Public Law 117-180)[6], of which Division F is titled the FDA User Fee Reauthorization Act of 2022 (FUFRA). FUFRA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize the MDUFA program for an additional 5 years. This iteration of the MDUFA program is referred to as "MDUFA V" and is effective from FY 2023 through FY 2027.

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 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 C of this report.

On August 18, 2017, the FDA Reauthorization Act of 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 through FY 2022. FDARA required "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 required 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 for the applicable fiscal year (section 904). Section 2004 of FUFRA retained these requirements for MDUFA V, and section 3626(b) of the Food and

[5] https://www.fda.gov/media/158308/download?attachment.

[6] https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf.

Drug Omnibus Reform Act of 2022 amended the FD&C Act to require reporting of additional information about the MDUFA program. This information is contained in Appendices D, E, F, and G 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 for an approval of a device submitted under section 515(c) of the FD&C Act. It does not include a supplement to such an application after it has been approved or a Premarket Report.
- **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 supplement to an approved Original PMA or Premarket Report that requires significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.
- **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 supplement to an approved Original PMA or Premarket Report that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.
- **Real-Time PMA Supplement** - A supplement to an approved Original PMA or Premarket Report that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested, and the Agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.
- **De Novo Classification Request -** A request made under section 513(f)(2) of the FD&C Act with respect to the classification of a device. In general, a request for FDA to classify a device for which there is no legally marketed predicate but for which general or general and special control provide a reasonable assurance

of safety and effectiveness.

- **Premarket Notification (510(k))** - A report submitted under section 510(k) of the FD&C Act. A 510(k) is submitted to FDA to demonstrate that a device to be marketed is substantially equivalent (SE) 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.[7]
- **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 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 SE 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, formal written feedback followed by a meeting or teleconference in which any additional feedback or clarification is documented in meeting minutes. 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), certain investigational new drug applications (INDs), a CLIA Waiver by Application, an Accessory Classification Request, or a marketing application. The request should include specific questions regarding review issues relevant to a planned IDE, IND, CLIA Waiver by Application, Accessory Classification Request, 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

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

the treatment, diagnosis, or prevention of a serious condition. A "non-priority BLA" is considered a "standard BLA."[8]

- **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.

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

II. MDUFA Review-Time Goals and Commitments

For this report, MDUFA V review goals include review goals with specific target percentages and shared outcome goals. The tables below summarize the review goal commitments agreed to in MDUFA V for FY 2023 through FY 2027.

A. Review Goals with Specific Target Percentages

Table 1 summarizes the 23 review goals agreed to in MDUFA V 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 a "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 2023 through FY 2027.

Table 1. Review-Time Goals and Commitment Targets

Submission Type	Review-Time Goal	Commitment Target				
		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
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%
De Novo Classification Requests						
Decision	150 FDA days	70%	70%	70%	70-80%*	70-90%*

Submission Type	Review-Time Goal	Commitment Target				
		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
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	90% if < 3585 or 75% up to 4300	90% if < 4060 or 80% up to 4300	90% of 4300 – 4700*	90% of 4300 – 4800*	90% of 4300 – Total Received*
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%

* With a performance improvement adjustment.

B. Shared Outcome Goals

Table 2 summarizes the review goals related to the shared outcomes agreed to in MDUFA V for relevant submission types and for each fiscal year from FY 2023 through FY 2027. 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 V commitment letter.

Table 2. MDUFA V's Shared Outcome Goals

Submission Type	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Original PMAs and Panel-Track PMA Supplements					
Total TTD Goal (Days)	290	290	285	285-275*	285-270*
510(k) Premarket Notifications					
Total TTD Goal (Days)	128	124	112	112-108*	112-108*

* With a performance improvement adjustment.

III. MDUFA V Review Goal Performance

A. Summary of Review Goal Performance Results

For this report, MDUFA V review goals include review goals with specific target percentages and shared outcome goals. Tables 3 and 4 summarize FDA's preliminary MDUFA V review goal performance results in FY 2023. FDA will continue to report on its MDUFA IV review goal performance results until it can determine if it has met or missed each goal for which it has received sufficient submissions to determine the goal performance results (see Appendix A of this report).

Each fiscal year, FDA has the following 25 MDUFA V review goals: 23 review goals with specific target percentages and two shared outcome goals. FDA received FY 2023 submissions to calculate performance results for 16 of the 25 MDUFA V review goals. As of September 30, 2023, for those 16 review goals, two review goals were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 review goals (including the two shared outcome 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). For the remaining 9 (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 (three goals) or there were no submissions (six goals).

B. Review Goals with Specific Target Percentages

Tables 3 and 4 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]. Additional details on FDA's review goal performance results can be found in the MDUFA Quarterly Performance Reports posted on FDA's website.[9]

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]).

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

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

- *Completed Overdue [C]* = the number of submissions with a MDUFA action as of September 30th of the applicable fiscal year 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 30th of the applicable fiscal year.

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

- *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, the Highest Possible Review Goal Performance [H] = ([B] + [D]) / [A].

For certain submissions, the MDUFA V 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 result. 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 was calculated 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 results 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 2023 Preliminary Performance Data

FDA received FY 2023 submissions to calculate performance results for 16 of the 25 MDUFA V review goals. As of September 30, 2023, for those 16 review goals, two

review goals were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 review goals (including the two shared outcome 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). For the remaining nine (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 (three goals) or there were no submissions (six goals).

For goals for which FDA received a sufficient MDUFA cohort to calculate performance results and had at least one "Completed" submission, Table 3 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, 2023, FDA had met two review goals with a specific target percentage and missed no review goal.

Table 3. FY 2023 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	64	54	1	9	0	95%	98%	98%
Decision with No Advisory Committee Input	61	16	0	45	0	90%	100%	100%
Decision with Advisory Committee Input	3	0	0	3	0	90%	§	§
180-Day PMA Supplements								
Substantive Interaction	172	121	6	45	0	95%	95%	97%
Decision	172	61	2	109	0	95%	97%	99%
Real-Time PMA Supplements								
Decision	245	172	2	71	0	95%	99%	99%
De Novo								
Decision	74	22	0	51	1	70%	96%	99%
510(k) Premarket Notifications†								

Substantive Interaction	3,222	2651	82	482	7	95%	97%	97%
Decision	3,203	1,759	11	1,427	6	95%	99%	99%
CLIA Waiver by Applications								
Substantive Interaction[#]	2	1	1	0	0	90%	§	§
Decision with No Advisory Committee Input	3	3	0	0	0	90%	§	§
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	14	13	0	1	0	90%	100% **(MET)**	100%
Decision with No Advisory Committee Input	14	4	0	10	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	3,639	3,062	38	538	1	90% if < 3585 (75% up to 4300)	99% **(MET)**	99%
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	6	0	0	6	0	90%	N/A	100%
BLA Manufacturing Supplements Requiring Prior Approval[†]	81	65	0	16	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	1	0	0	1	0	90%	N/A	100%
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 2023; 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.

One CLIA Waiver was denied before Substantive Interaction.

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

C. Shared Outcome Goals (FY 2023 Through FY 2027)

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 V commitment letter. A PMA cohort is considered closed when 95 percent of applications in the MDUFA V cohort have reached a decision. A 510(k) cohort is considered closed when 99 percent of submissions in the MDUFA cohort have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER.

FDA's performance in the MDUFA V shared outcome goals (as well as whether the goal was met or missed) as of September 30, 2023, is shown in **bold** text in Table 4. The FY 2023 510(k) cohort and the FY 2023 PMA cohort 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.

Table 4. MDUFA V's Shared Outcome Goals

Submission Type	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Original PMAs and Panel-Track PMA Supplements					
TTD Goal (Days)	290	290	285	285-275**	285-270**
TTD Performance (Days)	*	*	*	*	*
510(k) Premarket Notifications					
TTD Goal (Days)	128	124	112	112-108**	112-108**
TTD Performance (Days)	*	*	*	*	*

* As of September 30, 2023, the fiscal year cohort had not met the decision threshold to calculate performance results.
** With a performance improvement adjustment.

D. Progress on Goals Relevant to Performance Improvement Adjustments

1. Overview

Section 738(c)(4) of the FD&C Act provides for increases in fee revenue above the annual total revenue amount to support performance improvements in FY 2025, FY 2026, and/or FY 2027 if the following review goals are met based on data available as of certain dates specified in the statute:

- PMA decision
- 510(k) decision
- PMA Shared Outcome Total Time to Decision
- 510(k) Shared Outcome Total Time to Decision
- De Novo decision
- Pre-Submission written feedback

Performance of the Pre-Submission written feedback goal is to be determined based on data available as of 6 months following the close of the fiscal year at issue (e.g., for FY 2023, based on data available as of March 31, 2024). Performance of the other goals is to be determined based on data available as of 18 months following the close of the fiscal year at issue (e.g., for FY 2023, based on data available as of March 31, 2025).

As of September 30, 2023, for purposes of the performance improvement adjustments, the first five goals are pending, and preliminary data indicates that the Pre-Submission written feedback goal for FY 2023 will be met.

2. PMA and 510(k) Decision Goals and Shared Outcome Total Time to Decision

Preliminary performance data regarding FY 2023 are contained in the tables and text above and indicate that all four goals are pending.

3. De Novo Decision

Preliminary performance data regarding FY 2023 are contained in the table and text above and indicate that the goal is pending.

4. Pre-Submission Written Feedback

Preliminary performance data regarding FY 2023 are contained in the table and text above and indicate that the Pre-Submission written feedback goal will be met for FY 2023.

IV. MDUFA Review Workloads: FY 2018 Through FY 2023

Table 5 compares review workloads for submission types with MDUFA review goals for FY 2023 and a 5-year average (FY 2018 through FY 2022).

- The review workload reflects the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee).
- 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 2023 was calculated for 15 submission types that had data available to calculate a 5-year average. Four of the 15 submission types did not receive any submissions for FY 2023. De Novo Classification requests and Standard Original BLAs had a notable workload increase in FY 2023 compared to the 5-year average.

Table 5. Review Workload by Submission Type

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	5-Year Average(FY 2018 to FY 2022)	FY 2023 Compared to 5-Year Average
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	77	59	80	79	47	76	68	12%
180-Day PMA Supplements	196	196	184	196	151	175	185	-5%
Real-Time PMA Supplements	341	375	358	288	276	245	328	-25%
510(k) Premarket Notifications	3591	3776	3830	4084	3858	4062	3828	6%
De Novo Classification Requests	56	62	69	63	80	97	66	47%
CLIA Waiver by Applications	4	9	1	3	1	3	4	-25%
Dual 510(k) and CLIA Waiver by Applications	11	6	6	4	10	14	7	100%

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	5-Year Average(FY 2018 to FY 2022)	FY 2023 Compared to 5-Year Average
Pre-Submissions	2783	3253	3383*	3172*	3180*	3904	3154	24%
BLAs								
Priority Original BLAs	0	0	0	0	0	0	0	0%
Standard Original BLAs	14	4	0	2	1	6	4	50%
BLA Manufacturing Supplements Requiring Prior Approval	94	54	92	52	48	81	68	19%
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0	0%
Standard BLA Efficacy Supplements	1	8	2	0	0	1	2	-50%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	17	0	0	0	0	4	-100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	7	0	1	0	2	0	2	-100%

* Due to a reallocation of resources for COVID-19 activities, this figure does not include Pre-Submissions resubmitted after being closed without feedback.

Appendix A: MDUFA IV Updated Performance Results

A. Summary of MDUFA IV Performance Results

For each fiscal year covered by MDUFA IV, FDA had the following 25 review goals: 22 review goals with specific target percentages, a Pre-Submission written feedback goal, and two shared outcome goals. Updated performance data through September 30, 2023, including completed and pending reviews, indicate that FDA has sufficient data to calculate performance results on 16 FY 2022 goals, 13 FY 2021 goals, and 16 FY 2020 goals. FDA met (or has the potential to meet) seven of the 16 FY 2022 review goals, four of the 13 FY 2021 review goals, and 12 of the 16 FY 2020 review goals. FDA's ability to meet its MDUFA IV performance goals was impacted by the significant increase of premarket submissions due to the COVID-19 public health emergency (PHE), resulting in nine missed FY 2022 review goals, nine missed FY 2021 review goals, and four missed FY 2020 review goals.

Table A-1. 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%
De Novo Classification Requests						
Decision	150 FDA days	50%	55%	60%	65%	70%

Submission Type	Review-Time Goal	Commitment Target				
		FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
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%

B. Updated FY 2022 Performance Results

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, 2023, for those 16 review goals, five review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed, and the two shared outcome 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). For the remaining nine of the 25 review goals, FDA did not receive any submissions (for six goals), or the received MDUFA cohort was insufficient to calculate performance (for three goals).

C. Updated FY 2021 Performance Results

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, 2023, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, and nine review goals were sufficiently complete to determine the outcome and were missed. For the remaining 12 of the 25 review goals, FDA did not receive any submissions (for seven goals), or the received MDUFA cohort was insufficient (in single or combined years) to calculate performance (for five goals).

D. Updated FY 2020 Performance Results

1. Review Goals

FDA received enough FY 2020 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, 12 review goals were sufficiently complete to determine the outcome and were met and four review goals were sufficiently complete to determine the outcome and were missed. For the remaining 9 of the 25 review goals, FDA did not receive any submissions (for seven goals), or the received MDUFA cohort was insufficient to calculate performance (for two goals).

E. Review Goals with Specific Target Percentages

1. FY 2022 Updated Performance Data

FDA received FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, five review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed, and the two shared outcome 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).

For the remaining nine of the 25 review goals, FDA did not receive any submissions (for six goals), or the received MDUFA cohort was insufficient to calculate performance (for three goals). For goals for which FDA received a sufficient MDUFA cohort to calculate performance results and had at least one "Completed" submission, Table A-2 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, 2023, FDA had met five review goals with a specific target percentage (including the Pre-Submission written feedback goal) and missed nine. Specifically, FDA met the (1) Pre-Submission Written Feedback; (2) De Novo Classification Requests - Decision; (3) Standard Original BLAs Decision goal; (4) BLA Manufacturing Supplements Requiring Prior Approval Decision goal; and (5) Class 2 Original BLA and BLA Efficacy Supplement Resubmissions Decision goal. FDA 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) Real-Time PMA Supplements Decisions; (6) 510(k) Premarket Notifications - Substantive Interaction; (7) 510(k) Premarket Notifications – Decision review goals; (8) Dual 510(k) and CLIA Waiver by Applications Substantive Interactions; and (9) Dual 510(k) and CLIA Waiver by Applications Decision.

Table A-2. FY 2022 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	45	39	5	1	0	95%	89% **(MISSED)**	89%
Decision with No Advisory Committee Input	45	32	5	7	1	90%	84% **(MISSED)**	87%
Decision with Advisory Committee Input	2 (0)	1 (0)	0 (0)	1 (0)	0 (0)	90%	‡	‡
180-Day PMA Supplements								
Substantive Interaction	147	116	31	0	0	95%	79% **(MISSED)**	79%
Decision	143	115	20	7	1	95%	85% **(MISSED)**	85%
Real-Time PMA Supplements								
Decision	271	253	18	0	0	95%	85% **(MISSED)**	85%

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]
De Novo								
Decision	74	51	16	4	3	70%	73% **(MET)**	74%
510(k) Premarket Notifications†								
Substantive Interaction	3,572	3,129	433	7	3	95%	85% **(MISSED)**	85%
Decision	3,260	2,928	221	67	44	95%	92% **(MISSED)**	92%
CLIA Waiver by Applications§								
Substantive Interaction	5 (1)	0 (0)	3 (0)	0 (0)	0 (0)	90%	‡	‡
Decision with No Advisory Committee Input	5 (1)	2 (1)	3 (0)	0 (0)	0 (0)	90%	‡	‡
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications ¶								
Substantive Interaction	14 (10)	0 (0)	13 (9)	0 (0)	1 (1)	90%	0% **(MISSED)**	0%
Decision with No Advisory Committee Input	14 (10)	1 (0)	8 (5)	0 (0)	5 (5)	90%	7% **(MISSED)**	7%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,987	2,285	702	0	4	1,950	2285 **(MET)**	N/A
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	1	1	0	0	0	90%	100% **(MET)**	100%
BLA Manufacturing Supplements Requiring Prior Approval	48	48	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%	*	*

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]
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2	2	0	0	0	90%	100% **(MET)**	100

* No submissions were received in FY 2023; 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 2020, FY 2021, and FY 2022 submissions.
¶ The performance shown is from a combined MDUFA cohort of FY 2021 and FY 2022 submissions.

F. FY 2021 Updated Performance Data

FDA had a sufficiently complete MDUFA cohort to determine the outcome for 11 of the 23 review goals with specific target percentages, including the Pre-submission written feedback goal. For the remaining 12 goals, FDA did not receive any submissions (for seven goals), or the received MDUFA cohort was insufficient (in single or combined years) to calculate performance results (for five goals).

For goals for which FDA received a sufficient MDUFA cohort to calculate performance results and had at least one "Completed" submission, Table A-3 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 Table A-3.

In summary, as of September 30, 2023, FDA had met four review goals with a specific target percentage and missed seven. 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) De Novo Decision; (6) 510(k) Premarket Notifications - Substantive Interaction; and (7) 510(k) Premarket Notifications – Decision review goals.

Table A-3. 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	52	18	0	0	90%	74% **(MISSED)**	74%
Decision with Advisory Committee Input	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	90%	#	#
180-Day PMA Supplements								
Substantive Interaction	185	152	33	0	0	95%	82% **(MISSED)**	82%
Decision	183	163	19	0	1	95%	89% **(MISSED)**	89%
De Novo Classification Requests								
Decision	56	36	17	0	3	65%	64% **(MISSED)**	64%
510(k) Premarket Notifications†								
Substantive Interaction†	3,751	3,277	467	1	6	95%	87% **(MISSED)**	87%
Decision	3,399	3,006	360	11	22	95%	89% **(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)	3 (2)	0 (0)	0 (0)	90%	#	#
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	4	0	4	0	0	90%	#	#
Decision with No Advisory Committee Input	4	1	3	0	0	90%	#	#
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*

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]
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
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.
§ 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 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.

G. FY 2020 Updated Performance Data

By September 30, 2023, FDA had a sufficiently complete MDUFA cohort to determine the outcome for the one remaining review goal with a specific target percentage from the FY 2020 cohort. In summary, FDA met the review goals for Original PMA, PDP, Panel Track PMA Supplements, and Premarket Reports – Decision with Advisory No Committee Input.

Table A-4. 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	67	5	0	0	90%	93% **(MET)**	93%

H. 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, 2023, is shown in **bold** text in the table below. The FY 2020 PMA cohort met the decision threshold to calculate the average TTD, and FDA met the goal. The FY 2021 PMA and FY 2021 510(k) cohorts met the decision threshold to calculate the average TTD, and FDA missed these goals. The FY 2022 510(k) cohort 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.

Table A-5. 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)**	277 **(MET)**	305 **(MISSED)**	*
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
TTD Performance (Days)	123 **(MET)**	128 **(MISSED)**	139 **(MISSED)**	141 **(MISSED)**	*

* As of September 30, 2023, the fiscal year cohort had not met the decision threshold to calculate performance results.

Appendix B: Definition 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. 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), filed (PMA), or submitted (CLIA Waiver by Application). FDA days begin on FDA's date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted (510(k) or De Novo 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 inspection • Not Approvable • Withdrawal (including Deletions) • Denial
180-Day PMA Supplements	• Approval • Approvable • Not Approvable

Submission Type	MDUFA Decisions
Real-Time PMA Supplements	• Approval • Approvable • Not Approvable
510(k)s	• 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, formal written feedback followed by a meeting or teleconference in which additional feedback or clarifications are documented in meeting minutes. A Pre-Submission provides the opportunity for an applicant to obtain FDA's feedback prior to an intended submission of an IDE, certain INDs,[11] a CLIA Waiver by Application, an Accessory Classification Request, or a marketing application. The request should include specific questions regarding review issues relevant to a planned IDE, IND, IND, CLIA Waiver by Application, Accessory

[11] Certain devices subject to premarket review through a BLA under section 351 of the Public Health Service Act are studied under an IND.

Classification Request, or marketing application or marketing application (e.g., questions regarding pre-clinical testing protocols or data requirements; design and performance of clinical studies and acceptance criteria). A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or 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:

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

- TPLC Advisory Program Pilot interactions.

- General information requests initiated through the Division of Industry and Consumer 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: recommendations for 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.

F. Review Workload: The review workload reflects the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee).

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
Pre-Submissions	CDRH and CBER
BLAs and BLSs	CBER only

H. Substantive Interaction: Substantive Interaction is an email, letter, teleconference, video conference, 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 C: 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.

Table C-1 provides the requested information for the past 5 years in 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. For FY 2019 and FY 2020, the number of De Novo classification requests received includes those that passed eCopy and user fee requirements. On September 9, 2019, FDA published a final guidance describing its acceptance review policy and procedures for De Novo classification requests and explained that it intended to operationalize those policies by November 8, 2019. In addition, the Agency's final rule identifying regulatory requirements for acceptance and content of a De Novo classification request took effect on January 3, 2022. Therefore, for the reporting beginning in FY 2021 (the first full fiscal year where refuse-to-accept review was operationalized), the number of De Novo classification requests received includes those that passed eCopy and user fee requirements and were accepted for review.

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 and MDUFA V performance goals 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, 2023, FY 2019 and FY 2020 had closed cohorts. For these cohorts, FDA met the statutory timelines for issuing a final decision on a De Novo classification request 20 to 34 percent of the time. Fiscal years 2021 and 2022 are not currently closed. Therefore, these data may change. For FY 2019 to FY 2022, FDA

responded to 513(g) requests within the statutory time frame 20 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.

Table C-1. Performance Data for MDUFA IV and V Submissions with Statutory Time Frames

Submission Type	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
De Novo Classification Requests Under 513(f)(2)					
Number received that passed applicable administrative requirements	62	69	56	74	74
Number completed with a Granted, Declined, or Withdrawn decision	62	64	53	67	22
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory time frame of 120 days*	21	13	7	16	0
Percent that met the statutory time frame†	34%	20%	13%	22%	0%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)					
Number received that passed applicable administrative requirements	132	132	151	133	141
Number to which FDA responded within the statutory time frame of 60 days	47	47	44	29	35
Percent that met the statutory time frame‡	36%	36%	29%	22%	25%
Postmarket Surveillance Plans					
Number received	11	28	29	13	12
Number of FDA responses within 60 days of receipt	6	21	25	9	9
Percent that met the statutory time frame	55%	75%	86%	69%	75%

* 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 D: Additional Information Required Under Section 738A(a)(1)(A)(ii) of the FD&C Act

Section 738A(a)(1)(A)(ii) of the FD&C Act requires the MDUFA annual performance report to include the following (for CDRH only):

- The number of premarket applications filed under section 515 per fiscal year for each review division;
- The number of reports submitted under section 510(k) of the FD&C Act per fiscal year for each review division;
- The number of expedited development and priority review designations under section 515C (actually section 515B) per fiscal year;
- The number of IDE applications submitted under section 520(g) per fiscal year, including for each review division; and
- The number of expedited development and priority review requests and designations under section 515B per fiscal year, including for each review division.

Table D-1 addresses the requirements of section 738A(a)(1)(A)(ii) of the FD&C Act. 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." The table also provides the number of IDE applications submitted under section 520(g) per fiscal year, including for each review division, and the number of expedited development and priority review requests and designations under section 515B per fiscal year, including for each review division.

Relevant information about the 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, 2023.

- "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, 2023.

- “IDE applications” are defined as the number of original IDE applications submitted under section 520(g) received as of September 30, 2023.

- “Expedited development and priority review requests,” referred to in the table as “Breakthrough Device Designation Requests,” are defined as the number of expedited development and priority review requests under section 515B that had received a decision or were pending a decision as of September 30, 2023.

- Expedited development and priority review designations,” referred to in the table as “Breakthrough Device Designations,” are defined as the number of expedited development and priority review designations under section 515B granted as of September 30, 2023. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.

- In the 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. 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.

- 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 are therefore not included in Table D-1. 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.

- The statute requires FDA to provide information on submissions reviewed only by CDRH. However, to ensure consistency with other tables in this report, information on the submissions reviewed by CBER is included in the numbers below for FY 2023.

Table D-1. FY 2023 MDUFA Cohorts by CDRH's OHTs and CBER

Submission Type	MDUFA Cohort	OHT1	OHT2	OHT3	OHT4	OHT5	OHT6	OHT7*†	OHT8†	CBER¶
Original PMA, PDP, Panel-Track PMA Supplements, and Premarket Reports										
Substantive Interaction	64	7	18	3	8	3	4	18	0	3
Decision with No Advisory Committee Input	61	7	16	2	8	3	4	18	0	3
Decision with Advisory Committee Input	3	0	2	1	0	0	0	0	0	0
180-Day PMA Supplements										
Substantive Interaction	172	16	56	21	8	24	7	35	1	4
Decision	172	16	56	21	8	24	7	35	1	4
Real-Time PMA Supplements										
Decision	245	24	137	19	6	17	5	32	2	3
510(k) Premarket Notifications ‡										
Substantive Interaction	3222	424	336	401	538	237	585	223	436	31
Decision	3203	433	340	395	534	241	567	223	439	31
IDEs										
Number of IDE Applications	363	42	74	36	33	74	29	46	9	20
Breakthrough Devices										
Number of Breakthrough Device Designation Requests	398	19	64	39	24	82	34	107	19	10
Number of Breakthrough Device Designations§	131	6	14	20	8	22	24	27	8	2

* This office is sometimes referred to as the Office of In Vitro Diagnostics and Radiological Health."
† OHT7 was divided into OH7 and OHT8 during FY 2022.
‡ 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.
§ As of September 30, 2023, the FY2023 receipt cohort was 80.4 percent closed.
¶ The statute requires FDA to provide information on submissions reviewed only by CDRH. However, to ensure consistency with other tables in this report, information on the submissions reviewed by CBER is included in the numbers for FY 2023.

Appendix E: Analysis of the Use of Funds

Section 738A(a)(1)(A)(v) of the FD&C Act 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 738A(a)(2) of the FD&C Act requires the issuance of corrective action reports. The required corrective action report is provided in Appendix F. The remaining required information is below.

A. Analysis of the Use of Funds

Section 738A(a)(1)(A)(v) of the FD&C Act 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

Table E-1 addresses section 738A(a)(1)(A)(v)(I) of the FD&C Act pertaining to MDUFA, which requires FDA to include data showing the 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 –

(a) 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

(b) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

Table E-1 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, 2023. "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, 2023.

- 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 are therefore 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, 2023. 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, 2023.

- *Completed Overdue [D]* = the number of Completed [B] submissions that had not met the MDUFA goal as of September 30, 2023.

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] agency" 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	NSE

- *Pending [F]* = 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, 2023.

- *Pending Overdue [H]* = the number of Pending [F] submissions that had not met the goal as of September 30, 2023.

- *Overdue (Completed + Pending) [I]* = the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year and represents the number of submissions that had not met the MDUFA goal as of September 30, 2023. Overdue [I] includes both Completed Overdue [D] and Pending Overdue [H] submissions ([I] = [D] + [H]).

Table E-1. FY 2023 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	63	55	54	1	40	8	8	0	1
Decision with No Advisory Committee Input	60	16	16	0	1	44	44	0	0
Decision with Advisory Committee Input	3	0	0	0	*0*	3	3	0	0
180-Day PMA Supplements									
Substantive Interaction	172	*127*	121	6	*65*	45	45	0	6
Decision	172	*63*	61	2	*2*	109	109	0	2
Real-Time PMA Supplements									
Decision	245	*174*	172	2	*5*	71	71	0	2
510(k)									
Substantive Interaction*	3,222	*2733*	2,651	82	*1,758*	489	482	7	89
Decision*	3,203	*1770*	1,759	11	34	1433	1,427	6	17

* 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

Table E-2 addresses section 738A(a)(1)(A)(v)(II) of the FD&C Act 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 2001(b) of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

For this report, "performance-enhancement goals" are defined as any non-review goal described in the MDUFA V 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 16 performance-enhancement goals due in FY 2023, all of which were completed on time, except for one. Two additional goals due at the end of MDUFA V were met ahead of schedule.

Table E-2. FY 2023 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 with the QMOE Program. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's nonconformity management process.	9/30/2023	Y	9/30/2023	**FY 2023 Audit Schedule:** As described in the FY 2022 MDUFA annual performance report, a call for topics to be included in the FY 2023 Audit Schedule was sent to industry on 6/2/2022. In FY 2023, after considering the industry input provided, FDA conducted a deficiency letter baseline audit (of FY 2022 letters), the MDUFA V required deficiency letter audit (of FY 2023 letters), and four audits of CDRH's Quality Management System processes. **FY 2024 Audit Schedule:** The FY 2024 data call for audit topics was sent to industry in Q3 FY 2023, and the audit schedule will be finalized in Q1 FY 2024.
Quality Management At least once per year, FDA will report on the results of the audits, best practices identified and shared across OHTs, and the actions taken in response to nonconformities associated with the nonconformity management process.	9/30/2023	Y	9/30/2023	Results from five of the six FY 2023 audits (mentioned above) were discussed at the FY 2023 4th Quarter MDUFA Performance meeting with industry (https://www.fda.gov/media/173923/download). This review included actions taken in response to minor nonconformities. Because these five audits were QMS focused or served as a baseline for a subsequent audit, identification of best practices across OHTs did not apply. As stated in the MDUFA V commitment letter (section V.B.), FDA will review the results from the MDUFA V required deficiency letter audits "with industry no later than the first quarterly meeting of the following fiscal year." This review will include best practices identified and shared across OHTs and the actions taken in response to nonconformities (if any are found).
Financial Transparency FDA will publish a MDUFA 5-year financial plan no later than the end of the 2nd quarter of FY 2023. The financial plan will include the Agency's annual hiring targets.	3/31/2023	Y	3/31/2023	The MDUFA V Five-Year Financial Plan for FY23 to FY27 was posted on March 31, 2023 (https://www.fda.gov/media/166630/download). This initial financial plan includes the MDUFA V annual hiring targets. No later than the end of the 2nd quarter of each subsequent fiscal year, FDA will publish updates to the 5-year plan as of the end of the prior fiscal year.
Carryover Balance No less than annually, FDA and industry will work together to seek alignment on how best to utilize available funds in the carryover balance to improve the process for the review of device applications – e.g., the performance on submission types with performance goals and/or quality management programs. FDA and industry will use, as input for the discussion, workload information, performance objectives, and ongoing reported performance.	9/30/2023	Y	9/30/2023	Discussion regarding use of available funds in the carryover balance occurred during the Q4 FY 2023 MDUFA Performance meeting with industry. More details on the MDUFA carryover balance can be found in the FY 2023 MDUFA Annual Financial Report.

Performance-Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Hiring goals Minimum hiring goal for FY 2023: 144 hires	9/30/2023	N		FDA met 98% (141/144) of the goal of 144 MDUFA V hires during FY 2023. Recruitment is in process for the remaining three hires, which will be completed in FY 2024. Additional tracking processes have been put into place to improve MDUFA hiring in the future.
Program and Process Implementation‡				
Deficiency Letters By January 1, 2023, the Agency will update the 2017 guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions; Guidance for Industry and FDA Staff" to clarify what constitutes a statement of the basis for the deficiency and continue alignment with [principles described in the MDUFA V commitment letter].	1/1/2023	Y	10/26/2022	On 10/26/2022, FDA published the final guidance document "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" to clarify what constitutes a statement of basis for the deficiency (https://www.fda.gov/media/71735/download).
Deficiency Letters FDA will train staff and managers on the updated "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" guidance.	2/28/2023	Y	12/14/2022	FDA conducted staff training on the updated guidance to relevant FDA staff after it was published on 10/26/2022. FDA provided this training in 15 office-level sessions, from 11/01 to 12/14/2022.
Enhanced Use of Consensus Standards By the end of FY 2023, FDA will complete the Accreditation Scheme for Conformity Assessment (ASCA) pilot.	9/30/2023	Y	9/19/2023	Transition from the ASCA pilot to a long-term program was publicly announced on 9/19/2023 via publication of a cover letter on three ASCA guidances and extensive communications initiative.
Enhanced Use of Consensus Standards FDA will report annually on the progress of the ASCA program.	1/30/2023	Y	1/30/2023	An annual report was published on time detailing the performance of the ASCA program in CY2022 (https://www.fda.gov/media/164923/download).
Patient Science and Engagement Issue a draft guidance providing best practices on incorporating into premarket studies clinical outcome assessments, including their use as primary or co-primary endpoints. A clinical outcome assessment describes or reflects how a person feels, functions, or survives and can be reported by a healthcare provider, a non-clinical observer (such as a parent) through performance of an activity or task, or the patient.	9/30/2027	Y	4/5/2023	CDER, CBER, and CDRH issued the draft guidance "Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory). This guidance describes how stakeholders (patients, caregivers, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product (including medical device) development and regulatory decision-making. On May 4, 2023, FDA hosted a webinar (https://www.youtube.com/watch?v=ibtK3PzJOqg) for patients, industry, and other interested stakeholders to discuss and answer questions about the draft guidance.

Performance-Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Real-World Evidence By the end of FY 2023, FDA will publish a document requesting public comment on how FDA should use any portion of the user fee funding that may be distributed to any external organization(s) other than National Evaluation System for health Technology (NEST) to support premarket real-world evidence.	9/30/2023	Y	1/18/2023	FDA opened a public docket for stakeholders to offer specific comments on how the FDA should use device user fee funding that may be distributed to an external organization other than NEST (https://www.regulations.gov/docket/FDA-2023-N-0156).The docket opened on 1/18/2023 and closed on 3/20/2023.
Real-World Evidence If any portion of the user fee funding is distributed to an external organization(s) other than NEST, the funding will be accounted for in FDA's quarterly MDUFA report.	9/30/2023	Y	9/30/2023	FDA provided funding updates in FDA's quarterly MDUFA reporting.
Digital Health Finalize the draft guidance "Content of Premarket Submissions for Device Software Functions" by 18 months from close of the comment period.	8/2/2023	Y	6/14/2023	The final guidance "Content of Premarket Submissions for Device Software Functions" published June 14, 2023 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions).
Digital Health Publish draft guidance describing a process to evaluate a predetermined change control plan for digital health devices.	9/30/2027	Y	4/3/2023	A draft digital health guidance published April 3, 2023 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial). The draft guidance provides recommendations on the information to be included in a Predetermined Change Control Plan that may be provided in a marketing submission for machine learning-enabled device software functions.
International Harmonization Commencing in FY 2023, assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents and make this information publicly available to enhance clarity and transparency.	9/30/2023	Y	9/30/2023	FDA began the assessment of IMDRF technical document implementation. FDA will report on progress as part of the annual assessment of international harmonization activities described in the strategic plan.
International Harmonization By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described in the MDUFA V commitment letter.	9/30/2023	Y	9/19/2023	The draft strategic plan was issued for public comment on Sep 19, 2023 (https://www.fda.gov/media/172187/download?attachment).
Total Product Life Cycle (TPLC) Advisory Program In FY 2023, enroll up to 15 products in a "soft launch" in one OHT.	9/30/2023	Y	9/30/2023	As noted in the *Federal Register* notice dated October 12, 2022, FDA announced plans for a "soft launch" of the TPLC Advisory Program (TAP) Pilot beginning on January 1, 2023 (https://www.federalregister.gov/documents/2022/10/12/2022-21835/medical-devices-voluntary-total-product-life-cycle-advisory-program-pilot). During the "soft launch" of the TAP Pilot, FDA enrolled 12 products in OHT2 between January 1, 2023, and September 30, 2023. Selection of OHT2 included consideration of OHT2's historical number of granted Breakthrough designations, workload, and available staffing and expertise, consistent with the MDUFA V commitment letter.

Performance-Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Total Product Life Cycle (TPLC) Advisory Program Regularly review TAP Pilot progress with industry, share feedback, and assess the impact of the TAP Pilot and opportunities for improvement.	9/30/2023	Y	9/30/2023	FDA has provided updates to industry regarding the TAP Pilot at MDUFA Quarterly meetings. In addition, FDA has worked closely with TAP Pilot participants to obtain feedback regarding their experience in the pilot.

‡ Performance-enhancement goals described in Section V ("Process Improvements") of the MDUFA V commitment letter.

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

The following information addresses section 738A(a)(1)(A)(v)(III) of the FD&C Act, which 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 2001(b) of the Medical Device User Fee Amendments of 2022. FDA also provides updates to information provided in previous annual performance reports on the most common causes and trends of external or other circumstances affecting the ability of CDRH, ORA, or FDA to meet review-time and performance-enhancement goals identified in the letters described in section 201(b) of MDUFA IV.

B. FY 2023 Goals (Preliminary)

As indicated in other sections of this report, FDA received sufficient FY 2023 submissions to calculate performance results for 16 of the 25 MDUFA V review goals. As of September 30, 2023, for those 16 review goals, two review goal were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 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 16 performance-enhancement goals due in FY 2023, all of which were completed on time, except for one. Two additional goals due at the end of MDUFA V were met ahead of schedule.

With only one missed goal and 14 goals still pending, it is not yet possible to identify common causes and trends affecting the ability of CDRH, ORA, or FDA to meet the goals. If, at the end of future fiscal years, the FY 2023 review goal cohorts are sufficiently closed and data indicate that FDA has missed FY 2023 goals, FDA will provide an update to the required information in future reports.

For a description of FY 2023 corrective efforts, see Appendix F.

C. FY 2022 Goals (Updated)

As indicated in other sections of this report, FDA received FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, five review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed, and the two shared outcome 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). For the remaining nine of the 25 review goals, FDA did not receive any submissions (for six goals), or the received MDUFA cohort was insufficient to calculate performance (for three goals).

In addition, FDA had 19 performance-enhancement goals due in FY 2022, and two additional performance-enhancement goals awaiting a dependency. All 19 performance-enhancement goals due in FY 2022 were met. Of the two goals awaiting a dependency, one was met with the issuance of the draft guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" on December 19, 2023, and the other is still awaiting a dependency. The final guidance "Electronic Submission Template for Medical Device 510(k) Submissions"[12] included a "transition period" before the requirement that 510(k) submissions, unless exempted, be provided as electronic submissions. As discussed in the FY 2022 MDUFA performance report, this transition period is a necessary prerequisite for updating the eCopy guidance document and ended as of October 1, 2023 (.

With nine missed review goals and two still pending (of the 25 FY 2022 review goals), it is clear that, for the reasons described below, the COVID-19 pandemic 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 PHE. 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 and through the end of FY 2022, FDA received over 8,500 medical device emergency use authorization (EUA) and pre-EUA submissions. FDA 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 through FY 2022, FDA 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

[12] www.fda.gov/media/152429/download.

as addressing supply chain shortages and counterfeit products related to COVID-19. Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act had ended. With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50 percent.

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 unrelated to the common causes and trends described above, FDA will provide an update to the required information in future reports.

For a summary of the types of circumstances and trends impacting FDA's ability to meet the FY 2022 review goals missed in the prior fiscal year, see the FY 2022 annual performance report. For a description of corrective efforts, see Appendix F.

D. 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, 2023, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed. As stated in previous annual performance reports, all eight performance-enhancement goals were met.

With nine missed review goals (of the 25 FY 2021 review goals), it is clear that, for the reasons described above under the update for FY 2022 goals, the COVID-19 pandemic impacted the ability of CDRH, ORA, or FDA to meet all the goals.

For a summary of the types of circumstances and trends impacting FDA's ability to meet the FY 2021 review goals missed in prior fiscal years, see the FY 2021 and FY 2022 annual performance reports. For a description of corrective efforts, see Appendix F.

E. FY 2020 Goals (Updated)

As indicated in other sections of this report and in both the FY 2021 and FY 2020 MDUFA performance reports, FDA received sufficient FY 2020 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals and had 10 performance-enhancement goals due in FY 2020.

As of September 30, 2023, for those 16 review goals, 12 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. As stated in previous annual performance reports, FDA completed all 10 performance-enhancement goals, nine of which were completed on time.

With four missed goals (of the 25 FY 2020 review goals), it is clear that, for the reasons described above under the update for FY 2022 goals, the COVID-19 pandemic impacted the ability of CDRH, ORA, or FDA to meet all the goals.

For a summary of the types of circumstances and trends impacting FDA's ability to meet the FY 2020 review and performance-enhancement goals missed in prior FYs, see the FY 2020, FY 2021, and FY 2022 annual performance reports. For a description of corrective efforts, see Appendix F.

Appendix F: FY 2023 Corrective Action Report

Under section 738A(a)(2) of the FD&C Act, 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.

A. Executive Summary

Table F-1. FY 2023 Performance-Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Infrastructure	FDA missed one performance-enhancement goal in FY 2023. FDA met 98% (141/144) of the goal of 144 MDUFA V hires during FY 2023.	Recruitment is in process for the remaining three hires, which will be completed in FY 2024. Additional tracking processes have been put into place to improve MDUFA hiring in the future.

Table F-2. FY 2022 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goals	Corrective Action Plan
Review Goals	FDA received FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, five review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed, and the two shared outcome 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). For the remaining nine of the 25 review goals, FDA did not receive any submissions (for six goals) or the received MDUFA cohort was insufficient to calculate performance (for three goals). See the discussion on the impact of the COVID-19 PHE on FDA's workload in Appendix E 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.	FDA has missed nine FY 2022 review goals. Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the declared PHE under section 319 of the Public Health Service Act ended. With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50%. In addition, 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 (electronic Submission Template And Resource (eSTAR)), which became mandatory beginning in FY 2024 • Piloting of voluntary eSTAR submission template in De Novo and Pre-Submission programs

Table F-3. 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, 2023, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, and nine review goals (including two shared outcome 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) De Novo Decision; (6) Substantive Interaction for 510(k) Premarket Notifications; (7) Decision for 510(k) Premarket Notifications; (8) Total Time to Decision for PMA; and (9) Total Time to Decision for 510(k). FDA and industry share two review outcome goals, neither of which were met. The shared TTD goal for 510(k) submissions for FY 2021 was 112 days. The actual FY 2021 performance was 141 days. The shared TTD goal for PMA submissions was 300 days, and the actual FY 2020 performance was 305 days. See the discussion on the impact of the COVID-19 PHE on FDA's workload in Appendix E 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.	FDA missed nine FY 2021 review goals. Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act ended. With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50% and has not currently missed any MDUFA V goals. In addition, 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), which became mandatory beginning in FY 2024 • Piloting of voluntary eSTAR submission template in De Novo and Pre-Submission programs

Table F-4. 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 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, 12 review goals were sufficiently complete to determine the outcome and were met, 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 outcome goals, one of which was met and one of which was not met 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. The shared TTD goal for PMA submissions was 310 days, and the actual FY 2020 performance was 277 days. See the discussion on the impact of the COVID-19 PHE on FDA's workload in Appendix E 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.	FDA missed three FY 2020 review goals, and FDA and industry missed one FY 2020 shared outcome goal (i.e., 510(k) TTD). Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act ended. With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50%. 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), which became mandatory beginning in FY 2024 • Piloting of voluntary eSTAR submission template in De Novo and Pre-Submission programs

B. MDUFA Review Goals

The following section addresses section 738A(a)(2)(B)(i) through (iii) of the FD&C Act, 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, 2023. "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, 2023. These definitions are consistent with the interpretation of similar statutory requirements that 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 FY 2020 through FY 2023 cohorts. Specifically, see section C.1 of this appendix for a summary of FY 2023 performance results, and see sections D.1, E.1, and F.1 of this appendix for a summary of FY 2022, FY 2021, and FY 2020 performance results, including met and missed goals.

C. FY 2023 Review Goal Performance Results

1. Summary of Performance Results

FDA received FY 2023 submissions to calculate performance results for 16 of the 25 MDUFA V review goals. As of September 30, 2023, for those 16 review goals, two review goals were sufficiently complete to determine the outcome and were met, no review goals were sufficiently complete to determine the outcome and were missed, and 14 review goals (including the two shared outcome 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). For the remaining nine (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 (i.e., for three goals) or there were no submissions (i.e., for six goals).

2. Justification

FDA did not miss any FY 2023 review goals. Therefore, no justification is needed.

3. Corrective Actions

FDA did not miss any FY 2023 review goals. Therefore, no corrective action is needed.

D. FY 2022 Review Goal Performance Results

1. Summary of Performance Results

FDA received FY 2022 submissions to calculate performance results for 16 of the 25 MDUFA IV review goals. As of September 30, 2023, for those 16 review goals, five review goals were sufficiently complete to determine the outcome and were met, nine review goals were sufficiently complete to determine the outcome and were missed, and the two shared outcome 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). For the remaining nine of the 25 review goals, FDA did not receive any submissions (for six goals), or the received MDUFA cohort was insufficient to calculate performance (for three goals).

Additionally, of the 4,035 submissions within relevant FY 2022 PMA and 510(k) MDUFA cohorts, 70 510(k) submissions, six 180-Day PMA Supplements, and 16 PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. Of the submissions meeting these criteria:

- Fifty-nine of 70 510(k)s, two of six 180-Day PMA Supplements, and 12 of 16 Real-Time PMA Supplements are in the In Vitro Diagnostic (IVD) office;

- Eleven of 70 510(k)s, one of six 180-Day PMA Supplements, and four of 16 Real-Time PMA Supplements are in the office responsible for the review of PPE devices;

- Two of the six 180-Day PMA Supplements were “bundled” (one review conducted for multiple submission); and

- One 180-Day PMA Supplement was delayed due to a supply chain issue the submitter faced while the submission was under review.

The primary circumstances contributing to submissions missing a MDUFA goal but achieving a positive decision during the first cycle review were FDA’s shifted priorities during the COVID-19 pandemic. For submissions delayed due to the COVID-19 pandemic, FDA worked with the applicant interactively (instead of sending a deficiency letter) to resolve all deficiencies.

2. Justification

From FY 2020 through FY 2022, FDA responded to the unprecedented COVID-19 PHE. 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 and

through the end of FY 2022, FDA received over 8,500 medical device EUA and pre-EUA submissions. FDA 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 through FY 2022, FDA 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 PHE, 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.

3. Corrective Actions

As noted above, throughout FY 2020 to FY 2022, FDA prioritized its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic evolved, the volume of new EUA submissions for COVID-19-related products lessened in FDA's IVD and non-IVD offices. This reduction allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels. FDA has reduced the backlog of submissions with missed MDUFA IV goals by over 50 percent and has reversed submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases.

Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act ended.[13] With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50 percent.

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

[13] https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf.

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;[14] FDA further published a final guidance on a 510(k)-specific electronic submission template[15] 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.[16] Additional templates for De Novo requests and Pre-Submissions have been developed and are currently being piloted for voluntary use.

Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. On October 1, 2023, FDA began requiring 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.[17] 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 one additional final Safety and Performance Based Pathway guidance documents in FY 2023. As of September 30, 2023, 10 final guidance documents for this pathway had been published.[18] 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. Early data from this effort indicate that both FDA review time and industry review time for 510(k)s within a

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions.
[16] https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program.
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.
[18] See https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway.

relevant device type are reduced following the publication of a safety and performance guidance document.

E. FY 2021 Review Goal Performance Results (Updated)

1. 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, 2023, for those 13 review goals, four review goals were sufficiently complete to determine the outcome and were met, and nine review goals were sufficiently complete to determine the outcome and were missed. The nine 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) Decisions for De Novo Submissions; (6) Substantive Interaction for 510(k) Premarket Notifications; (7) Decisions for 510(k) Premarket Notifications; (8) Total Time to Decision goal for Original PMAs, and Panel-Track Supplements; and (9) Total Time to Decision goal for 510(k) Premarket Notifications.

Additionally, of the 4,294 submissions within relevant FY 2021 PMA and 510(k) MDUFA cohorts, 94 510(k) submissions, three Original and Panel-Track PMA Supplements, 11 180-Day PMA Supplements, and 11 PMA Real-Time Supplements missed a review time goal but were approved during the first cycle review. Of the submissions meeting these criteria:

- Fifty-one of 94 510(k)s, all three Original and Panel-Track PMA supplements, eight of 11 180-Day PMA Supplements, and seven of 11 Real-Time PMA Supplements are in the IVD office;

- Forty-three of 94 510(k)s, three of 11 180-Day PMA Supplements, and three of 11 Real-Time PMA Supplements are in the office responsible for the review of PPE devices.

The primary circumstances contributing to submissions missing a MDUFA goal but achieving a positive decision during the first cycle review were FDA's shifted priorities during the COVID-19 pandemic. For submissions delayed due to the COVID-19 pandemic, FDA worked with the applicant interactively (instead of sending a deficiency letter) way to resolve all deficiencies. For the remaining Real-Time PMA supplement, FDA worked interactively with the sponsor to resolve issues rather than send a formal deficiency letter.

2. 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 goals are shared outcome goals 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 submitter took to respond to deficiencies identified by FDA when the submission is on hold (i.e., is not under review by FDA). Both FDA and industry contributed to missing the shared outcome goal for Original PMAs and Panel-Track Supplements. In FY 2021, compared to FY 2020, FDA increased the number of days it took to review Original PMAs and Panel-Track Supplements by 7 days and increased the number of days it took to review 510(k) submissions by 5 days. In addition, industry days increased by 21 days in FY 2021 compared to FY 2020 for Original PMA and Panel-Track Supplements and decreased by 3 days for 510(k)s. Factors that may have contributed to missing the FY 2021 TTD goals include an increased size and complexity of medical device submissions, a lack of consistent formatting of submissions, and the COVID-19 PHE.

3. Corrective Actions

As noted above, throughout FY 2020 to FY 2022, FDA prioritized its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic evolved, the volume of new EUA submissions for COVID-19-related products lessened in FDA's IVD and non-IVD offices. This reduction allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels. FDA has reduced the backlog of submissions with missed MDUFA IV goals by over 50 percent and has reversed submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases.

Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act ended.[19] With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50 percent.

[19] https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf

Both FDA and industry share responsibility to achieve the TTD goals. 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 goals 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;[20] FDA further published a final guidance on a 510(k)-specific electronic submission template[21] 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.[22] Additional templates for De Novo requests and Pre-Submissions have been developed and are currently being piloted for voluntary use.

Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. On October 1, 2023, FDA began requiring 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.[23] 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 one additional final Safety and Performance Based Pathway guidance documents in FY 2023. As of September 30,

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[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.
[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions.
[22] https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program.
[23] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

2023, 10 final guidance documents for this pathway had been published.[24] 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. Early data from this effort indicate that both FDA review time and industry review time for 510(k)s within a relevant device type are reduced following the publication of a safety and performance guidance document.

F. FY 2020 Review Goal Performance (Updated)

1. Summary of Performance

By the end of FY 2023, 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 twelve 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.

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 submissions, 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.

The primary circumstances contributing to submissions missing a MDUFA goal but achieving a positive decision during the first cycle review were FDA's shifted priorities during the COVID-19 pandemic. For submissions delayed due to the COVID-19 pandemic, FDA worked with the applicant interactively (instead of sending a deficiency letter) to resolve all deficiencies. For the other 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.

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

2. 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 outcome 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 PHE.

As discussed above, FDA prioritized its work related to the COVID-19 PHE, which significantly impacted the FY 2020 cohort. In addition, during the COVID-19 PHE, 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.

3. Corrective Actions

As noted above, throughout FY 2020 to FY 2022, FDA prioritized its COVID-19-related work to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic evolved, the volume of new EUA submissions for COVID-19-related products lessened in FDA's IVD and non-IVD offices. This reduction allowed FDA to begin focusing review resources back to MDUFA-related activities, bringing review performance back to "pre-COVID" levels. FDA has reduced the backlog of submissions with missed MDUFA IV goals by over 50 percent and has reversed submission delays for new submissions. Review times have begun to improve, and continued improvement is expected as hiring is increased and EUA work decreases.

Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and other final guidance documents to facilitate timely access to medical devices after the PHE declared under section 319 of the Public Health Service Act ended.[25] With the May 11, 2023, end of the PHE, FDA's focus shifted to completing overdue MDUFA IV submissions and meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50 percent.

The TTD goal for 510(k)s decreased 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;[26] FDA further published a final guidance on a 510(k)-specific electronic submission template[27] 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.[28] Additional templates for De Novo and Pre-Submissions have been developed and are currently being piloted for voluntary use.

Initial data indicate that the use of eSTAR is achieving the objective of producing well-organized and complete 510(k) submissions. On October 1, 2023, FDA began requiring 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.[29] This pathway expands upon the Abbreviated 510(k) program and is an optional pathway for certain well-understood device types

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[25] https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf.

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

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

[28] https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program.

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

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 one additional final Safety and Performance Based Pathway guidance documents in FY 2023. As of September 30, 2023, 10 final guidance documents for this pathway had been published.[30] 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. Early data from this effort indicate that both FDA review time and industry review time for 510(k)s within a relevant device type are reduced following the publication of a safety and performance guidance document.

F. MDUFA Performance-Enhancement Goals

The following section addresses section 738A(a)(2)(B)(i) and (iv) of the FD&C Act, 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 2023 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 V commitment letter.

FDA had 16 performance-enhancement goals due in FY 2023, all of which were completed on time, except for one. Two additional goals due at the end of MDUFA V were met ahead of schedule. Details on the missed goal are provided below.

G. Infrastructure

1. Summary of Performance

FDA met 98 percent (141/144) of the goal of 144 MDUFA V hires during FY 2023.

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

2. Justification

Only three positions were not filled by September 30, 2023, due to recruitment challenges.

3. FY 2023 Corrective Actions

Recruitment is in process for the remaining three hires, which will be completed in FY 2024. Additional tracking processes have been put into place to improve MDUFA hiring in the future.

Appendix G: Rationale for MDUFA Program Changes

Section 738A(a)(1)(A)(iv) of the FD&C Act requires the following annual MDUFA performance reporting requirements:

- Data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 738, and the number of full time equivalents funded by budget authority (BA) 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;

- Data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of device applications, including identifying drivers of such changes; and changes in the total average cost per full-time equivalent in the medical device review program;

- 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; and

- Data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of medical device application types.

The information below fulfills these reporting requirements.

A. Changes in the Number of Individuals Hired as Agreed in the MDUFA V Commitment Letter, the Number of Remaining Vacancies, the Number of Full-Time Equivalents (FTEs) Funded by Fees Collected Pursuant to Section 738, and the Number of FTEs Funded by BA by Division Within CDRH, CBER, ORA, and OC

This section addresses the requirement to provide data, analysis, and a discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022, the remaining vacancies, and the number of FTEs funded by BA and user fees at FDA by each division within CDRH, CBER, ORA, and OC.

1. Changes in the Number of Individuals Hired as Agreed Upon in the MDUFA V Commitment Letter and Remaining Vacancies

Table G-1 provides data to show changes in the number of MDUFA V hires, from FY 2022 to FY 2023, as agreed upon in the MDUFA V commitment letter. Relevant information about the data provided is as follows:

- *Number of MDUFA V Hires* = the number of hires under MDUFA V. A "hire" is defined as someone who has been confirmed as on board by the date indicated in a full-time position. Hires may be recruited from outside FDA, or, in some cases, a hire can be a current FDA employee who is changing positions within the agency. The MDUFA V commitment letter states:

  > Enhancements to the medical device review program require that FDA recruit, hire and retain sufficient numbers and types of technical, scientific, and other program experts to support the process for the review of device applications. MDUFA V provides significant new resources to FDA to support these activities.
  >
  > To help ensure that FDA accomplishes hiring in accordance with the assumptions underlying the agreement, FDA will establish annual hiring goals for each year of MDUFA V.
  >
  > The minimum hiring goals for FY 2023-2025 are:
  >
  > *FY 2023*: 144 hires
  > *FY 2024*: 42 hires
  > *FY 2025*: 24 hires

  The MDUFA V commitment letter further states:

  > FDA and Industry have agreed that, if performance improvement adjustments are triggered for each year per Section III [of the MDUFA V commitment letter], the Agency will increase hiring to support the enhanced goals . . . .
  >
  > In FY 2025, if performance improvement adjustments are made to the Pre-Submission Written Feedback goal per Section III, FDA will increase the hiring goal by 59 hires to a total of 83 hires. As part of the process for establishing the user fee rates for FY 2025, FDA will also calculate the hiring goal for that year and include the goal in the associated *Federal Register* fee-setting notice . . . .

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

The Agency is providing data on the number of MDUFA V hires 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].

- *Change in Number Hired [C]* = the number of MDUFA V hires during the most recent fiscal year minus the number of MDUFA V hires during the prior fiscal year ([C] = [B] - [A]).

- *Remaining Vacancies (FY 2023)* = the minimum MDUFA V hiring goal for FY 2023 minus the number of MDUFA V hires during FY 2023.

In summary, FDA made 141 MDUFA V hires during FY 2023, and had three remaining vacancies at the end of the fiscal year.

Table G-1. Changes in Number Hired and Remaining Vacancies

Center	Number Hired in FY 2022*	Number Hired in FY 2023	Change in Number Hired	Remaining Vacancies in FY 2022*	Remaining Vacancies in FY 2023	Change in Number of Remaining Vacancies
CDRH	0	141	141	0	0	0
CBER	0	0	0	0	3	3
ORA	0	0	0	0	0	0
OC	0	0	0	0	0	0
Total	**0**	**141**	**141**	**0**	**3**	**3**

* MDUFA V became effective in FY 2023; therefore, there were no MDUFA V hires in FY 2022 and no MDUFA V vacancies to report for FY 2022.

2. Changes in the Number of FTEs Funded by Fees and Number of FTEs Funded by BA by Division Within CDRH, CBER, ORA, and OC

The data in Table G-2 show changes in the number of FTEs funded by fees collected pursuant to section 738 of the FD&C Act and the number of FTEs funded by BA in FY

2023 by each division within CDRH, CBER, ORA, and OC. Relevant information about the data provided is as follows:

- *Number of MDUFA Program FTEs Funded by Fees and BA.* Table G-2 reflects the number of FTEs funded by fees and the number of FTEs funded by BA 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[31] to equate to one FTE and are provided for the most recent fiscal year.

The information in the table is provided by offices within CDRH, including the sub-offices within OPEQ. This approach to report by offices within CDRH is consistent with the interpretation of similar statutory reporting requirements addressed in other sections of this report. For CBER, ORA, and OC, the information in the table is also reported at the office level.

Table G-2. Number of FTEs Funded by Fees and Number of FTEs Funded by Budget Authority by Division Within CDRH, CBER, OC, and ORA

Center and Office	Number of FTEs Funded by BA		Change in the Number of FTEs Funded by BA	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2022	FY 2023		FY 2022	FY 2023	
CDRH*						
Office of the Center Director (OCD)	7.90	8.60	0.70	20.30	20.10	-0.20
Office of Product Evaluation and Quality (OPEQ)	295.90	361.30	65.40	686.40	697.60	11.20
Office of Communication and Education (OCE)	21.60	20.60	-1.00	57.30	46.40	-10.90
Office of Management (OM)	28.50	72.70	44.20	78.90	75.60	-3.30
Office of Policy (OP)	5.80	6.70	0.90	17.20	14.80	-2.40
Office of Science and Engineering Laboratories (OSEL)	14.10	12.00	-2.10	47.80	37.80	-10.00
Office of Strategic Partnership and Technology Innovation (OST)	24.50	30.60	6.10	62.10	56.40	-5.70
Office of Digital Transformation¶ (formerly known as Office of Information Management and Technology (OIMT))	1.30	1.30	0.00	3.50	3.20	-0.30
Working Capital Fund (WCF)*	56.30	53.04	-3.26	46.40	56.50	10.10

[31] https://www.whitehouse.gov/wp-content/uploads/2018/06/a11.pdf.

Center and Office	Number of FTEs Funded by BA		Change in the Number of FTEs Funded by BA	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
CBER						
Office of Biostatistics and Epidemiology (OBE) / Office of Biostatistics and Pharmacovigilance (OBPV)†	1.21	1.42	0.21	3.88	3.34	-0.53
Office of Blood Research and Review (OBBR)	32.04	39.37	7.33	32.49	26.06	-6.43
Office of Compliance and Biologics Quality (OCBQ)	5.05	6.07	1.02	5.93	5.86	-0.07
Office of Tissues and Advanced Therapies (OTAT) / Office of Therapeutic Products (OTP)§	4.25	5.35	1.10	5.18	4.96	-0.22
Office of Vaccines Research and Review (OVRR)	0.03	0.02	0.00	0.00	0.00	0.00
Office of Communication Outreach and Development (OCOD)	1.39	1.93	0.54	3.79	3.60	-0.19
Office of the Center Director (OCD)	3.18	1.72	-1.46	3.88	2.10	-1.78
Office of Regulatory Operations (ORO)‡	0.72	2.73	2.02	3.46	4.24	0.78
Office of Management (OM)	3.45	3.90	0.45	6.43	5.75	-0.67
OIMT	0.27	0.34	0.06	0.50	0.37	-0.13
WCF*	4.66	4.83	0.16	4.97	5.19	0.22
OC						
Office of the Commissioner – Immediate Office (OC-IO)	1.60	4.70	3.10	1.06	2.74	1.68
Office of Chief Counsel (OCC)	14.00	14.00	0.00	9.14	8.11	-1.03
Office of Chief Scientist (OCS)	4.30	3.30	-1.00	2.82	1.91	-0.91
Office of Clinical Policy and Programs (OCPP)	11.70	13.30	1.60	7.67	7.72	0.05
Office of Digital Transformation (ODT)	0.00	0.80	0.80	0.45	0.50	0.05
Office of External Affairs (OEA)	2.30	2.50	2.50	1.48	1.43	-0.05
Office of Global Policy and Strategy	0.10	0.00	0.00	0.07	0.00	-0.07
Office of Enterprise Management Services (OEMS)	0.00	6.00	6.00	2.56	3.48	0.92
Office of Operations	9.50	8.27	-1.23	3.20	4.80	1.60
Office of Policy, Legislation, and International Affairs (OPLIA)	13.30	11.30	-2.00	8.71	6.58	-2.13

WCF*	4.50	2.29	-2.21	2.11	3.19	1.08
Center and Office	**Number of FTEs Funded by BA**	**Change in the Number of FTEs Funded by BA**	**Number of FTEs Funded by Fees**			**Change in the Number of FTEs Funded by Fees**
ORA						
Office of Medical Devices and Radiological Health Operations (OMDRHO)	32.00	40.16	8.16	10.40	10.03	-0.37
WCF*	2.50	3.14	0.64	1.25	0.76	-0.49

* This table includes MDUFA program FTEs calculated through 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 BA. FTE reported here were rolled into the WCF, which is now an operational expenditure from the Centers.

† CBER's Office of Biostatistics and Epidemiology was reorganized to the Office of Biostatistics and Pharmacovigilance in FY 2023.

§ CBER's Office of Tissues and Advanced Therapies was reorganized to the Office of Therapeutic Products in FY 2023.

‡ The FY 2023 reorganization of CBER created a new office – the Office of Regulatory Operations. Prior to the reorganization, this office was under the Office the Center Director.

¶ This office was formerly called "OIMT." CDRH currently pays for a few employees assigned under ODT (staff in ODT ORG while on CDRH Home CAN).

Totals may not add up due to rounding.

B. Changes in the Fee Revenue Amounts, the Costs for the Process for the Review of Device applications, and the Average Total Cost Per FTE in the Medical Device Review Program

Section 738A(a)(1)(iv)(II) of the FD&C Act requires FDA to provide data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of device applications, including identifying drivers of such changes and changes in the average total cost per FTE in the medical device review program. Accordingly, Table G-3 provides data for the MDUFA fee revenue amounts, MDUFA process costs, and the average total cost per MDUFA process FTE for FY 2022 and FY 2023, as well as the changes in these amounts from FY 2022 to FY 2023. 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. Total Review Process Cost includes BA + user fee expenditures.
- *Average Total Cost Per FTE* represents the Total MDUFA Payroll Cost (BA + user fee expenditures) divided by the total MDUFA process FTEs (BA + fee funded).

In FY 2023, FDA had net collections of $312 million in medical device user fees, which is an increase of $51 million compared to FY 2022. This increase can be attributed to increased resources under the MDUFA V agreement to support new performance enhancements. FDA spent approximately $716 million toward the device review process in FY 2023, which is a $91-million increase from FY 2022. This change can be attributed to an increase in MDUFA-related work and hiring. The 5-percent increase from FY 2022 to FY 2023 in the average cost of a MDUFA process FTE can be attributed to several factors, including, but not limited to, the cost-of-living increase effective January 1, 2023, and the use of 21st Century Cures hiring and pay authorities. Detailed financial information for the MDUFA program can be found in the FY 2023 MDUFA financial report.

Table G-3. MDUFA Fee Revenues, Process Cost, and Average Total Payroll Cost Per FTE

Revenue/Cost	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Fee Revenue Amounts (Net Collections*)	$260,321,107	$311,810,191	+20%
Review Process Cost (Cost of MDUFA Program Activities)	$625,818,538	$716,363,936	+14%
Average Total Payroll Cost Per FTE	$193,229	$202,050	+5%

* The net collections reflect the amount of fees collected, net any refunds or adjustments that occurred during that fiscal year.

C. Number of Employees for Whom Time Reporting Is Required

Section 738A(a)(1)(iv)(III) of the FD&C Act requires FDA to provide—for CDRH, CBER, ORA, and OC—the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, Table G-4 provides the number of employees within CDRH, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2023.

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

Table G-4. FY 2023 Time-Reporting Requirements

Center	Employees for Whom Time Reporting Is Required	Employees for Whom Time Reporting Is Not Required
CDRH	2,156	13
CBER	1,260	8
ORA	4,592	0
OC	61	2,606
Total	**8,069**	**2,627**

D. Changes in the Average FTE Hours Required to Complete Review of Medical Device Application Types

Section 738A(a)(1)(A)(iv)(IV) of the FD&C Act requires that FDA provide data, analysis, and discussion of the changes in the average FTE hours required to complete the review of medical device application types.

Table G-5. Changes in Average FTE Hours to Complete Review

Application Type	Average Hours Required to Complete Application Reviews FY 2022	Average Hours Required to Complete Application Reviews FY 2023	Change from FY 2022 to FY 2023
PMA*	2095	1863	-232
180 Day Supplements	238	234	-4
Real Time Supplements	32	32	0
510(k)	97	95	-2
De Novo	662	575	-87
BLA*	261	285	24
Total	**3,385**	**3,084**	**-301**

* The "PMA" category includes Original PMAs, panel track supplements, and premarket reports. The "510(k)" category includes 510(k)s, Dual 510(k)s and CLIA waivers by application, and Third-Party 510(k)s. The "BLA" category includes Original BLAs and Efficacy Supplements.

To calculate the average hours required to complete review of each medical device application type listed above, FDA summed the total hours reported in the Insight Time Reporting system for each application type within the respective fiscal year and divided by the total count of submissions completed in that fiscal year for each respective application type.

The change in average hours required to complete review of PMAs and De Novos from FY 2022 to FY 2023 can be attributed to the extended hold times experienced during the pandemic from FY 2020 to FY 2022, coupled with the transition back to routine operations in FY 2023, when premarket submissions were no longer granted extended hold times. This led to an influx of submissions coming off hold and being completed in FY 2023, which increased the denominator in the calculated average, even though most of the hours spent on those submissions coming off extended holds were spent in previous fiscal years and therefore were not included in the numerator for the FY 2023 average calculation. Thus, the large number of PMAs and De Novos coming off hold and completed in FY 2023 led to what will likely be a transitory drop in the calculated average hours required to complete review. FDA expects the average hours required to complete review for PMAs and De Novos to stabilize as the impact of the pandemic lessens going forward.

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

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