FY 2020

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee Amendments

Commissioner's Report

I am pleased to present the U.S. Food and Drug Administration's (FDA's or the Agency's) fiscal year (FY) 2020 Performance Report to Congress for the Medical Device User Fee Amendments (MDUFA). The enactment of the fourth authorization of MDUFA in 2017 (MDUFA IV) reauthorized medical device user fees for 5 additional years (FY 2018 through FY 2022). This is the 18th report on medical device user fee review performance; FY 2020 is the third year of MDUFA IV.

Reauthorization of the medical device user fee program has helped to expedite the availability of innovative new products in the market by boosting the Agency's medical devices regulatory review capacity through hiring new staff and providing other resources. MDUFA IV represents a commitment between the U.S. medical device industry and FDA to increase the efficiency of regulatory processes, reducing the total time it takes to make decisions on safe and effective medical devices.

FDA's performance continued to be strong in FY 2020. Preliminary performance data through September 30, 2020, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) all 15 of the review goals for which FDA has a sufficient MDUFA Cohort to calculate performance. In FY 2019, FDA has met (or has the potential to meet) all 17 of the review goals for which FDA had a sufficient MDUFA Cohort to calculate performance. FDA had 10 performance enhancement goals in FY 2020, and 9 of 10 of the performance enhancement goals were completed on time.

We believe the actions that FDA has taken under MDUFA IV have had a positive impact on the device review process, such as the addition of more rigorous shared outcome goals, new goals for Pre-Submissions and De Novo classification requests, and a number of new performance enhancement goals. These completed actions demonstrate our continued commitment to strengthening our medical device review programs, providing predictable device review processes, and increasing the efficiency with which medical devices are developed and made available to patients.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

ASCA – Accreditation Scheme for Conformity Assessment

BLA – Biologics License Application

CAPA – Corrective and Preventive Action

CBER – Center for Biologics Evaluation and Research

CDRH – Center for Devices and Radiological Health

CLIA – Clinical Laboratory Improvement Amendments

DICE – Division of Industry and Consumer Education

FDA – U.S. Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FDASIA – Food and Drug Administration Safety and Innovation Act

FTE – Full Time Equivalent

FY – Fiscal Year (October 1 to September 30)

GMP – Good Manufacturing Practice

IDE – Investigational Device Exemption

IR – Interactive Review

MDUFA – Medical Device User Fee Amendments

NSE – Not Substantially Equivalent

OC – Office of the Commissioner

OHTs – Offices of Health Technology

OIR – Office of In Vitro Diagnostics and Radiological Health

OPEQ – Office of Product Evaluation and Quality

ORA – Office of Regulatory Affairs

PDP – Product Development Protocol

PMA – Premarket Approval Application

RTA – Refuse to Accept

SE – Substantially Equivalent

TTD – Total Time to Decision

Executive Summary

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

This report presents preliminary data on the success of the U.S. Food and Drug Administration (FDA) in meeting FY 2020 MDUFA IV goals and updated data on FDA's success in meeting FY 2019 and FY 2018 MDUFA IV goals.

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

All data presented in this report are as of September 30, 2020.

Preliminary FY 2020 Performance

Review Goals

FDA has 25 MDUFA IV review goals: 23 review goals with specific target percentages and two shared outcome goals. In FY 2020, FDA had a sufficient MDUFA Cohort to calculate performance for 15 review goals (i.e., 13 review goals with specific target percentages and two shared outcome goals) of the 25 review goals. Of these 15 review goals, as of September 30, 2020, four had a cohort that was sufficiently complete to determine the outcome. For these four goals, FDA met the outcome goal. Preliminary data, including completed and pending reviews, indicate that FDA has the potential to meet the 11 remaining review goals for which the cohort is not yet sufficiently complete to determine the outcome. The FDA has fulfilled the MDUFA review goal commitment for all goals which have a sufficiently complete cohort.

Performance Enhancement Goals

FDA had 10 performance enhancement goals with required completion dates in FY 2020. As of September 30, 2020, FDA had completed all 10 of these goals, 9 of which were completed on time.

Updated FY 2019 Performance

Review Goals

In FY 2019, FDA had a sufficient MDUFA Cohort to calculate performance for 17 review goals (i.e., 15 review goals with specific target percentages and two shared outcome goals) of the 25 review goals. Of these 17 review goals, as of September 30, 2020, 13 had a cohort that was sufficiently complete to determine the outcome. For these 13 goals, FDA met the outcome goal, and FDA continues to have the potential to meet the four remaining review goals for which the cohort is not yet sufficiently complete to determine the outcome. The FDA has fulfilled the MDUFA review goal commitment for all goals which have a sufficiently complete cohort.

Updated FY 2018 Performance

Review Goals

In FY 2018, FDA had a sufficient MDUFA Cohort to calculate performance for 18 review goals (i.e., 16 review goals with specific target percentages and two shared outcome goals) of the 25 review goals. Of these 18 review goals, as of September 30, 2020, all 18 had a cohort that was sufficiently complete to determine the outcome. For these 18 goals, FDA met the outcome goal.

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Introduction

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

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

Performance Presented in This Report

MDUFA Review Goals

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

This report presents preliminary review goal performance for the FY 2020 MDUFA IV cohort submissions. This report also includes updated review goal performance information for FY 2018 and FY 2019 MDUFA IV cohort submissions.

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

- Unless otherwise noted, all performance data are as of September 30, 2020.
- Unless otherwise noted, review goal performance is based on FDA's combined performance on MDUFA submissions reviewed in the Center for Devices and Radiological Health (CDRH) and/or the Center for Biologics Evaluation and Research (CBER), depending on submission type. This is different from the MDUFA Quarterly Performance Reports located on FDA's website,[3] in which performance is reported separately for each Center. Details of which Center

[1] www.fda.gov/media/102699/download.
[2] www.fda.gov/about-fda/user-fee-performance-reports/mdufa-performance-reports.
[3] www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports.

reviews each submission type are outlined in Appendix A of this report.

- With the exception of shared outcome goals and the Pre-Submission written feedback goal, only review goals with specific target percentages (e.g., 90 percent) are presented in this report. Information on review goals without target percentages can be found in the MDUFA IV Quarterly Performance Reports.

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

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

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

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

- As agreed upon, “FDA days” refers to the calendar days in which a submission is under review by FDA. FDA days begin on FDA’s date of receipt of the Refuse to Accept (RTA)-acceptable submission or of the amendment to the submission that enables the submission to be accepted or filed.

- “Review-time goals” are defined as the time period, identified by the number of calendar days or FDA days, for when individual submissions are to have an interaction or be acted on. An “on-time” (or “within goal”) “review” indicates that an action was completed within the number of days specified by the review-time 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 from 50 to 95 percent of the time, depending on the specific goal and fiscal

year.

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

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

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

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

- Preliminary review goal performance for FY 2020 submissions is shown as the percentage of submissions completed within goal as of September 30, 2020, excluding any submissions that have not yet reached their due date. The highest possible percent of reviews that may be completed within goal is shown as the highest possible review goal performance.

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

MDUFA Performance Enhancement Goals

For this report, "performance enhancement goals" are defined as any non-review goal identified in the letters described in section 201(b) of MDUFA IV for the applicable fiscal year. Performance information on the FY 2020 performance enhancement goals is located in Appendices D and E of this report.

Additional Performance Data

On May 5, 2017, the Consolidated Appropriations Act, 2017 (Public Law 115-31) was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year ending September 30, 2017. Senate Report 114-259 directed FDA to provide

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

performance information related to medical devices—specifically, the extent to which the Agency's responses meet statutory timeframes and total numbers for De Novo classification requests under section 513(f)(2), for requests for information about classification under section 513(g), and for postmarket device surveillance plan submissions under section 522 (also known as a "section 522 plan"). These data are contained in Appendix B of this report.

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

Submission Types Included in This Report

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

- **Original PMA** - An application providing scientific and medical data to demonstrate a reasonable assurance that a Class III medical device is safe and effective for its intended use.[5]

- **PDP** - A PDP allows an applicant to reach an early agreement with FDA as to what will be done to demonstrate the safety and effectiveness of a new device. Early interaction in the development cycle of a device allows an applicant to address the concerns of FDA before expensive and time-consuming resources are expended. A PDP that has been declared completed by FDA is considered to have an approved PMA.

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

- **Premarket Report for Reprocessed Single Use Devices** - A type of premarket application required for high-risk devices originally approved for a single use (that is, use on a single patient during a single procedure) that a manufacturer has reprocessed for an additional use. Reprocessors of certain single use devices are required to submit premarket reports instead of PMAs.

- **180-Day PMA Supplement** - A supplemental application to an approved PMA or premarket report that requests approval of a significant change in aspects of a device, such as its design, specifications, or labeling, when demonstration of a reasonable assurance of safety and effectiveness either does not require new clinical data or requires only limited clinical data.

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

- **De Novo Classification Request** - The De Novo classification process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide a reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process.

[5] For more information on PMAs, see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm.

Devices that are classified into Class I or Class II through a De Novo classification request may be marketed and used as predicates for future premarket notification (i.e., 510(k)) submissions.

- **Premarket Notification (510(k))** - A premarket submission made to FDA to demonstrate that a device to be marketed is substantially equivalent to a legally marketed predicate device that is not subject to the PMA review process. Applicants must compare their proposed device to one or more similar legally marketed devices and support their substantial equivalence claim.[6]

- **Clinical Laboratory Improvement Amendments (CLIA) Waiver** - A categorization issued by FDA allowing certain laboratory tests to be performed by laboratories with a CLIA Certificate of Waiver.

- **CLIA Waiver by Application** - A submission providing data to demonstrate 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 a 510(k) clearance and CLIA waiver, such submissions demonstrate that a laboratory test is substantially equivalent to a legally marketed device, as appropriate, and is simple and has an insignificant risk of erroneous results.

- **Pre-Submission** - A formal written request from an applicant for feedback from FDA that is provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A "Pre-Submission meeting" is a meeting or teleconference in which FDA provides its substantive feedback on the Pre-Submission. A Pre-Submission provides the opportunity for an applicant to obtain FDA's feedback prior to an intended submission of an Investigational Device Exemption (IDE) or marketing application. The request should include specific questions regarding review issues relevant to a planned IDE or marketing application.

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

- **BLA Supplement** - A supplemental application to an approved BLA requesting approval of a change to a licensed biological product. When the change has the substantial potential to affect the safety or effectiveness of the product, FDA's approval is required prior to product distribution. A supplement to an approved

[6] For more information on 510(k)s, see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.
[7] For more information on BLAs, see www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

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.

MDUFA IV Review-Time Goals and Commitments

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

Review Goals with Specific Target Percentages

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

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

Review-Time Goals and Commitment Targets

Submission Type	Review-Time Goal	Commitment Target				
		FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision with No Advisory Committee Input	180 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee Input	320 FDA days	90%	90%	90%	90%	90%
180-Day PMA Supplements						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision	180 FDA days	95%	95%	95%	95%	95%
Real-Time PMA Supplements						
Decision	90 FDA days	95%	95%	95%	95%	95%
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	1,530	1,645	1,765	1,880	1,950

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

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%

Shared Outcome Goals

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

(TTD) within a closed cohort and are based on the methodology prescribed in the MDUFA IV commitment letter.

MDUFA IV's Shared Outcome Goals

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

MDUFA IV Review Goal Performance

Summary of Review Goal Performance

For this report, MDUFA IV review goals include review goals with specific target percentages, Pre-Submission written feedback goals, and shared outcome goals. The tables below summarize FDA's MDUFA IV review goal performance in FY 2018, FY 2019, and FY 2020.

Each fiscal year, FDA has the following 25 MDUFA IV review goals: 23 review goals with specific target percentages (including one Pre-Submission written feedback goal) and two shared outcome goals. In FY 2020, FDA received submissions in 17 of the 25 review goals. Preliminary data indicate that FDA has met, or has the potential to meet, all 17 of the review goals for which FDA received submissions in FY 2020. In FY 2019, FDA received submissions in 19 of the 25 review goals. Updated data indicate that FDA has met, and continues to have the potential to meet, all 19 of the review goals for which FDA received submissions in FY 2019. In FY 2018, FDA received submissions in 18 of the 25 review goals. Updated data indicate that FDA met all 18 of the review goals for which FDA received submissions in FY 2018.

Review Goals with Specific Target Percentages

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

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

- *MDUFA Cohort [A]* = the number of submissions Completed Within Goal [B], Completed Overdue [C], Pending Within Goal [D], and Pending Overdue [E] ([A] = [B] + [C] + [D] + [E]).
- *Completed Within Goal [B]* = the number of submissions with a MDUFA action as of September 30, 2020, that met the MDUFA goal.
- *Completed Overdue [C]* = the number of submissions with a MDUFA action as of September 30, 2020, that did not meet the MDUFA goal.

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

- *Pending Within Goal [D]* = the number of submissions without a MDUFA action that were still within the goal as of September 30, 2020.
- *Pending Overdue [E]* = the number of submissions without a MDUFA action that were past the goal as of September 30, 2020.
- *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 a fiscal year cohort is sufficiently complete to determine the outcome, this column indicates whether FDA met ("(MET)" in the tables below) or missed ("(MISSED)" in the tables below) the goal.
- *Highest Possible Review Goal Performance [H]* = the scenario when all pending submissions within the goal are completed within that goal. [H] is calculated by adding all submissions Pending Within Goal [D] to those already Completed Within Goal [B] divided by the MDUFA Cohort [A]. Therefore, Highest Possible Review Goal Performance [H = ([B] + [D]) / [A].
- For certain submissions, the MDUFA IV commitment letter states it is acceptable to combine a MDUFA Cohort of less than 10 submissions (from any one fiscal year) with the MDUFA Cohort of other fiscal year(s) in order to form a combined cohort of 10 or more submissions and calculate a combined performance. Applicable submissions include PMA submissions that require Advisory Committee and CLIA Waiver by Application submissions (including "Dual 510(k) and CLIA Waiver by Applications"). If performance has been calculated in this way, the table will include data from the combined cohort (used to calculate performance), followed by data from the single fiscal year (in parentheses). Performance for applicable review goals will not be calculated if, after combining with other fiscal year cohort(s), a combined cohort does not include at least 10 submissions.

FY 2020 Preliminary Performance Data

In FY 2020, FDA had a sufficient MDUFA Cohort to calculate performance for 13 of the 23 review goals with specific target percentages. For the remaining 10 goals, FDA did not receive any submissions (7 goals) or the MDUFA Cohort was insufficient (in single or combined years) to calculate performance (3 goals). Of the 13 goals for which FDA received a sufficient MDUFA Cohort to calculate performance, all have at least one "Completed" submission and a calculable "Current Review Goal Performance" and "Highest Possible Review Goal Performance."

In four of the 13 review goals with specific target percentages for which FDA received a sufficient MDUFA Cohort to calculate performance, the FY 2020 cohorts were sufficiently complete to determine the outcome. These goals (as well as whether the goal was met or missed) are shown in **bold** text in the table below. For these four goals (i.e., Dual 510(k) and CLIA Waiver by Application – Substantive Interaction, Pre-Submission Provide Written Feedback, BLA Manufacturing Supplements Requiring Prior Approval, and Class 2 Original BLA and BLA Efficacy Supplement Resubmissions), FDA met the outcome goal.

FY 2020 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	73	60	3	10	0	95%	95%	96%
Decision with No Advisory Committee Input	71	26	1	44	0	90%	96%	99%
Decision with Advisory Committee Input	8‡ (2)	5 (0)	0 (0)	2 (2)	1 (0)	90%	‡	‡
180-Day PMA Supplements								
Substantive Interaction	183	128	6	49	0	95%	96%	97%
Decision	183	87	0	95	1	95%	99%	99%
Real-Time PMA Supplements								
Decision	356	262	0	94	0	95%	100%	100%
De Novo Classification Requests								
Decision	58	10	0	44	4	50%	71%	93%
510(k) Premarket Notifications								
Substantive Interaction†	3,032	2,515	83	427	7	95%	97%	97%
Decision	3,057	1,691	11	1,346	9	95%	99%	99%
CLIA Waiver by Applications #								
Substantive Interaction	1§	0	0	0	1	90%	§	§
Decision with No Advisory Committee Input	1§	0	0	0	1	90%	§	§
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*

* No submissions were received in FY 2020; 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 Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.
‡ Per an agreement in the MDUFA IV commitment letter, the MDUFA Cohort from this fiscal year was combined with the cohort from a prior fiscal year because the prior fiscal year cohort was insufficient (< 10) to calculate performance. However, the combined cohort was also insufficient (< 10) to calculate performance. Therefore, performance will be calculated in a future fiscal year when a combined cohort of 10 or more submission is achieved.
§ The MDUFA Cohort for this fiscal year is insufficient (< 10) to calculate performance. Therefore, per an agreement in the MDUFA IV commitment letter, performance will be calculated in a future fiscal year when a combined cohort of 10 or more submissions is achieved.
# One CLIA Waiver was withdrawn before Substantive Interaction, and Withdrawn counts as a decision.

FY 2020 Preliminary Performance Data (continued)

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	11‡ (6)	11 (6)	0 (0)	0 (0)	0 (0)	90%	**100% ** (MET)**	100%
Decision with No Advisory Committee Input	11‡ (6)	5 (1)	1 (0)	5 (5)	0 (0)	90%	83% **	91%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,606	2,342	264	N/A	N/A	1,530	**2,342 (MET)**	N/A
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	0	0	0	0	0	90%	*	*
BLA Manufacturing Supplements Requiring Prior Approval	81	79	0	2	0	90%	**100% † (MET)**	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	0	90%	*	*
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	0	0	0	90%	**100% (MET)**	100%

* No submissions were received in FY 2020; therefore, no performance can be reported.
† Final review goal performance may change once all pending submissions are completed, but the Review Goal will still be met even if all pending submissions do not meet the goal.
‡ Per an agreement in the MDUFA IV commitment letter, the MDUFA Cohort from this fiscal year was combined with the cohort from a prior fiscal year because the prior fiscal year cohort was insufficient (< 10) to calculate performance. Now that a combined cohort of 10 or more submissions has been achieved, performance can be calculated.
** Performance was calculated from a combined MDUFA Cohort of FY 2019 and FY 2020 submissions.

FY 2019 Updated Performance Data

In FY 2019, FDA had a sufficient MDUFA Cohort to calculate performance for 15 of the 23 review goals with specific target percentages. For the remaining eight goals, FDA did not receive any submissions (five goals) or the MDUFA Cohort was insufficient (in single or combined years) to calculate performance (three goals). As of September 30, 2020, the FY 2019 cohorts for 13 of the 15 review goals with specific target percentages for which FDA received a sufficient MDUFA Cohort to calculate performance were sufficiently complete to determine the outcome. These goals (as well as whether the goal was met or missed) are shown in **bold** text in the table below. For these 13 goals, FDA met the outcome goal (and will continue to do so even if all pending submissions do not meet the goal), and FDA continues to have the potential to meet the two remaining goals (Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports – Decision with No Advisory Committee Input; 180-Day PMA Supplements - Decision) for which the cohort is not sufficiently complete to determine the outcome.

FY 2019 Updated Performance Data

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports								
Substantive Interaction	58	57	1	0	0	95%	**98% (MET)**	98%
Decision with No Advisory Committee Input	56	45	5	6	0	90%	90%	91%
Decision with Advisory Committee Input	6‡ (2)	5 (1)	0 (0)	0 (0)	1 (1)	90%	‡	‡
180-Day PMA Supplements								
Substantive Interaction	196	194	2	0	0	95%	**99% (MET)**	99%
Decision	190	175	5	10	0	95%	97%	97%
Real-Time PMA Supplements								
Decision	366	366	0	0	0	95%	**100% (MET)**	100%
De Novo Classification Requests								
Decision	62	47	10	2	3	50%	**82%†† (MET)**	79%
510(k) Premarket Notifications								
Substantive Interaction†	3,483	3,391	84	8	0	95%	**98% †† (MET)**	98%
Decision	3,183	3,070	28	84	1	95%	**99% †† (MET)**	99%
CLIA Waiver by Applications #								
Substantive Interaction	11§ (7)	11 (7)	0 (0)	0 (0)	0 (0)	90%	**100% ** (MET)**	100%
Decision with No Advisory Committee Input	12§ (8)	11 (7)	0 (0)	1 (1)	0 (0)	90%	**100% ** †† (MET)**	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*

* No submissions were received in FY 2019; 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 Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.

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

§ Per an agreement in the MDUFA IV commitment letter, the MDUFA Cohort from this fiscal year was combined with the cohort from a prior fiscal year because the prior fiscal year cohort was insufficient (< 10) to calculate performance. Now that a combined cohort of 10 or more submissions has been achieved, performance can be calculated.

One CLIA Waiver was withdrawn before Substantive Interaction, and Withdrawn counts as a decision.

** Performance was calculated from a combined MDUFA Cohort of FY 2018 and FY 2019 submissions.

†† Final review goal performance may change once all submissions "Pending Within Goal" (column [D]) are completed, but the Review Goal will still be met even if all pending submissions do not meet the goal.

FY 2019 Updated Performance Data (continued)

Submission Type	MDUFA Cohort [A]	Completed Within Goal [B]	Completed Overdue [C]	Pending Within Goal [D]	Pending Overdue [E]	Review Goal [F]	Current Review Goal Performance [G]	Highest Possible Review Goal Performance [H]
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	5§	5	0	0	0	90%	§	§
Decision with No Advisory Committee Input	5§	4	1	0	0	90%	§	§
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	3,101	2,917	184	N/A	N/A	1,530	**2,917 (MET)**	N/A
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	4	4	0	0	0	90%	**100% (MET)**	100%
BLA Manufacturing Supplements Requiring Prior Approval	54	53	1	0	0	90%	**98% (MET)**	98%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	2	2	0	0	0	90%	**100% (MET)**	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	17	17	0	0	0	90%	**100% (MET)**	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	0	90%	*	*

* No submissions were received in FY 2019; therefore, no performance can be reported.
§ The MDUFA Cohort for this fiscal year is insufficient (< 10) to calculate performance. Therefore, per an agreement in the MDUFA IV commitment letter, performance will be calculated in a future fiscal year when a combined cohort of 10 or more submissions is achieved.
** Performance was calculated from a combined MDUFA Cohort of FY 2018 and FY 2019 submissions.

FY 2018 Updated Performance Data

In FY 2018, FDA had a sufficient MDUFA Cohort to calculate performance for 16 of the 23 review goals with specific target percentages. For the remaining seven goals, FDA did not receive any submissions (four goals) or FDA determined the MDUFA Cohort was insufficient (in single or combined years) to calculate performance (three goals). As of September 30, 2020, the FY 2018 cohorts for 16 review goals with specific target percentages for which FDA received a sufficient MDUFA Cohort to calculate performance were sufficiently complete to determine the outcome. For 15 of the review goals, the cohorts were sufficiently complete by September 30, 2019, and FDA met the outcome goal (see the FY 2019 report for details). Details on FDA's final performance for the one goal that was not sufficiently complete on September 30, 2019 (but is sufficiently complete now) is below. For this goal, FDA met the outcome goal.

FY 2018 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	68	68	0	0	0	90%	**100% (MET)**	100%

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.

As of September 30, 2020, the 510(k) and PMA cohorts for FY 2018 had met the decision threshold to calculate the average TTD, and both cohorts had met the goal. FDA's performance in these cohorts (as well as whether the goal was met or missed) is shown in **bold** text in the table below.

As of September 30, 2020, neither the 510(k) nor the PMA cohorts for FY 2019 or FY 2020 had met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2019 and FY 2020 in future reports once the cohorts have met the decision threshold.

MDUFA IV's Shared Outcome Goals

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

* As of September 30, 2020, the fiscal year cohort had not met the decision threshold to calculate performance.

MDUFA Review Workloads: FY 2015 Through FY 2020

The table below compares review workloads for submission types with MDUFA review goals for FY 2020 and a 5-year average (FY 2015 through FY 2019).

- The review workload reflects the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee). Details of which administrative requirements apply to which submission type are outlined in Appendix A.
- Five-year averages and comparisons are calculated only for submission types that had MDUFA review goals in the entire 5-year period. Review workload is reported as "N/A" for years when a submission type did not have MDUFA review goals.
- Review workload numbers may differ from the MDUFA Cohort numbers presented in other tables because submissions closed without MDUFA decisions are not included in the MDUFA Cohort.

The review workload in FY 2020 was calculated for 13 of the 15 submission types that had data available to calculate a 5-year average. The other two submission types were new to MDUFA IV and did not have the 5-year historical data. Five of the 13 submission types did not receive any submissionsfor FY 2020. Therefore, three are showing a 100 percent change from FY 2020 as compared to the 5-year average, one had no submissions over the 5-year period, and one had a 5-year average less than one. BLA Manufacturing Supplements Requiring Prior Approval had a notable workload increase in FY 2020 compared to the 5-year average. Class 2 Original BLA and BLA Efficacy Supplement Resubmissions had a notable workload decrease in FY 2020 compared to the 5-year average.

Review Workload by Submission Type

Submission Type	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	5-Year Average (FY 2015 to FY 2019)	FY 2020 Compared to 5-Year Average
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	75	74	70	77 †	59	80	71	12.7%
180-Day PMA Supplements	203	210	276	199	196 †	186	217	-14.3%
Real-Time PMA Supplements	340	329	338	341	375 †	359	345	4.1%
510(k) Premarket Notifications	3,781	3,677	4,098	3,591	3,776 †	3,837	3785	1.4%
De Novo Classification Requests	n/a	n/a	n/a	56	62	69	*	*
CLIA Waiver by Applications	11	9	7	4	9	1	8	-87.5%
Dual 510(k) and CLIA Waiver by Applications	3	1	6	11	6	6	5	20.0%
Pre-Submissions	n/a	n/a	n/a	2,783	3,253 †	3,382 ‡	*	*
BLAs								
Priority Original BLAs	2	1	1	0	0	0	0	0%
Standard Original BLAs	2	26	5	14	4	0	10	-100.0%
BLA Manufacturing Supplements Requiring Prior Approval	19	47	38	94	54 †	92	65	41.5%
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0	0%
Standard BLA Efficacy Supplements	1	1	1	8	2	0	2	-100.0%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	2	1	1	17	0	4	-100.0%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	16	28	40	7	0	1	15	-93.3%

* No 5-year average is available due to a lack of MDUFA review goals in some years.
† Data were updated from the FY 2019 MDUFA Performance Report to Congress.
‡ This does not include Pre-Submissions resubmitted after being closed without feedback due to a reallocation of resources for COVID-19 activities.

Appendices

Appendix A: Definitions of Key Terms

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

- an application for premarket approval under section 515 of the FD&C Act;
- a premarket notification under section 510(k) of the FD&C Act;
- a De Novo classification request under section 513(f)(2) of the FD&C Act;
- a Pre-Submission;
- a CLIA waiver by application;
- a Dual 510(k) and CLIA waiver by application; or
- a BLA or supplement to a BLA under the Public Health Service Act.

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

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

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

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

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

BLAs have many application categories: Priority Original, Standard Original, Priority Efficacy Supplements, Standard Efficacy Supplements, Manufacturing Supplements Requiring Prior Approval, Class I Original BLA and BLA Efficacy Supplement Resubmissions, and Class II Original BLA and BLA Efficacy Supplement Resubmissions. Submissions placed on Application Integrity Program Hold will be removed from the MDUFA Cohort.

E. Pre-Submission: A Pre-Submission includes a formal written request from an applicant for feedback from FDA that is provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission meeting is a meeting or teleconference in which FDA provides its substantive feedback on the Pre-Submission. A Pre-Submission provides the opportunity for an applicant to obtain FDA's feedback prior to an intended submission of an IDE or marketing application. The request should include specific questions regarding review issues relevant to a planned IDE or marketing application (e.g., questions regarding pre-clinical and clinical testing protocols or data requirements). A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. Certain forms of FDA's feedback to applicants, such as the following, are not considered Pre-Submissions because they represent information that can be readily addressed by the FDA review team or are another type of submission:

- General information requests initiated through the Division of Industry and Consumer Education
- General questions regarding FDA's policy or procedures
- Meetings or teleconferences that are intended to be informational only, including, but not limited to, those intended to educate the review team on new device(s) with significant differences in technology from currently available devices or to update FDA about ongoing or future product development without a request for FDA's feedback on specific questions related to a planned submission
- Requests for clarification on technical guidance documents, especially when contact is recommended by FDA in the guidance document. However, the following requests should generally be submitted as a Pre-Submission to ensure appropriate input from multiple reviewers and management: consultation on device types not specifically addressed in the guidance document; clarification of nonclinical or clinical studies not addressed in the guidance document; and requests regarding use of an alternative means to address recommendations specified in the guidance document.
- Phone calls or email messages to reviewers that can be readily answered based on a reviewer's experience and knowledge and do not require the involvement of a broader number of FDA staff beyond the routine involvement of the reviewer's supervisor and more experienced mentors.
- Interactions requested by either the applicant or FDA during the review of a marketing application (i.e., following the submission of a marketing application but prior to FDA reaching a decision).

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

Submission Type	Applicable Administrative Requirements
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	eCopy, User Fee
180-Day PMA Supplements	eCopy, User Fee
Real-Time PMA Supplements	eCopy, User Fee
510(k)s (non-Third Party)	eCopy, User Fee
510(k)s (Third Party)	eCopy
De Novo Classification Requests	eCopy, User Fee
CLIA Waiver by Applications	None

Submission Type	Applicable Administrative Requirements
Dual 510(k) and CLIA Waiver by Applications	eCopy, User Fee
Pre-Submissions	eCopy
Priority Original BLAs	eCopy, User Fee
Standard Original BLAs	eCopy, User Fee
BLA Manufacturing Supplements Requiring Prior Approval	eCopy
Priority BLA Efficacy Supplements	eCopy, User Fee
Standard BLA Efficacy Supplements	eCopy, User Fee
Class I Original BLA and BLA Efficacy Supplement Resubmissions	eCopy
Class II Original BLA and BLA Efficacy Supplement Resubmissions	eCopy

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

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

H. Substantive Interaction: Substantive Interaction is an email, letter, teleconference, video conference, fax, or other form of communication, such as a request for Additional Information or a Major Deficiency letter, by FDA notifying the applicant of substantive deficiencies identified in the initial submission review, or a communication stating that FDA has not identified any deficiencies in the initial submission review and that any further minor deficiencies will be communicated through interactive review. An approval or clearance letter issued on or prior to the Substantive Interaction goal date will qualify as a Substantive Interaction. If substantive issues warranting issuance of an Additional Information or Major Deficiency letter are not identified, interactive review should be used to resolve any minor issues and facilitate a decision by FDA. In addition, interactive review will be used where, in FDA's estimation, it will lead to a more efficient review process during the initial review cycle (i.e., prior to a Substantive Interaction) to resolve minor issues such as revisions to administrative items (e.g., 510(k) Summary/Statement, Indications for Use statement, environmental impact assessment, financial disclosure statements); a more detailed device description; omitted engineering drawings; revisions to labeling; or clarification regarding nonclinical or clinical study methods or data. Minor issues may still be included in an Additional Information or Major Deficiency letter where related to the resolution of the substantive issues (e.g., a modification of the proposed Indications for Use may lead to revisions in labeling and administrative items) or if these minor issues were still unresolved following interactive review attempts. Both interactive review and Substantive Interactions will occur on the review clock except upon the issuance of an Additional Information or Major Deficiency Letter that stops the review clock.

I. BLA-Related Definitions:

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

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

(a) Final printed labeling
(b) Draft labeling
(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
(d) Stability updates to support provisional or final dating periods
(e) Commitments to perform Phase 4 studies, including proposals for such studies
(f) Assay validation data
(g) Final release testing on the last one or two lots used to support approval

(h) A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class I category)
(i) Other minor clarifying information (determined by the Agency as fitting the Class I category)
(j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry

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

Appendix B: Performance Information for De Novo, 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 met statutory time frames. Specifically, FDA was directed to report (1) the number of De Novo classification requests under section 513(f)(2) 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 section 522 (also known as a "section 522 plan") for which FDA responded within 60 days.

The table below provides the requested information in the three categories and includes the percentage of submissions for which FDA met its statutory timelines. This is followed by additional information about each of the three submission types. The number of De Novo classification requests received includes those that passed eCopy requirements (FY 2016 and FY 2017) or passed eCopy and user fee requirements (FY 2018 through FY 2020). The number of 513(g) submissions received are those that passed user fee requirements.

FDA reports that between FY 2016 and FY 2020, FDA met statutory timelines for issuing a final decision on a De Novo classification request 31 to 60 percent of the time, responded to 513(g) requests within the statutory timeframe 26 to 36 percent of the time, and met the statutory timeframe for responding to a section 522 (Postmarket Surveillance) plan 38 to 79 percent of the time.

Performance Data for Submissions with Statutory Timeframes

Submission Type	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
De Novo Classification Requests Under 513(f)(2)					
Number received that passed applicable administrative requirements	54	101	56	62	69
Number completed with a Granted, Declined, or Withdrawn decision	53	101	55	57	10
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory timeframe of 120 days*	32	60	17	21	4
Percent that met the statutory timeframe†	60%	59%	31%	37%	40%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)					
Number received that passed applicable administrative requirements	109	133	115	132	153
Number to which FDA responded within the statutory timeframe of 60 days	36	37	41	47	40
Percent that met the statutory timeframe‡	33%	28%	36%	36%	26%
Postmarket Surveillance Plans					
Number received	43	14	13	11	28
Number of FDA responses within 60 days of receipt	22	11	5	6	21
Percent that met the statutory timeframe	51%	79%	38%	55%	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 C: Additional Information from FDARA's Section 903 Requirement

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

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

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

(III) The number of expedited development and priority review designations under section 515C[9] per fiscal year.

The information below fulfills these requirements.

Number of Premarket Applications Filed and Reports Submitted

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

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

- "Premarket applications filed under section 515" are defined as submissions reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2020. This definition is consistent with the interpretation of identical statutory language in section 904 of FDARA and is addressed in other sections of this report.
- "Reports submitted under section 510(k)" are defined as submissions reviewed as Premarket Notifications (510(k)s) (including those reviewed as Third Party 510(k) submissions) that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2020. This definition is consistent with the

[9] "Section 515C" appears in the original. The expedited development and priority review provisions appear in section 515B of the FD&C Act; there is no section 515C.

interpretation of identical statutory language in section 904 of FDARA and is addressed in other sections of this report.

- In performance reports for FY 2018 and FY 2019, "each review division" was defined as each of the divisions within CDRH's Office of Device Evaluation and Office of In Vitro Diagnostics and Radiological Health (OIR). In performance reports for FY 2020 and later, "each review division" is defined as each of the Offices of Health Technology (OHTs) within CDRH's Office of Product Evaluation and Quality (OPEQ). OPEQ and OHTs were established as part of CDRH's 2019 reorganization,[10] 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 and FY 2019. This definition is also consistent with the interpretation of similar statutory language in other parts of section 903 of FDARA and addressed in other sections of this report.
- Consistent with other parts of this report, the MDUFA Cohort is based on a fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.
- Also consistent with other parts of this report, submissions that were closed without a MDUFA decision are not included in the MDUFA Cohort and, therefore, are not included in the table below. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without a MDUFA decision, please refer to the review workload tables in other sections of this report.
- As stipulated in FDARA, the numbers below include only submissions reviewed by CDRH and do not include submissions reviewed by CBER. This is different from other parts of this report where the MDUFA Cohort includes submissions from both CDRH and CBER.

[10] See "Reorganization of the Center for Devices and Radiological Health" (https://www.fda.gov/about-fda/center-devices-and-radiological-health/reorganization-center-devices-and-radiological-health#changes).

FY 2020 MDUFA Cohorts by CDRH's OHTs

Submission Type	MDUFA Cohort (CDRH only)	OHT1	OHT2	OHT3	OHT4	OHT5	OHT6	OHT7*
Original PMA, PDP, Panel-Track PMA Supplements, and Premarket Reports								
Substantive Interaction	70	6	22	6	3	3	2	28
Decision with No Advisory Committee Input	68	6	20	6	3	3	2	28
Decision with Advisory Committee Input	2	0	2	0	0	0	0	0
180-Day PMA Supplements								
Substantive Interaction	175	29	70	16	7	24	2	27
Decision	175	29	70	16	7	24	2	27
Real-Time PMA Supplements								
Decision	351	15	192	36	13	24	9	62
510(k) Premarket Notifications								
Substantive Interaction	3136	408	330	346	525	173	585	624
Decision	3017	420	338	345	525	172	578	639

* This office is sometimes referred to as OIR.

Number of Expedited Development and Priority Review Designations

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

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

- The number of breakthrough device designations represents the number of designation requests granted as of September 30, 2020, in the relevant fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.
- As stipulated in FDARA, the numbers below include only designation requests reviewed by CDRH and do not include those reviewed by CBER.

CDRH Breakthrough Device Designations

Cohort	Number of Breakthrough Device Designations
FY 2018	62
FY 2019	120
FY 2020	128*
FY 2021	†
FY 2022	†

*As of 9/30/2020, the FY 2020 cohort was 71% closed.
† As of 9/30/2020, the fiscal year had not yet begun but will be included in future reports.

Appendix D: Analysis of Use of Funds

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

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

Analysis of Use of Funds

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

Differences Between Aggregate Numbers

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

> (aa) the number of applications filed and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and
>
> (bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the applicable fiscal year.

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

- *MDUFA Cohort [A]* = "aggregate number of premarket applications filed under section 515 and aggregate reports submitted under section 510(k)." The MDUFA Cohort [A] includes both Completed [B] and Pending [F] submissions ([A] = [B] + [F]). "Premarket applications filed under section 515" are defined as submissions

reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2020. "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, 2020. This definition is consistent with the interpretation of identical statutory language in section 903 of FDARA and is addressed in other sections of this report.

- Consistent with other parts of this report, the MDUFA Cohort is based on a fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.
- Also consistent with other parts of this report, submissions that were closed without a MDUFA decision are not included in the MDUFA Cohort and, therefore, are not included in the table below. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without a MDUFA decision, please refer to the review workload tables in other sections of this report.
- *Completed [B]* = the number of submissions with a MDUFA action as of September 30, 2020. 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, 2020.
- *Completed Overdue [D]* = the number of Completed [B] submissions that had not met the MDUFA goal as of September 30, 2020.
- *Major deficiency letters, not approvable letters, denials [E]* = "aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the [A]gency" and represents the number of times Completed [B] submissions had this specific action (or equivalent) for each MDUFA goal. Specific actions relevant to each MDUFA goal and submission type are as follows:

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

- *Pending [F]* = "(aa) the number of applications filed and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year." Pending [F] includes both Pending Within Goal [G] and Pending Overdue [H] submissions ([F] = [G] + [H]).
- *Pending Within Goal [G]* = the number of Pending [F] submissions that had met the goal as of September 30, 2020.
- *Pending Overdue [H]* = the number of Pending [F] submissions that had not met the goal as of September 30, 2020.
- *Overdue (completed + pending) [I]* = "(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) of MDUFA IV for the applicable fiscal year" and represents the number of submissions that had not met the MDUFA goal as of September 30, 2020. Overdue [I] includes both Completed Overdue [D] and Pending Overdue [H] submissions ([I] = [D] + [H]).

FY 2020 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	73	63	60	3	45	10	10	0	3
Decision with No Advisory Committee Input	71	27	26	1	1	44	44	0	1
Decision with Advisory Committee Input	2	0	0	0	*0*	2	2	0	0
180-Day PMA Supplements									
Substantive Interaction	183	134	128	6	73	49	49	0	6
Decision	183	87	87	0	3	96	95	1	1
Real-Time PMA Supplements									
Decision	355	262	262	0	6	93	93	0	0
510(k)									
Substantive Interaction*	3,032	2598	2,515	83	1,574	434	427	7	90
Decision*	3,057	1702	1,691	11	19	1355	1,346	9	20

* 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 Decision data, but only non-Third Party 510(k)s are included in Substantive Interaction data.

Performance Enhancement Goals

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

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

In summary, FDA had 10 performance enhancement goals with required completion dates in FY 2020. All goals have been completed, 9 of which were completed on time.

FY 2020 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Infrastructure[†]				
Quality Management – The Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's Corrective and Preventive Action (CAPA) process.	9/30/2020	Y	3/31/2020	In Q1 and Q2 of FY 2020, FDA and industry communicated about areas of interest for its ongoing audit plan. FDA incorporated this feedback, along with other information, to identify areas to audit. CDRH's Quality Management Program at the Office of the Center Director, which is ISO 9001:2015 certified for the provision of quality management and organizational excellence tools and services, executed the following audits in FY 2020: • **Two audits** examined deficiency letters (see additional information below). ***CAPA Result***: The number of deficiencies adhering to FDA's deficiency content policy increased. • **One audit** examined Pre-Submissions (see additional information below). • **One audit** examined the Biocompatibility Focal Point Program. • **Eight audits** examined CDRH's quality management system (QMS). ***Results***: Overall, it appears that the QMS is functioning as intended. This finding was further verified through an external ISO 9001:2015 surveillance audit by a certifying body. There were no nonconformities to address.
Quality Management – FDA will complete audits in the following areas: Deficiency letters and Pre-Submissions.	9/30/2020	Y	Deficiency letters (7/23/2019) Pre-Submission (9/29/2020)	**Deficiency letters (three audits since FY 2019):** • **FY 2019 audit (met the MDUFA goal)**: Assessed the number of deficiencies adhering to FDA's deficiency content policy[11] (also referred to as "Four-Part Harmony" or "4PH"). Findings showed three of four parts of the 4PH policy were well understood and implemented. However, one part was less represented, could have been interpreted in multiple different ways, and would have benefitted from clarity. A nonconformity was logged and corrective actions were put in place (CAPA). • **Baseline audit FY 2020:** For use as baseline for future audits, the FY 2019 audit sample was reassessed using the clarified 4PH policy from CAPA above. In addition, auditors used the clarified 4PH policy to examine and baseline the pre-written deficiencies used by CDRH's Submission Memo and Review Template (SMART) tool. • **Follow-up audit FY 2020**: Assessed progress after implementation of additional corrective actions beyond the clarified 4PH policy. Findings showed improvement. • **Future audits:** An external audit is planned for FY 2021 as part of Phase 2 of the "Independent Assessment of Review Process Management" (a separate MDUFA Performance Enhancement goal). Additional internal follow-up audits will be conducted, as necessary.

[11] This deficiency content policy is defined in FDA's "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" guidance (see https://www.fda.gov/media/71735/download) and internal procedures.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
				Pre-Submissions • **FY 2020 audit (met the MDUFA goal)**: Assessed the relationship between Pre-Submissions and premarket submissions (510(k), De novo, PMA) and the time between Pre-Submission feedback and the premarket submission. • **Future audits:** A planned audit will investigate the feedback given in the Pre-Submission and its impact on the linked premarket submission. An external audit is also planned for FY 2021 as part of Phase 2 of the "Independent Assessment of Review Process Management" (a separate MDUFA Performance Enhancement goal).
IT Infrastructure for Submission Management – FDA will issue a draft guidance document on the use of electronic submission templates.	10/1/2019	Y	9/26/2019	FDA published a draft guidance on 9/26/2019 and a final guidance, titled "Providing Regulatory Submissions for Medical Devices in Electronic Format – Submissions Under Section 745A(b) of the FD&C Act," on 7/15/2020 (see https://www.fda.gov/media/131064/download).
Training - FDA will achieve Kirkpatrick Level 3 for curriculum-based premarket training through an assessment of work performance behavior changes and will evaluate the effectiveness of the impact of curriculum-based premarket training activities on relevant premarket program metrics and goals (Kirkpatrick Level 4).	9/30/2020	Y	Kirkpatrick Level 3 (9/30/2017) Kirkpatrick Level 4 (7/31/2020)	**Kirkpatrick Level 3** In September 2017, CDRH administered a Level 3 (application and behavior) evaluation 12 months post-program completion for the FY 2016 through FY 2018 cohorts of the Reviewer Certification Program (RCP), FDA's curriculum-based premarket training program. The FY 2019 RCP cohorts were assessed in February 2020. **Kirkpatrick Level 4** In July 2020, CDRH administered a Level 4 (impact and effectiveness) evaluation for the FY 2016 through FY 2019 RCP cohorts.
Fee Setting, Fee Collections, and Workload - If the collections are in excess of the resources needed to meet performance goals given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and industry will work together to assess how best to utilize those resources to improve performance on submission types with performance goals and/or quality management programs, using, as input for the discussion: workload information, performance objectives and ongoing reported performance.	12/31/2019	Y	11/15/2019	FY 2018 Total Collections less unearned revenue equaled $189,221,510 in funding available for use compared to the Inflation-adjusted statutory revenue target of $193,291,000. This did not result in excess revenue for the year that could be utilized; therefore, a discussion of the use of excess funding was not necessary.
Program and Process Implementation‡				
Enhanced Use of Consensus Standards – FDA will provide an annual report on the progress of the Accreditation Scheme for Conformity Assessment (ASCA) program.	1/31/2020	Y	1/31/2020	On 1/31/2020, FDA published the calendar year 2019 annual report on the progress of the ASCA program on (see https://www.fda.gov/media/134852/download).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Enhanced Use of Consensus Standards – FDA will develop and initiate the pilot of the ASCA program with stakeholder input. a. FDA intends to pilot the inclusion of recognized standards of public health significance when specific pass/fail criteria are part of the standard.	9/30/2020	Y	9/25/2020	FDA published three final guidances on 9/25/2020, officially launching the ASCA pilot. These guidances finalize the ASCA draft guidance FDA published on 9/23/2019 and outline details of the ASCA Pilot programs operations: 1. "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" final guidance (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program); 2. "Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme Conformity Assessment (ASCA) Pilot Program" final guidance (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and); and 3. "Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" final guidance (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme). See also the ASCA web page at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca .
Third Party Review – FDA will issue a final guidance within 12 months of the conclusion of the public comment period for the draft guidance titled "510(k) Third Party Review Program."	12/13/2019*	N	3/12/2020	FDA published a final guidance, titled "510(k) Third Party Review Program," on 3/12/2020 (see https://www.fda.gov/media/85284/download). See also Appendix E.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Patient Engagement & the Science of Patient Input– FDA will hold one or more public meetings to discuss the topics below and publish the findings and next steps. a. Discuss approaches for incorporating PPI and PRO as evidence in device submissions, as well as other ways of advancing patient engagement; b. Discuss ways to use patient input to inform clinical study design and conduct, with the goal of reducing barriers to patient participation and facilitating recruitment and retention; c. Discuss specific examples and case histories for PPIs and PROs to ensure clarity and understanding by workshop attendees; and d. Identify priority areas where decisions are preference-sensitive and PPI data can inform regulatory decision-making to advance the design and conduct of patient preference studies in high impact areas. Publish the priority areas in the *Federal Register* for public comment following the public meeting.	9/30/2020	Y	9/30/2020	FDA held four public meetings and published the findings and next steps to meet all parts (a-d) of this commitment: 1. Held the Patient Engagement Advisory Committee Meeting, titled "Patient Engagement in Medical Device Clinical Trials," from October 11-12, 2017 (see https://www.fda.gov/advisory-committees/patient-engagement-advisory-committee/2017-meeting-materials-patient-engagement-advisory-committee) and published a draft guidance, titled "Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations," on 9/24/2019 (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations). 2. Held a collaborative workshop titled "Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation," which was hosted by the Centers of Excellence in Regulatory Science and Innovation and FDA, from December 7-8, 2017 (see https://www.fda.gov/science-research/advancing-regulatory-science/advancing-use-patient-preference-information-scientific-evidence-medical-product-evaluation); and published a summary of the proceedings and expert panelist-recommended next steps in "The Patient – Patient-Centered Outcomes Research" on 11/22/2019 (see https://link.springer.com/article/10.1007/s40271-019-00396-5). 3. Published a *Federal Register* notice on patient preference-sensitive priorities on 5/3/2019 (see https://www.federalregister.gov/documents/2019/05/03/2019-09051/list-of-patient-preference-sensitive-priorities-establishment-of-a-public-docket-request-for); 4. Held a public meeting, titled "ISPOR/FDA Summit: Using Patient Preference Information in Medical Device Regulatory Decisions: Benefit Risk and Beyond," on 9/29/2020 (see https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-using-patient-preference-information-medical-device-regulatory-decisions-benefit-risk); and 5. Held a public meeting, titled "Patient-Reported Outcomes (PROs) and Medical Device Evaluation: From Conception to Implementation," 9/30/2020 (see https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-devices-virtual-public-meeting-patient-reported-outcomes-pros-and-medical-device-evaluation) and published a draft guidance, titled "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation," on 8/31/2020 (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Program and Process Assessments§				
Independent Assessment of Review Process Management (Phase 2) – FDA will award the contract.	3/31/2020	Y	1/9/2020	The contract was awarded to Booz Allen Hamilton. **Period of Performance**: 1/9/2020-10/1/2021

* "Target goal date" is not explicitly defined in the MDUFA IV commitment letter but is implied based on another commitment happening first.
† Performance enhancement goals are described in Section III ("Infrastructure") of the MDUFA IV commitment letter.
‡ Performance enhancement goals are described in Sections II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA IV commitment letter.
§ Performance enhancement goals are described in Section V ("Independent Assessment of Review Process Management") of the MDUFA IV commitment letter.

Common Causes and Trends Impacting the Ability to Meet Goals

The following table addresses section 738A(a)(1)(A)(v)(III) of the FD&C Act as added by section 904(b)(1) of FDARA, pertaining to MDUFA, 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 201(b) of MDUFA IV.

FY 2020 Goals

In total, FDA had 35 MDUFA goals in FY 2020: 25 review goals and 10 performance enhancement goals. In FY 2020, FDA had a sufficient MDUFA Cohort to calculate performance for 15 of the 25 review goals. As indicated in other sections of this report, in FY 2020, FDA met four of the 15 review goals for which FDA received a sufficient MDUFA Cohort to calculate performance, but 11 have not yet reached sufficient closure to determine the outcome. FDA also had 10 performance enhancement goals with required completion dates in FY 2020. In FY 2020, FDA completed all 10 goals, 9 of which were completed on time. With only one missed goal and 11 goals still pending (of 35 MDUFA goals for FY 2020), 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 2020 review goal cohorts are sufficiently closed and data indicate FDA has missed additional FY 2020 goals, FDA will provide the required information in future reports.

Cause or Trend	Impact on FDA Ability to Meet Goals
Not yet applicable. Will provide in future reports as necessary.	*Not yet applicable. Will provide in future reports as necessary.*

FY 2019 Goals (Updated)

In total, FDA had 37 MDUFA goals in FY 2019: 25 review goals and 12 performance enhancement goals. In FY 2019, FDA had a sufficient MDUFA Cohort to calculate performance for 17 of the 25 review goals. As indicated in other sections of this report, in FY 2019, FDA met 13 of the 17 review goals for which FDA received a sufficient MDUFA Cohort to calculate performance, but four have not yet reached sufficient closure to determine the outcome. FDA also had 12 performance enhancement goals with required completion dates in FY 2019. In FY 2019, FDA completed 11 of the 12 goals, 10 of which were completed on time.

With only two missed goals and four goals still pending (of 37 MDUFA goals for FY 2019), 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 2019 review goal cohorts are sufficiently closed and data indicate FDA has missed additional FY 2019 goals, FDA will provide the required information in future reports.

Cause or Trend	Impact on FDA Ability to Meet Goals
Not yet applicable. Will provide in future reports as necessary.	*Not yet applicable. Will provide in future reports as necessary.*

FY 2018 Goals (Updated)

In total, FDA had 37 MDUFA goals in FY 2018: 25 review goals and 12 performance enhancement goals. In FY 2018, FDA had a sufficient MDUFA Cohort to calculate performance for 18 of the 25 review goals. As indicated in other sections of this report, in FY 2018, FDA met all 18 of these review goals. FDA also had 12 performance enhancement goals with required completion dates in FY 2018. In FY 2018, FDA completed all 12 goals, 11 of which were completed on time.

With only one missed goal, it is not possible to identify common causes and trends affecting the ability of CDRH, ORA, or FDA to meet the goals. Additionally, as indicated in the FY 2018 Corrective Action Report (in Appendix F of the FY 2018 MDUFA Performance Report to Congress), FDA concluded that there were no systemic issues with the process related to this goal and no corrective action was needed to prevent future reoccurrences.

Cause or Trend	Impact on FDA Ability to Meet Goals
Not applicable. FDA missed only one goal in FY 2018.	*Not applicable. FDA missed only one goal in FY 2018.*

Appendix E: FY 2020 Corrective Action Report

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

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

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

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

Executive Summary

FY 2020 Review Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal	Corrective Action Plan
Review Goals	In FY 2020, FDA had a sufficient MDUFA cohort to calculate performance for 15 review goals. Preliminary performance data through September 30, 2020, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) all 15 of these goals. However, with submissions still pending, it is too soon to determine the final performance for the full FY 2020 cohort of review goals. It is also too soon to determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. FDA will provide this information, in subsequent corrective action reports, once all FY 2020 cohorts are sufficiently complete.	FDA has not yet missed any FY 2020 review goals. FDA will provide corrective actions for any missed FY 2020 review goals in subsequent corrective action reports.

FY 2019 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal	Corrective Action Plan
Review Goals	In FY 2019, FDA had a sufficient MDUFA cohort to calculate performance for 17 review goals. Preliminary performance data through September 30, 2020, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) all 17 of these goals. However, with submissions still pending, it is too soon to determine final performance for the full FY 2019 cohort of review goals. It is also too soon to determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. FDA will provide this information, in subsequent corrective action reports, once all FY 2019 cohorts are sufficiently complete.	FDA has not yet missed any FY 2019 review goals. FDA will provide corrective actions for any missed FY 2019 review goals in subsequent corrective action reports.

FY 2018 Review Goal Performance (Updated)

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal	Corrective Action Plan
Review Goals	In FY 2018, FDA had a sufficient MDUFA Cohort to calculate performance for 18 review goals. All of these FY 2018 cohorts are now sufficiently complete to determine the outcome, and FDA met all 18 review goals. Therefore, a "justification … for the types of circumstances and trends that contributed to missed review goal times" is not needed. Although FDA met all 18 FY 2018 review goals, FDA missed one FY 2018 performance enhancement goal. Therefore, "recommendations on ways in which the Secretary can improve and streamline the medical device application review process" are not needed. Two (of 3,649) submissions missed a review time goal but were approved during the first cycle review. For both submissions, FDA determined that working with the applicant interactively (instead of sending a request for Additional Information) would be the least burdensome way to resolve all deficiencies, and both received positive decisions shortly after the review goal.	FDA did not miss any FY 2018 review goals. No corrective action is needed.

FY 2020 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal	Corrective Action Plan
Program and Process Implementation	Publication of the "510(k) Third Party Review Program" final guidance was due within 12 months of the conclusion of the public comment period for the draft guidance, ending on 12/13/2019. As part of its standard process, FDA had allotted sufficient time to account for all necessary reviews and clearances and was on track to publish the "510(k) Third Party Review Program" final guidance on time. However, while the guidance was undergoing clearance, the guidance clearance process changed. Specifically, Executive Order 13891 was released in October 2019, which directed implementation of additional administrative procedures and clearance processes for guidance documents. This guidance was identified as being subject to OMB review at the time, which significantly impacted the clearance timeline. The timing of this process change (toward the end of the clearance cycle), made it impossible for FDA to take immediate actions to revise the timeline and still meet the MDUFA goal.	FDA conducted a root cause analysis and concluded that the requirement to implement a change in the guidance clearance process on a document already in the late stages of clearance caused the delay. FDA is now aware of the change and has accounted for the process change by incorporating the time needed for the additional process steps into guidance clearance process timelines.

MDUFA Review Goals

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

- "Applications or reports submitted under section 515" are defined as submissions reviewed as Original PMAs, PDPs, Panel-Track PMA Supplements, 180-Day PMA Supplements, Real-Time PMA Supplements, or Premarket Reports that had received a MDUFA decision or were pending a MDUFA decision as of September 30, 2020. "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, 2020. These definitions are consistent with the interpretation of similar statutory language in section 903, and other parts of section 904, of FDARA and are addressed in other sections of this report.
- "Missed review time goals but were approved during the first cycle review" are submissions in a MDUFA Cohort with a MDUFA decision that did not meet the MDUFA goal and did not include a request for Additional Information or a Major Deficiency letter.

This section includes all MDUFA review goals as they pertain to submissions in the FYs 2018, 2019, and 2020 cohorts.

FY 2020 Review Goal Performance

A. Summary of Performance:

FDA has not yet missed any FY 2020 review goals. In FY 2020, FDA had a sufficient MDUFA Cohort to calculate performance for 17 of the 25 review goals and met five of those 17 goals. However, as indicated in other sections of this report, MDUFA review goal performance data are based on a fiscal year receipt cohort. Although preliminary data for FY 2020 indicate FDA has the potential to meet the remaining 12 review goals for which FDA had a sufficient MDUFA Cohort to calculate performance, with submissions still pending, it is too soon to determine final performance for the full FY 2020 cohort of review goals. If, at the end of future

fiscal years, the FY 2020 cohorts are sufficiently complete to determine the outcome, FDA will provide updated information in future reports on any missed goals.

Additionally, with submissions still pending, it is too soon to determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. FDA will provide this information, in subsequent corrective action reports, once all FY 2020 cohorts are sufficiently complete.

B. Justification:

It is too soon to determine if a justification is needed.

C. FY 2020 Corrective Actions:

It is too soon to determine if a corrective action is needed.

FY 2019 Review Goal Performance (Updated)

A. Summary of Performance:

FDA has not yet missed any FY 2019 review goals. In FY 2019, FDA had a sufficient MDUFA Cohort to calculate performance for 19 of the 25 review goals and met 15 of those 19 goals. However, as indicated in other sections of this report, MDUFA review goal performance data are based on a fiscal year receipt cohort. Although preliminary data for FY 2019 indicate FDA has the potential to meet the remaining four review goals for which FDA had a sufficient MDUFA Cohort to calculate performance, with submissions still pending, it is too soon to determine final performance for the full FY 2019 cohort of review goals. If, at the end of future fiscal years, the FY 2019 cohorts are sufficiently complete to determine the outcome, FDA will provide information in future reports on any missed goals.

Additionally, with relevant submissions still pending, it is too soon to determine the types of circumstances, in the aggregate, under which relevant submissions missed review time goals but were approved during the first cycle review. FDA will provide this information, in subsequent corrective action reports, once all FY 2019 cohorts are sufficiently complete.

D. Justification:

It is too soon to determine if a justification is needed.

E. FY 2020 Corrective Actions:

It is too soon to determine if a corrective action is needed.

FY 2018 Review Goal Performance (Updated)

A. Summary of Performance:

FDA did not miss any FY 2018 review goals. In FY 2018, FDA had a sufficient MDUFA Cohort to calculate performance for 18 of the 25 review goals. As indicated in other sections of this report, all of these FY 2018 cohorts were sufficiently complete to determine the outcome, and FDA met all 18 review goals.

Additionally, of the 3,649 submissions within relevant FY 2018 PMA and 510(k) MDUFA Cohorts,[12] two submissions missed a review time goal but were approved during the first cycle review. For both submissions, FDA determined that working with the applicant interactively (instead of sending a request for Additional Information) would be the least burdensome way to resolve all deficiencies, and both received positive decisions shortly after the review goal.

B. Justification:

FDA did not miss any FY 2018 review goals; therefore, no justification is needed.

C. FY 2020 Corrective Actions:

FDA did not miss any FY 2018 review goals; therefore, no corrective action is needed.

[12] Relevant MDUFA Cohorts for this information are as follows: Original PMA, PDP, Panel-Track PMA Supplements and Premarket Reports – Decision with No Advisory Committee Input (FY 2018 MDUFA Cohort = 68), Original PMA, PDP, Panel-Track PMA Supplements and Premarket Reports – Decision with Advisory Committee Input (FY 2018 MDUFA Cohort = 4), 180-Day PMA Supplements – Decision (FY 2018 MDUFA Cohort = 195), Real-Time PMA Supplements – Decision (FY 2018 MDUFA Cohort = 339), 510(k) Premarket Notification – Decision (FY 2018 MDUFA Cohort = 3,043).

MDUFA Performance Enhancement Goals

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

This section presents performance enhancement goals with required completion dates in FY 2020 that did not meet their specified goal. Consistent with other sections of this report, "performance enhancement goals" are defined as any non-review performance goal identified in the MDUFA IV commitment letter. Performance enhancement goals with specified completion dates in FY 2021 and FY 2022 will be covered in subsequent corrective action reports.

FDA had 10 performance enhancement goals with required completion dates in FY 2020. In FY 2020, FDA completed these 10 goals, 9 of which were completed on time. Details on the one goal that requires a justification and corrective action are provided below.

Program and Process Implementation

A. Summary of Performance:

Publication of the "510(k) Third Party Review Program" final guidance was due within 12 months of the conclusion of the public comment period for the draft guidance, ending on 12/13/2019. The guidance was published on 3/12/2020.[13]

B. Justification:

As part of its standard process, FDA had allotted sufficient time to account for all necessary reviews and clearances and was on track to publish the "510(k) Third Party Review Program" final guidance on time. However, while the guidance was undergoing clearance, the guidance clearance process changed. Specifically, Executive Order 13891 was released in October 2019, which directed additional administrative procedures and clearance processes for guidance documents. This guidance was identified as being subject to OMB review at the time, which significantly impacted the clearance timeline. The timing of this process change (toward the end of the clearance cycle), made it impossible for FDA to take immediate actions to revise the timeline and still meet the MDUFA goal.

C. FY 2020 Corrective Actions:

FDA conducted a root cause analysis and concluded that the requirement to implement a change in the guidance clearance process on a document already in

[13] See https://www.fda.gov/media/85284/download.

the late stages of clearance caused the delay. FDA is now aware of the change and has accounted for the process change by incorporating the time needed for the additional process steps into guidance clearance process timelines.

Appendix F: Rationale for MDUFA Program Changes

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

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

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

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

The information below fulfills these requirements.

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

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

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

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

The table below provides data to show changes in the number of FTEs hired, as agreed upon in the MDUFA IV commitment letter, from FY 2019 to FY 2020. Relevant information about the data provided is as follows:

- *Number of MDUFA IV Positions Filled* = the number of people hired under MDUFA IV. The MDUFA IV commitment letter states, "The Agency will apply user fee revenues to reduce the ratio of review staff to front line supervisors in the premarket review program to improve consistency. The Agency will also apply user fee revenues to enhance and supplement scientific review capacity by hiring device application reviewers as well as leveraging external experts needed to assist with the review of device applications" (section III-B) and "to support the National Evaluation System for health Technology ... by … hiring FDA staff with expertise in the use of [real-world evidence]" (section IV-H). However, the MDUFA IV commitment letter does not specify numerical hiring goals in terms of FTEs. Therefore, the Agency is providing data on the number of MDUFA IV positions filled through the end of the relevant fiscal year. Although some positions are filled from outside FDA, in some cases, a position can also be filled by a current FDA employee who is changing positions within the Agency. Numbers are provided cumulatively through the most recent fiscal year [B] and prior fiscal year [A].[14]
- *Change in Positions Filled (FY 2020) [C]* = the cumulative number of MDUFA IV positions filled through the most recent fiscal year minus the cumulative number of MDUFA IV positions filled through the prior fiscal year ([C] = [B] - [A]). This is equivalent to the number of MDUFA IV positions filled using MDUFA IV user fee revenues in the most recent fiscal year.

In summary, FDA filled 174 MDUFA IV positions through the end of FY 2020 (the most recent completed fiscal year). This amount is 47 positions higher than the 127 MDUFA IV positions filled through the end of FY 2019. FDA plans to allocate a total of 217 MDUFA IV positions through the end of FY 2021.

FDA has committed to improving its hiring and retention of scientific staff, as described in the MDUFA IV commitment letter. As initiatives associated with these commitments span the course of MDUFA IV, FDA continues to strive to hire and retain experienced scientific staff. However, FDA has encountered several challenges regarding interest, salaries, and expertise that have contributed to the difficulty in attracting and recruiting qualified staff. For example, competition with well-known tech innovation locations, the creation of new scientific and technical professional fields, and fewer candidates with a hybrid of specialties have resulted in hiring delays for the MDUFA program. In spite of these challenges, hiring is a key priority, and FDA remains focused on the recruitment and retention of skilled staff.

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

MDUFA IV Positions Filled

Center	Number of MDUFA IV Positions Filled		Change in MDUFA IV Positions Filled (FY 2020) [C] ([B] – [A])
	Through FY 2019 [A]	Through FY 2020 [B]	
CDRH	123	170	47
CBER	4	4	0
ORA	0	0	0
OC	0	0	0
Total	**127**	**174**	**47**

Change in the Number of FTEs Funded by Budget Authority at FDA by Division Within CDRH, CBER, ORA and OC

The table below provides data to show the change from FY 2019 to FY 2020 in the number of FTEs funded by budget authority at FDA by each division within CDRH, CBER, ORA, and OC. All numbers in the table below have been rounded to the nearest tenths place. Relevant information about the data provided is as follows:

- *Number of MDUFA Program FTEs Funded by Budget Authority.* The table reflects the number of FTEs funded by budget authority for the MDUFA program. For this report, "budget authority" refers to FDA's non-user fee annual appropriations. The numbers in the table below reflect use of 2080 compensable hours to equate to one FTE and are provided for the most recent fiscal year [B] and the prior fiscal year [A].
- *Change in Number of MDUFA Program FTEs Funded by Budget Authority [C] =* the number of MDUFA program FTEs funded by budget authority in the most recent fiscal year minus the number of MDUFA program FTEs funded by budget authority in the prior fiscal year ([C] = [B] – [A]).
- To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," for CDRH, the information in the table is broken down to the offices within CDRH and the sub-offices within OPEQ. OPEQ, offices within OPEQ, the Office of Policy, and the Office of Strategic Partnerships and Technology Innovation were established as part of CDRH's 2019 reorganization, which was completed on September 30, 2019.[15] This approach is consistent with the interpretation of similar statutory language in other parts of section 903 of FDARA that are addressed in other sections of this report. For CBER, ORA, and OC, the information in the table is broken down to the office level.

[15] See "Reorganization of the Center for Devices and Radiological Health" (https://www.fda.gov/about-fda/center-devices-and-radiological-health/reorganization-center-devices-and-radiological-health#changes).

In summary, FDA's MDUFA Process FTE funded by budget authority decreased from FY 2019 to FY 2020. This decrease was primarily due to adjustments in workload priorities during FY 2020 to address the COVID-19 pandemic.

MDUFA Program FTEs Funded by Budget Authority

Center & Office	Number of MDUFA Program FTEs Funded by Budget Authority**		Change in Number of MDUFA Program FTEs Funded by Budget Authority [C]
	FY 2019 [A]	FY 2020 [B]	
CDRH*			
OCD	7.7	5.6	-2.1
OPEQ			
OPEQ-OHT1	*52.1*	*34.1*	-18
OPEQ-OHT2	*64.9*	*59.1*	-5.8
OPEQ-OHT3	*56.9*	*42*	-14.9
OPEQ-OHT4	*41.8*	*11.6*	-30.2
OPEQ-OHT5	*38.3*	*31.2*	-7.1
OPEQ-OHT6	*36*	*33.5*	-2.5
*OPEQ-OHT7^*	*106.5*	*45.7*	-60.8
OPEQ-OCEA	*75.6*	*36.1*	-39.5
OPEQ-ORP	*32.3*	*16.6*	-15.7
OPEQ-IO	*26.7*	*9.6*	-17.1
OCE	54.9	27.9	-27
OM	47.6	31.7	-15.9
OP	9.9	4.5	-5.4
OSEL	65.4	14.2	-51.2
OST	30.8	20.7	-10.1
OIMT	4.2	2.5	-1.7
WCF	53.2	39.6	-13.6
CBER†			
OBE	3.5	3.4	-0.1
OBRR	51.4	43.5	-7.9
OCBQ	8.2	5.6	-2.6
OTAT	2.3	2.7	0.4
OVRR	0	0.2	0.2
OCOD	4.1	3.1	-1
OD	7.4	5.9	-1.5
OM	6.3	5.4	-0.9
OIMT	0.6	0.5	-0.1
WCF	6.2	5.5	-0.7
ORA‡			

Center & Office	Number of MDUFA Program FTEs Funded by Budget Authority**		Change in Number of MDUFA Program FTEs Funded by Budget Authority [C]
	FY 2019 [A]	FY 2020 [B]	
OMDRHO	28	27	-1
WCF	2.5	2.4	-0.1
OC§			
OC-IO	2.3	0	-2.3
OCC	17.7	15.1	-2.6
OCS	4	2.3	-1.7
OCPP	3.9	12.4	8.5
OEA	3.3	2.4	-0.9
OHI	0.9	0.8	-0.1
OO	7.6	8.1	0.5
OPLIA	14	10.4	-3.6
OSMP	19.8	0.1	-19.7
WCF	6.5	5.2	-1.3

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

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

This section addresses the requirement in section 738A(a)(1)(A)(iv)(II) of the FD&C Act, as added by section 903(b)(2) of FDARA, to provide "data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of devices, including identifying drivers of such changes." Accordingly, the table below provides data for the MDUFA fee revenue amounts and process costs for FY 2019 and FY 2020, and the changes in these amounts from FY 2019 to FY 2020. Relevant information about the data provided is as follows:

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

In summary, in FY 2020, FDA had net collections of $295 million in medical device user fees, which is an increase of $87 million compared to FY 2019. Excess collections in FY 2020 have been attributed to an increase in the number of new establishment registrations, which has led to the higher collection balance. FDA believes that the increase is due to the registration of new establishments with FDA that are engaged in the manufacture, preparation, propagation, compounding, or processing of COVID-19-related devices. FDA spent nearly $472 million in user fees and budget authority for the device review process, which is a decrease of about $12 million compared to FY 2019. This decrease was primarily due to COVID-19 pandemic-associated work that was not part of the process for the review of device applications. Detailed financial information for the MDUFA program can be found in the FY 2020 MDUFA Financial Report.

MDUFA Fee Revenues and Cost

Revenue/Cost	FY 2019 [A]	FY 2020 [B]	Change [C]
Fee Revenue Amounts (Net Collections) [1]	$208,098,889	$295,402,430	$87,303,541
Review Process Cost	$483,338,372	$471,643,425	-$11,694,947

[1] This includes unearned revenue.

Number of Employees for Whom Time Reporting Is Required

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

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

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

- The numbers in the table represent the number of employees that were required to report their time and the number of employees who were not required to report their time as of September 30, 2020.
- These data reflect time reporting across all employees in each entity, rather than only those engaged in MDUFA program activities.

FY 2020 Time Reporting Requirements

	Number of Employees	
Center	Time Reporting Required	Time Reporting Not Required
CDRH	1,896	15
CBER	1,119	8
ORA	3,106	1,682
OC	483	1,479
Total	6,604	3,184

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U.S. Food and Drug Administration

This report was prepared by FDA's Office of Planning, in collaboration with the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health. For information on obtaining additional copies, contact:

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