FY 2019

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 or the Agency) Fiscal Year (FY) 2019 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 five additional years (FY 2018 through FY 2022). This is the 17th report on medical device user fee review performance; FY 2019 is the second year of MDUFA IV.

Reauthorization of the medical device user fee program has helped to expedite the availability of innovative new products to 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 to reduce the total time it takes to make decisions on safe and effective medical devices.

FDA's performance continued to be strong in FY 2019. Preliminary performance data through September 30, 2019, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) all 21 of the review goals for which FDA received submissions in FY 2018, all 19 of the review goals for which FDA received submissions in FY 2019, and 11 of 13 of the performance enhancement goals due in FY 2019.

We believe the actions that FDA has taken under MDUFA IV had a positive impact on the device review process, such as 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.

Stephen M. Hahn
Commissioner of Food and Drugs

Acronyms

ASCA – Accreditation Scheme for Conformity Assessment

BLA – Biologics License Application

CBER – Center for Biologics Evaluation and Research

CDRH – Center for Devices and Radiological Health

CLIA – Clinical Laboratory Improvement Amendments

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

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

NESTcc – National Evaluation System for health Technology Coordinating Center

NSE – Not Substantially Equivalent

PDP – Product Development Protocol

PMA – Premarket Approval Application

RTA – Refuse to Accept

RWE – Real World Evidence

SaMD – Software as a Medical Device

SiMD – Software in a Medical Device

SE – Substantially Equivalent

SI – Substantive Interaction

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 (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 2019 MDUFA IV goals and updated data on FDA's success in meeting FY 2018 MDUFA IV goals.

This report also addresses additional performance data (including for MDUFA IV performance enhancement goals) required per the Consolidated Appropriations Act, 2017 (Public Law 115-31) and FDARA.

All data presented in this report are as of September 30, 2019.

Preliminary FY 2019 Performance

Review Goals

FDA has 25 MDUFA IV review goals: 23 review goals with specific target percentages and 2 shared outcome goals. FDA received submissions in 19 of the 25 review goals in FY 2019 (i.e., 17 review goals with specific target percentages and two shared outcome goals). Of these 19 review goals, as of September 30, 2019, two have a submission cohort that is sufficiently complete to determine the outcome. Preliminary data, including completed and pending reviews, indicate that FDA has met or has the potential to meet all 19 of the review goals for which FDA received submissions in FY 2019.

Performance Enhancement Goals

FDA had 12 performance enhancement goals with required completion dates in FY 2019. As of September 30, 2019, FDA has completed 11 of these 12 goals, 10 of which were completed on time.

Updated FY 2018 Performance

Review Goals

FDA received submissions in 21 of the 25 review goals in FY 2018 (i.e., 19 review goals with specific target percentages and two shared outcome goals). As of September 30, 2019, the FY 2018 cohorts for 18 of 21 review goals for which FDA received submissions are sufficiently complete to determine the outcome. For all 18 of these goals, the goal was met, and FDA continues to have the potential to meet the three remaining review goals for which the submission cohort is not yet sufficiently complete to determine the outcome.

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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 five 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 registration. 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 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 purposes of 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 review goal performance includes reviews of submissions pending from previous fiscal years and submissions received during the current fiscal year. This report presents preliminary review goal performance for FY 2019 MDUFA IV cohort submissions. This report also includes updated review goal performance information for FY 2018 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, 2019.
- Unless otherwise noted, review goal performance is based on FDA's combined performance on MDUFA submissions reviewed in the Center for Devices and Radiological Health (CDRH) and/or the Center for Biologics Evaluation and Research (CBER), depending on submission type. This is different from MDUFA Quarterly Performance Reports located on FDA's website,[3] where performance is reported separately for each Center. Details of which Center reviews each submission type are outlined in Appendix B of this report.
- With the exception of shared outcome and the Pre-Submission written feedback

[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.

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 was 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 B of this report.

- The Original Premarket Approval Applications (PMAs), Product Development Protocols (PDPs), Panel-Track PMA Supplements, and Premarket Reports performance section includes PMAs that are 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, all references to “FDA days” are those calendar days when a submission is under review by FDA. FDA days begin on the 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 in 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 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 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 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 2019 submissions is shown as the percentage of submissions completed within goal as of September 30, 2019, excluding any 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 Third Party 510(k)s. Information on CDRH 510(k) review goal performance without Third Party 510(k)s can be found in the MDUFA IV Quarterly Performance Reports located on FDA's website.[4]

MDUFA Performance Enhancement Goals

For purposes of 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 2019 performance enhancement goals is located in Appendices E and F 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 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), requests for information about classification under section 513(g), and postmarket device surveillance plan

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

submissions under section 522 (also known as a “section 522 plan”). This data are contained in Appendix C 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) and specified analyses of the use of funds (section 904) in the annual performance reports of each of the human medical product user fee programs, beginning in FY 2018. FDARA also requires FDA to publicly issue a corrective action report that either confirms that the Agency’s commitment letter goals were met and make recommendations for improvements or to identify which commitment letter goals were not met in MDUFA IV for the applicable fiscal year (section 904). This information is contained in Appendices 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.

- **PDP** - The PDP allows a sponsor to come to 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 a sponsor 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 generally 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 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 typically 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 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. 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 in intended use and technological characteristics to a legally marketed predicate device that is not subject to the PMA review process. Submitters must compare their proposed device to one or more similar legally marketed devices and support their substantial equivalency claims.

- **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** – An application providing data to demonstrate that a laboratory test is so simple and accurate as to render the likelihood of erroneous results by the user negligible.

- **Dual 510(k) and CLIA Waiver by Application** – Either (1) a single premarket submission to demonstrate that a laboratory test is substantially equivalent to a legally marketed device that is not subject to the PMA review process and is as simple and accurate as to render the likelihood of erroneous results by the user negligible or (2) a single premarket submission meeting both the definitions of a "premarket notification (510(k))" and a "CLIA waiver by application."

- **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 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 marketing approval for a biological product. A "priority BLA" is a product that would, if approved, involve a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. A "non-priority BLA" is considered a "standard BLA."

- **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 approval is required prior to product distribution. A supplement to an approved application proposing to make one or more changes to a product, its manufacturing, or its labeling that necessitates the submission of data from significant clinical studies is considered an "Efficacy Supplement."

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

BLAs:
www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber

PMAs:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm

510(k)s:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

MDUFA IV Review-Time Goals and Commitments

For purposes of 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 in 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 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 18	FY 19	FY 20	FY 21	FY 22
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%
510(k) Premarket Notifications						

Submission Type	Review-Time Goal	Commitment Target				
		FY 18	FY 19	FY 20	FY 21	FY 22
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.

Review-Time Goals and Commitment Targets (continued)

Submission Type	Review-Time Goal	Commitment Target				
		FY 18	FY 19	FY 20	FY 21	FY 22
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 shared outcomes agreed to in MDUFA IV for relevant submission types and for each year from FY 2018 through FY 2022. Shared outcome goals represent a commitment by both FDA and applicants and are reported as the average total time to decision (TTD) within a closed cohort and based on the methodology prescribed in the MDUFA IV commitment letter.

MDUFA IV Shared Outcome Goals

Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22
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 purposes of 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 and FY 2019.

Each fiscal year, FDA has 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 2019, FDA received submissions in 19 of the 25 review goals. Preliminary data indicate that FDA has met, or has 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 21 of the 25 review goals. Updated data indicate that FDA has met, and continues to have the potential to meet, all 21 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.[5]

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, 2019, that met the MDUFA goal.
- *Completed Overdue [C]* = the number of submissions with a MDUFA action as of September 30, 2019, that did not meet the MDUFA goal.
- *Pending Within Goal [D]* = the number of submissions without a MDUFA action that are still within the goal as of September 30, 2019.

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

- *Pending Overdue [E]* = the number of submissions without a MDUFA action that are past the goal as of September 30, 2019.
- *Review Goal [F]* = the target percentage of the relevant fiscal year MDUFA Cohort submissions that are required to meet the review-time goal (also referred to as "Commitment Target" in the previous section of this report).
- *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]).
- *Highest Possible Review Goal Performance [H]* = the scenario where 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 [G] = ([B] + [D]) / [A].

FY 2019 Preliminary Performance Data

In FY 2019, FDA received at least one submission for 17 of the 23 review goals with specific target percentages but did not receive any submissions for six of them. Of the 17 goals for which FDA received at least one submission, 16 have MDUFA Cohorts with at least one "Completed" submission and for which both a "Current Review Goal Performance" and "Highest Possible Review Goal Performance" can be calculated. "Current Review Performance" cannot be calculated for the remaining one goal for which FDA received at least one submission because the MDUFA Cohorts have only "Pending" (and no "Completed") submissions.

In 2 of the 17 review goals with specific target percentages for which FDA received at least one submission, the FY 2019 cohorts are sufficiently complete to determine the performance outcome. These goals (and the final performance) are shown in **bold** text in the table below. For both of these goals (i.e., BLA Manufacturing Supplements Requiring Prior Approval and Class 1 Original BLA and BLA Efficacy Supplement Resubmissions), the goal was met.

FY 2019 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	49	41	0	8	0	95%	100%	100%
Decision with No Advisory Committee Input	49	17	0	32	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
180-Day PMA Supplements								
Substantive Interaction	203	149	2	52	0	95%	99%	99%
Decision	203	88	2	111	2	95%	96%	98%
Real-Time PMA Supplements								
Decision	371	287	0	84	0	95%	100%	100%
De Novo Classification Requests								
Decision	62	25	0	37	0	50%	100%	100%
510(k) Premarket Notifications								
Substantive Interaction†	3,060	2,609	45	405	1	95%	98%	98%
Decision	3,003	1,747	6	1,246	4	95%	99%	100%
CLIA Waiver by Applications								
Substantive Interaction	8	5	0	3	0	90%	100%	100%
Decision with No Advisory Committee Input	8	4	0	4	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	5	4	0	1	0	90%	100%	100%
Decision with No Advisory Committee Input	5	0	0	5	0	90%	N/A	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,527	2,394	133	N/A	N/A	1,530	N/A	N/A

* 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.

FY 2019 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]
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	4	1	0	3	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	49	46	1	2	0	90%	98%	98%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	2	1	0	1	0	90%	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	17	17	0	0	0	90%	100%	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.

FY 2018 Updated Performance Data

In FY 2018, FDA received at least one submission for 19 of the 23 review goals with specific target percentages and did not receive any submissions for four of them. As of September 30, 2019, the FY 2018 cohorts for 18 of 19 review goals with specific target percentages for which FDA received at least one submission are sufficiently complete to determine the outcome. These goals (as well as the final "Current Review Goal Performance") are shown in **bold** text in the table below. For all 18 of these goals, the outcome goal was met, and FDA continues to have the potential to meet the one remaining goal (Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports – Decision with No Advisory Committee Input) for which the cohort is not sufficiently complete.

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								
Substantive Interaction	72	70	1	1	0	95%	99%	99%
Decision with No Advisory Committee Input	68	59	0	9	0	90%	100%	100%
Decision with Advisory Committee Input	4	4	0	0	0	90%	100%	100%
180-Day PMA Supplements								
Substantive Interaction	196	193	3	0	0	95%	98%	98%
Decision	195	186	0	6	3	95%	100%	98%
Real-Time PMA Supplements								
Decision	339	339	0	0	0	95%	100%	100%
De Novo Classification Requests								
Decision	56	44	11	1	0	50%	80%	80%
510(k) Premarket Notifications								
Substantive Interaction†	3,299	3,235	60	4	0	95%	98%	98%
Decision	3,043	2,969	29	44	1	95%	99%	99%
CLIA Waiver by Applications								
Substantive Interaction	4	4	0	0	0	90%	100%	100%
Decision with No Advisory Committee Input	4	4	0	0	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Dual 510(k) and CLIA Waiver by Applications								
Substantive Interaction	11	11	0	0	0	90%	100%	100%
Decision with No Advisory Committee Input	11	11	0	0	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,664	2,507	157	N/A	N/A	1,530	N/A	N/A

* No submissions were received in FY 2018; 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.

FY 2018 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]
BLAs								
Priority Original BLAs	0	0	0	0	0	90%	*	*
Standard Original BLAs	14	14	0	0	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	94	94	0	0	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	8	8	0	0	0	90%	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	0	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	7	7	0	0	0	90%	100%	100%

* No submissions were received in FY 2018; therefore, no performance can be reported.

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 and 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, 2019, neither the 510(k) nor the PMA cohorts for FY 2018 or FY 2019 have met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2018 and FY 2019 in future reports once the cohorts have met the decision threshold.

MDUFA IV Shared Outcome Goals

Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22
Original PMAs and Panel-Track PMA Supplements					
TTD Goal (Days)	320	315	310	300	290
Current Performance (Days)	*	*			
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
Current Performance (Days)	*	*			

* As of September 30, 2019, fiscal year cohort has not met the decision threshold to calculate performance.

MDUFA Review Workloads: FY 2015 Through FY 2019

The table below compares review workloads for submission types with MDUFA review goals for a five-year period (FY 2015 through FY 2019).

- 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 B.
- Five-year averages and comparisons are calculated only for submission types that had MDUFA review goals in the entire five-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.

Review workload in FY 2019 was calculated for 13 of the 15 workload categories where data was available to calculate a five-year average. The other two submission types were new to MDUFA IV and do not have the five-year historical data. Three of the 13 submission types did not receive any workload for FY 2019. Therefore, two are showing a 100 percent change from FY 2019 as compared to the five-year average and the third is not applicable. However, for the two submission types with a five-year average workload, Priority Original BLAs and Class II Original BLA and BLA Efficiency Supplement Resubmissions, the change was from one to zero and from 18 to zero, respectively. Priority BLA Efficacy Supplements did not have any workload over the five-year period. In comparison, submission types with noted increased workloads include Class 1 Original BLA and BLA Efficacy Supplement Resubmissions.

Review Workload* by Submission Type

Submission Type	FY 15	FY 16	FY 17	FY 18	FY 19	5-Year Average (FY 15 to FY 19)	FY 19 Compared to 5-Year Average
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	75	74	70	78	59	71	-16.9%
180-Day PMA Supplements	203	210	276	199	203	218	-6.9%
Real-Time PMA Supplements	340	329	338	341	379	345	9.9%
510(k) Premarket Notifications	3,781	3,677	4,098	3,591	3,774	3,784	-0.3%
De Novo Classification Requests†	N/A	N/A	N/A	56	62	N/A	N/A
CLIA Waiver by Applications	11	9	7	4	9	8	12.5%
Dual 510(k) and CLIA Waiver by Applications	3	1	6	11	6	5	20.0%
Pre-Submissions†	n/a	n/a	n/a	2,783	3,254	N/A	N/A
BLAs							
Priority Original BLAs	2	1	1	0	0	1	-100.0%
Standard Original BLAs	2	26	5	14	4	10	-60.0%
BLA Manufacturing Supplements Requiring Prior Approval	19	47	38	94	49	49	0.0%
Priority BLA Efficacy Supplements‡	0	0	0	0	0	0	N/A
Standard BLA Efficacy Supplements	1	1	1	8	2	3	-33.3%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	2	1	1	17	4	325.0%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	16	28	40	7	0	18	-100.0%

* Because of the change in the definition of “workload,” these numbers are slightly different from what was presented in reports from FY 17 or earlier.
† Because of the lack of MDUFA review goals in some years, no 5-year average is available.
‡ Because of zero submissions over the 5-year period, a percent change could not be computed.

Appendices

Appendix A: MDUFA III Performance Update

Summary of MDUFA III Performance

We believe the actions that FDA established under MDUFA III had a positive impact on the device review process, such as establishing a structured pre-submission program and submission acceptance criteria. These completed actions, along with our achievements in meeting MDUFA III review goals, 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.

Details on the 23 review goals (i.e., 21 review goals with specific target percentages and two shared outcome goals) agreed to for each of the five fiscal years in MDUFA III are provided in performance reports from previous fiscal years, as is FDA's final performance on the goals with specific target percentages. Details on FDA's final MDUFA III performance on the two shared outcome goals are below. In summary, FDA met 82 out of 83 review goals with specific target percentages for which FDA received submissions across all five years (i.e., FY 2013 through FY 2017) of the MDUFA III commitment. FDA had 22 review goals with specific target percentage that did not receive a submission in total for the same five years of the MDUFA III commitment. FDA also met seven of the 10 shared outcome goals.

Updated Shared Outcome Goal Performance (FY 2013 through FY 2017)

FDA had two shared outcome goals each fiscal year in MDUFA III, 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 and based on the methodology prescribed in the MDUFA III 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. Performance for submission types that are meeting or exceeding the goal as of September 30, 2019, is shown in **bold** text.

As of September 30, 2019, the 510(k) and PMA cohorts for all five years (i.e., FY 2013 through FY 2017) have met the decision threshold to calculate the average TTD and are listed below. FDA did not meet the shared outcome goal for 510(k)s in FY 2015, FY 2016, and FY 2017 but met the PMA and other 510(k) shared outcome goals. The 510(k) goal was missed by one day in FY 2015, eight days in FY 2016, and eight days in FY 2017.

MDUFA III Shared Outcome Goals

Submission Type	FY 13	FY 14	FY 15	FY 16	FY 17
Original PMAs and Panel-Track Supplements					
TTD Goal (Days)	395	395	390	390	385
Current Performance (Days)	**314**	**300**	**293**	**266**	**267**
510(k)					
TTD Goal (Days)	135	135	130	130	124
Current Performance (Days)	**124**	**125**	131	138	132

Appendix B: 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 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 those calendar days when a submission is considered to be under review at the Agency for submissions that have been accepted (510(k) or De Novo classification request) or filed (PMA) or submitted (CLIA Waiver by application). FDA Days begin on the 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
Real-Time PMA Supplements	• Approval • Approvable

Submission Type	MDUFA Decisions
	• 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 feedback prior to an intended submission of an IDE or marketing application. The request must 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. The following forms of FDA feedback to applicants 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 policy or procedures

- Meetings or teleconferences that are intended to be informational only, including, but not limited to, those intended to educate the review team on new device(s) with significant differences in technology from currently available devices or to update FDA about ongoing or future product development without a request for FDA feedback on specific questions related to a planned submission
- Requests for clarification on technical guidance documents, especially when contact is recommended by FDA in the guidance document. However, the following requests will generally need to be submitted as a Pre-Submission to ensure appropriate input from multiple reviewers and management: recommendations for device types not specifically addressed in the guidance document; recommendations for nonclinical or clinical studies not addressed in the guidance document; and requests to use 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 submission of a marketing application, but prior to FDA reaching a decision).

F. Review Workload: 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
Dual 510(k) and CLIA Waiver by Applications	eCopy, User Fee
Pre-Submissions	eCopy

Submission Type	Applicable Administrative Requirements
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 C: 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 the FDA to provide performance information related to medical devices including the extent to which the Agency's responses meet 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 to 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 include those that passed eCopy requirements (FY15 through FY17) or passed eCopy and user fee requirements (FY18). The number of 513(g) submissions received are those that passed user fee requirements.

FDA reports that between FY 2015 and FY 2019, 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 100 percent of the time.

Performance Data for Submissions with Statutory Timeframes

Submission Type	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
De Novo Classification Requests Under 513(f)(2)					
Number received that passed applicable administrative requirements	60	54	101	56	62
Number completed with a Granted, Declined or Withdrawn decision	60	53	101	55	25
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory timeframe of 120 days*	26	32	60	17	14
Percent that met the statutory timeframe†	43%	60%	59%	31%	56%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)					
Number received that passed applicable administrative requirements	104	109	133	115	132
Number to which FDA responded within the statutory timeframe of 60 days	30	36	37	41	34
Percent that met the statutory timeframe‡	29%	33%	28%	36%	26%
Postmarket Surveillance Plans					
Number received	40	43	14	13	11
Number of FDA responses within 60 days of receipt	16	22	11	5	6
Percent that met the statutory timeframe	40%	51%	79%	38%	55%

* 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.

‡ This data is 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 decision for longer than 60 FDA days as of the cutoff date.

Appendix D: Additional Information from FDARA 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. FDARA requires "additional information" in the annual performance reports of each of the human medical product user fee programs (section 903). 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[6] 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 FY 2018 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 received a MDUFA decision or are pending a MDUFA decision as of September 30, 2018. 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 received a MDUFA decision or are pending a MDUFA decision as of September 30, 2019. This definition is consistent with the

[6] 515C in original. The expedited development and priority review provisions appear in section 515B of the FD&C Act; there is no 515C.

interpretation of identical statutory language in section 904 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.
- As stipulated in FDARA, the numbers below include only submissions reviewed by CDRH and do not include submissions reviewed by CBER. This is different from other parts of this report, where the MDUFA Cohort includes submissions from both CDRH and CBER.

FY 2019 MDUFA Cohorts by CDRH Division

		MDUFA Cohort by CDRH Division											
		ODE							OIR				
Submission Type	**MDUFA Cohort (CDRH only)**	DAGRID	DCD	DNPMD	DOD	DOED	DRGUD	DSD	DCTD	DIHD	DMD	DMGP	DRH
Original PMA, PDP, Panel-Track PMA Supplements, and Premarket Reports													
Substantive Interaction	47	1	11	5	3	6	3	1	2	0	7	8	0
Decision with No Advisory Committee Input	47	1	11	5	3	6	3	1	2	0	7	8	0
Decision with Advisory Committee Input	0	0	0	0	0	0	0	0	0	0	0	0	0
180-Day PMA Supplements													
Substantive Interaction	146	7	64	13	5	19	7	8	4	1	4	11	3
Decision	87	4	39	7	4	13	1	5	4	1	0	8	1
Real-Time PMA Supplements													
Decision	285	10	138	26	14	23	20	14	11	11	12	6	0
510(k) Premarket Notifications													
Substantive Interaction	3,015	555	337	206	573	108	283	356	102	48	94	9	344
Decision	2,959	559	331	200	552	107	275	341	95	46	92	10	351

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 number(s) provided below is as follows:

- The number of breakthrough device designations represents the number of designation requests granted by September 30, 2019, 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.

Cohort*	Number of Breakthrough Device Designations
FY 2018	55
FY 2019	*106
FY 2020	†
FY 2021	†
FY 2022	†

*As of 9/30/2019, the FY 2019 cohort is 76% closed.
† As of 9/30/2019, the fiscal year has not yet begun but will be included in future reports.

Appendix E: 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. The analyses are to include information such as differences between aggregate numbers of submissions and certain types of decisions, analysis of performance goals, a determination of causes affecting the ability to meet goals, and requires the issuance of corrective action reports (§ 904). 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 difference between aggregate numbers of submissions and certain types of decisions, (II) the 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 the 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. More specifically, the table addresses the requirements of section 738A(a)(1)(A)(v)(I) of the FD&C Act as added by section 904(b)(1) of FDARA, in the following way:

- *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 received a MDUFA decision or are pending a MDUFA decision as of September 30, 2019. "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 received a MDUFA decision or are pending a MDUFA decision as of September 30, 2019. 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, 2019. 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 met the MDUFA goal.
- *Completed Overdue [D]* = the number of Completed [B] submissions that did not meet the MDUFA goal.
- *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 a Completed [B] submission had this specific decision (or equivalent) for each MDUFA goal. Specific decisions (or equivalent decisions) relevant to each MDUFA goal and submission type are as follows:

Submission Type	Relevant MDUFA Decision(s)
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 (NSE)

- *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 have met the goal as of September 30, 2019.
- *Pending Overdue [H]* = the number of Pending [F] submissions that have not met the goal as of September 30, 2019.
- *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 did not meet the MDUFA goal as of September 30, 2019. Overdue [I] includes both Completed Overdue [D] and Pending Overdue [H] submissions ([I] = [D] + [H]).

FY 2019 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	49	41	41	0	30	**8**	**8**	**0**	0
Decision with No Advisory Committee Input	49	17	17	0	4	**32**	**32**	**0**	0
Decision with Advisory Committee Input	0	0	0	0	*0*	**0**	**0**	**0**	0
180-Day PMA Supplements									
Substantive Interaction	203	151	149	2	71	52	52	0	2
Decision	203	90	88	2	1	113	111	2	4
Real-Time PMA Supplements									
Decision	371	287	287	0	25	84	84	0	0
510(k)									
Substantive Interaction*	3,060	2654	2,609	45	1,665	406	405	1	46
Decision*	3,003	1753	1,747	6	28	1,250	1,246	4	10

* 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 purposes of this report, "performance enhancement goals" are defined as any non-review goal described in MDUFA 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 12 performance enhancement goals with required completion dates in FY 2019. 11 of 12 goals have been completed, 10 of which were completed on time.

FY 2019 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.	9/30/2019	Y	9/30/2019	Internal audits were executed by CDRH's Quality Management Program at the Office of the Center Director, which is ISO 9001:2015 certified for the provision of quality manangement and organizational excellence tools and services. FDA and industry communicated about areas of interest for its ongoing audit plan in Q1 and Q2 of FY 2019. FDA incorporated this feedback, along with other information, to identify areas to audit and executed the following audits in FY 2019: • Use of Four-Part Harmony in deficiency letters. Results: Opportunities for improvement were identified and communicated. An additional audit is planned for FY2021 as part of Phase 2 of the "Independent Assessment of Review Process Management" (a separate FY 2021 Performance Enhancement Goal) • Five 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.
Program and Process Implementation‡				
Pre-Submissions – No later than 12 months after the close of the public comment period of the draft guidance titled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff," the Agency will issue a final guidance.	8/6/2019*	Y	5/7/2019	FDA published a final guidance titled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" on 5/7/2019 (https://www.fda.gov/media/114034/download).
Pre-Submissions – FDA will implement this guidance once final.	8/6/2019*	Y	5/7/2019	FDA published the final guidance on 5/7/2019. Additionally, FDA conducted staff training on 6/10/2019 and a public webinar with external stakeholders on 6/11/2019 (https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-q-submission-program-medical-device-submissions-june-11-2019-06112019-06112019).
Enhanced Use of Consensus Standards – FDA will provide an annual report on the progress of the Accreditation Scheme for Conformity Assessment (ASCA) program.	1/31/2019 (for FY18 report)	N	9/30/2019	FDA published the FY2018 annual report on the progress of the ASCA program on 9/30/2019 (https://www.fda.gov/media/131266/download). See also Appendix F.
Enhanced Use of Consensus Standards – FDA will establish a process for the accreditation of Accrediting Bodies (ABs) and to accredit Test Laboratories (TLs). FDA will issue a draft guidance by the end of FY 2019.	9/30/2019	Y	9/23/2019	FDA published a draft guidance titled "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" on 9/23/2019 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Enhanced Use of Consensus Standards – FDA will establish a process for reaccreditation and the suspension or withdrawal of accreditation of poor performing ABs and TLs. FDA will issue a draft guidance by the end of FY 2019.	9/30/2019	Y	9/23/2019	FDA published a draft guidance titled "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" on 9/23/2019 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program).
Third Party Review – FDA will implement a plan for eliminating routine re-review by FDA of Third Party reviews within 12 months.	9/13/2019*	Y	9/13/2019	FDA has taken many actions in the last 12 months (from 9/13/2018 to 9/13/2019) to eliminate routine re-review by FDA of Third Party reviews. These actions are consistent with the plan posted on 9/13/2018 (see (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/UCM620308.pdf). Specifically, FDA has completed the following: Published draft guidance (on 9/2018; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program) Provided Third Party Reviewers with access to new and better resources, including: • Web-based training (first device-specific training on 10/2018; see https://www.fda.gov/training-and-continuing-education/cdrh-learn#collapseSeven) • Early Interaction process (published on www.FDA.gov on 7/2019; see https://www.fda.gov/medical-devices/510k-third-party-review-program/interacting-early-fda-during-510k-review) • Updated channel to keep Third Party Review organizations informed (quarterly email updates established 9/2019) • Redacted review memos (trained Third Parties on how to access this resource on 9/2019) Established an FDA Framework to help determine when re-review is not needed. (Initial framework was developed in consultation with Accenture Federal Services and is being tested on 9/2019.) Monitored and continuously improved the program based on quality and efficiency measures: • Efficiency measures established with performance metrics published quarterly on FDA.gov (10/2018, 1/2019, 4/2019, 7/2019; see https://www.fda.gov/about-fda/cdrh-transparency/third-party-performance-metrics) • Quality measures established and monitored (3/2019) • Program improvement tracking system • (5/2019)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Real World Evidence (RWE) – FDA will contract with an organization to serve as the NEST Coordinating Center (NESTcc) to facilitate use of RWE to support premarket activities. The contract will specify actions the Coordinating Center will take to advance the use of RWE, including: a. Establish a framework to fund pilot projects to determine the usability of RWE for: i. Expanded indications for use ii. New clearances/approvals iii. Improved malfunction reporting b. No later than October 1, 2020, the Coordinating Center will hold a public meeting to review and evaluate the progress and outcomes (as of the date of the public meeting) of the pilots described in (H)(1) above. c. The pilots will take place over a period of three years, including data analysis, and the Coordinating Center will issue a publicly available report of the results. d. The pilots will include devices not currently subject to a registry. e. At the conclusion of the pilots, an independent third-party will conduct an assessment to evaluate the strengths, limitations, and appropriate use of RWE for informing premarket decision-making for multiple device types.	9/30/2019	Y	12/15/2017	On 12/15/2017, FDA awarded a grant to the Medical Device Innovation Consortium to establish NESTcc. This grant specifies the actions the Coordinating Center will take (including those defined in parts a) through e) of the MDUFA commitment) to advance the use of RWE. As of September 30, 2019, NESTcc is on track to meet all objectives specified in the grant. Specifically, the NESTcc has established 20 Test-Cases to determine the usability of RWE for: 1) expanded indications for use, 2) new clearances/approvals, and 3) improved malfunction reporting. They are also supporting independent third-party assessments to evaluate the strengths, limitations, and appropriate use of RWE for informing premarket decision-making for multiple device types.
Digital Health – FDA will explore opportunities to establish premarket approval/clearance pathways tailored to Software as a Medical Device (SaMD), Software inside of medical devices (SiMD), and novel digital health technologies that take into account RWE while incorporating principles established through international harmonization. To accomplish this task, the Agency will:	*See below*	*See below*	*See below*	FDA is taking a holistic approach to meeting this commitment by clarifying FDA's Digital Health policy per the 21st Century Cures Act, piloting a Software Precertification (Pre-Cert) approach, and other initiatives. See parts a), b), and c) below for specific tasks FDA has completed since the start of MDUFA IV, as of September 30, 2019.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
a. Engage with stakeholders, including industry, through roundtables, informal meetings, and teleconferences	9/30/2022	Y	Multiple	*All Stakeholders*: FDA actively engaged with stakeholders on the Software Pre-Cert Program Pilot. Specifically, FDA publicly posted three discussion papers with open public comment periods: (1) "Developing a Software Precertification Program: A Working Model" (https://www.fda.gov/media/119722/download), (2) "Software Precertification Program: Regulatory Framework for Conducting the Pilot Program within Current Authorities" (https://www.fda.gov/media/119724/download) and (3) "Software Precertification Program: 2019 Test Plan" (https://www.fda.gov/media/119723/download). FDA incorporated public input on the Software Pre-Cert Program via two updates to the "Developing a Software Precertification Program: A Working Model" discussion paper (originally published 4/26/2018, updated 6/19/2018 and 1/7/2019), a public stakeholder call (6/27/2018) and a public webinar (2/7/2019), and engaged with stakeholders via numerous presentations and panel discussions at multiple professional conferences. FDA also actively engaged with stakeholders on the Artificial Intelligence/Machine Learning based devices, via a discussion paper (published 4/2/2019; https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device) and solicited input via public comment period. *Industry*: FDA engaged with industry on software guidance at MDUFA Quarterly Performance Report meetings (see https://www.fda.gov/media/128160/download and FDAhttps://www.fda.gov/media/129693/download). FDA also solicited test cases from software organizations to help test components of the Software Pre-Cert Program (see https://www.fda.gov/medical-devices/digital-health-software-precertification-pre-cert-program/digital-health-software-precertification-pre-cert-program-participate-2019-test-plan).
b. Hold a public workshop	9/30/2022	Y	1/30/2018	On January 30-31, 2018, FDA held a public workshop titled "Fostering Digital Health Innovation: Developing the Software Precertification Program" (https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-fostering-digital-health-innovation-developing-software-precertification-program).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
c. Revise existing and/or publish new relevant guidance documents, including publishing a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" guidance (issued in 2005) by the end of FY2019. The Agency will incorporate applicable concepts from its Guidance for "Off-The-Shelf Software Used in Medical Devices" (actually entitled, "Off-The-Shelf Software Use in Medical Devices").	9/30/2019	N	See Appendix F	FDA published six final and two draft guidances related to Digital Health since the start of MDUFA IV, as of September 30, 2019: 1. "Software as a Medical Device (SAMD): Clinical Evaluation" final guidance (published 12/8/2017; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/software-medical-device-samd-clinical-evaluation-guidance-industry-and-food-and-drug-administration) 2. "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" final guidance (published 9/26/2019; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act) 3. "Policy for Device Software Functions and Mobile Medical Applications" final guidance (published 9/26/2019; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications) 4. "General Wellness: Policy for Low Risk Devices" final guidance (published 9/26/2019; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices) 5. "Off-The-Shelf Software Use in Medical Devices" final guidance (published 9/26/2019; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices) 6. "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communciations Devices" final guidance (published 9/26/2019; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices) 7. "Clinical and Patient Decision Support Software" draft guidance (published 12/8/2017 and 9/26/19; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-and-patient-decision-support-software) 8. "Multiple Function Device Products: Policy and Considerations" draft guidance (published 4/27/2018; see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations) FDA met the sub-part goal of the goal to "revise existing and/or publish new relevant guidance documents" by publishing eight documents by the end of FY 2019. FDA has and will

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
				continue to incorporate the public comments provided on these documents (as well as those from the discussion papers and public meeting cited in (a) and (b) above) into the content of other relevant draft and final guidance documents. For actions related to the other sub-part of the goal (to publish a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," see Appendix F below.
Program and Process Assessments§				
Independent Assessment of Review Process Management (Phase 1) – The contractor will evaluate the implementation of MDUFA III recommendations and publish a written assessment within 1 year of contract award.	12/31/2018*	Y	12/20/2018	For Phase 1 of the Independent Assessment, the contractor evaluated the implementation of MDUFA III recommendations and issued a final report titled "Medical Device User Fee Amendments IV Independent Assessment of Food and Drug Administration's Device Review Process Management" on December 20, 2018 (https://www.fda.gov/media/119435/download). Overall, no significant issues were identified.

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

Also of note, one performance enhancement goal with a required completion date in FY 2018 was inadvertently left out of last year's report. This goal was completed more than six months before the target goal date and is summarized below. That means FDA had 12 performance enhancement goals with required completion dates in FY 2018 (not 11 as previously reported), 11 of which (not 10, as previously reported) were completed on time.

FY 2018 Performance Enhancement Goals (Addendum)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Digital Health – FDA will publish a final guidance addressing when to submit a 510(k) for a software modification to an existing device within 18 months of the close of the comment period.	5/7/2018*	Y	10/25/2017	FDA issued a final guidance titled "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" on October 25, 2017 (https://www.fda.gov/media/99785/download).

* "Target goal date" is not explicitly defined in the MDUFA commitment letter but is implied based on another commitment happening first.

Common Causes and Trends Impacting 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, 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 2019 Goals

In total, FDA had 37 MDUFA goals in FY 2019: 25 review goals and 12 performance enhancement goals. In FY 2019, FDA received submissions in 19 of the 25 review goals. As indicated in other sections of this report, FDA has met two of the 19 review goals for which FDA received submissions in FY 2019, but 17 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 17 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 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 received submissions in 21 of the 25 review goals. As indicated in other sections of this report, FDA has met 18 of the 21 review goals for which FDA received submissions in FY 2018, but three have not reached sufficient closure to determine the outcome. 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 and three goals still pending (of 37 MDUFA goals for FY 2018), 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 2018 review goal cohorts are sufficiently closed and data indicate FDA has missed additional FY 2018 goals, FDA will provide the required information in future reports.

Cause or Trend	Impact 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.*

Appendix F: FY 2019 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 drugs, biologics, medical devices, and biosimilar biological products, and for other purposes. Among the provisions of Title IX, section 904 of FDARA requires FDA to publicly issue a corrective action report that details FDA's progress in meeting the review and performance enhancement goals identified in MDUFA IV for the applicable fiscal year.

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

If the Secretary determines, based on the analysis presented in the MDUFA annual report, that any review or performance enhancement goals for the applicable fiscal year were not met, the corrective action report shall include a justification, as applicable, for the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year. Such a description of corrective efforts is not required by statute for review time goals, but FDA is providing this information regardless in an effort to be complete. For review time goals (but not performance goals), the corrective action report shall also include a description of the types of circumstances, in the aggregate, under which submissions 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 2019 Review Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Review Goals	FDA received submissions for 19 review goals in FY 2019 and has met two review goals for which the submission cohort is sufficiently complete to determine the outcome. Based on preliminary data, FDA has the potential to meet all 17 of the remaining FY 2019 review goals for which FDA received submissions. However, with submissions still pending, it's too soon to determine final performance for the full FY 2019 cohort of review goals. As of September 30, 2019, no submissions missed review time goals but were approved during the first cycle review.	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 Date	Corrective Action Plan
Review Goals	FDA received submissions for 21 review goals in FY 2018 and has met all 18 review goals for which the submission cohort is sufficiently complete to determine the outcome. Based on preliminary data, FDA has the potential to meet all three of the remaining FY 2018 review goals for which FDA received submissions. However, with submissions still pending, it's too soon to determine final performance for the full FY 2018 cohort of review goals. As of September 30, 2019, no submissions missed review time goals but were approved during the first cycle review.	FDA will provide corrective actions for any missed FY 2018 review goals in subsequent corrective action reports.

FY 2019 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Program and Process Implementation	*Enhanced Use of Consensus Standards:* As part of its MDUFA goals, FDA commited to "establish an [ASCA Pilot] Program using FDA-recognized consensus standards." To meet this general goal, a number of technical issues required resolution before ASCA-associated documents could be published, including the FY 2018 annual report. Achieving resolution of these issues took longer than expected, causing a delay in the issuance of the FY 2018 annual report. *Digital Health:* The regulatory landscape surrounding SaMD, SiMD, and novel digital health technologies is unique and continuously evolving. As part of its MDUFA goals, FDA commited to publishing "relevant guidance documents" on this topic and did so eight times—the most recent of which were published on 9/26/2019. These final and draft guidances will provide necessary support to the draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."	*Enhanced Use of Consensus Standards:* FDA conducted a root cause analysis and concluded that the significant work that went into the development of the ASCA pilot and a delay in achieving resolution of technical issues were the main contributors to the delay in the issuance of the report. These issues have been resolved, and FDA is on track to provide the FY 2019 annual report on time. *Digital Health:* FDA conducted a root cause analysis and concluded that FDA met the goal to "revise existing and/or publish new relevant guidance documents" by publishing eight documents by FY 2019 and that no corrective action is needed for that sub-part of the goal. With respect to the sub-part of the goal related to publishing a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," FDA determined that issuance of the other guidances was a necessary prerequisite to issuing this guidance. With the other guidances now issued, no corrective actions are necessary as FDA is currently working on revising the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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 under which applications missed review time goals but were approved during the first cycle review, as applicable.

This section includes all MDUFA review goals as it pertains to submissions in the FY 2019 and FY 2018 cohorts.

FY 2019 Review Goal Performance

A. Summary of Performance:

FDA has not yet missed any FY 2019 review goals. In FY 2019, FDA received submissions in 19 of the 25 review goals and met two 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 indicate FDA has the potential to meet the remaining 17 review goals for which FDA received submissions in FY 2019, with submissions still pending, it's 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 updated information in future reports on any missed goals.

B. Justification:

Too soon to determine if a justification is needed.

C. FY 2020 Corrective Actions:

Too soon to determine if a corrective action is needed.

FY 2018 Review Goal Performance (Updated)

A. Summary of Performance:

FDA has not yet missed any FY 2018 review goals. In FY 2018, FDA received submissions in 21 of the 25 review goals and has met 18 of those 21 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 indicate FDA has the potential to meet the remaining three review goals for which FDA received submissions in FY 2018, with submissions still pending, it's too soon to determine final performance for the full FY 2018 cohort of review goals. If, at the end of future fiscal years, the FY 2018 cohorts are sufficiently complete to determine the outcome, FDA will provide information in future reports on any missed goals.

B. Justification:

Too soon to determine if a justification is needed.

C. FY 2019 Corrective Actions:

Too soon to determine if a corrective action is needed.

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 2019 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 commitment letter. Performance enhancement goals with specified completion dates in FY 2020 through FY 2022 will be covered in subsequent corrective action reports.

FDA had 12 performance enhancement goals with required completion dates in FY 2019. In FY 2019, FDA completed 11 of these 12 goals, 10 of which were completed on time. Details on the two goals that require justification and corrective action are provided below.

Program and Process Implementation

A. Summary of Performance:

(1) *Enhanced Use of Consensus Standards*: The FY 2018 annual report on the progress of the ASCA Pilot program was due on 1/31/2019. It was published on 9/30/2019 (see https://www.fda.gov/media/131266/download).

(2) *Digital Health*: FDA met the general goal to "revise existing and/or publish new relevant guidance documents…by the end of FY 2019" relevant to SaMD, SiMD, and novel digital health technologies by publishing eight guidance documents (six final and two draft). However, these documents did not include a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," which was due on 9/30/2019.

B. Justification:

(1) *Enhanced Use of Consensus Standards:* As part of its MDUFA goals, FDA commited to "establish an [ASCA Pilot] Program using FDA-recognized consensus standards." To meet this general goal, a number of technical issues required resolution before ASCA-associated documents could be published, including the FY 2018 annual report. Achieving resolution of these issues took longer than expected, causing a delay in the issuance of the FY 2018 annual report.

(2) *Digital Health*: The regulatory landscape surrounding SaMD, SiMD, and novel digital health technologies is unique and continuously evolving. As part of its MDUFA goals, FDA commited to publishing "relevant guidance documents" on this topic and did so eight times—the most recent of which were published on 9/26/2019. These final and draft guidances will provide necessary support to the draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

C. FY 2019 Corrective Actions:

(1) *Enhanced Use of Consensus Standards:* FDA conducted a root cause analysis and concluded that the significant work that went into the development of the ASCA pilot and a delay in achieving resolution of technical issues were the main contributors to the delay in the issuance of the report. These issues have been resolved, and FDA is on track to provide the FY 2019 annual report on time.

(2) *Digital Health*: FDA conducted a root cause analysis and concluded that FDA met the goal to "revise existing and/or publish new relevant guidance documents" by publishing eight documents by the end of FY 2019 and that no corrective action is needed for that sub-part of the goal. With respect to the sub-part of the goal related to publishing a draft revised version of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" FDA determined that issuance of the other guidances was a necessary prerequisite to issuing this guidance. With the other guidances now issued, no corrective actions are necessary as FDA is currently working on revising the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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

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