FY 2018

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee Amendments

Acting Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA or the Agency) Fiscal Year (FY) 2018 Performance Report to Congress for the Medical Device User Fee Amendments of 2017 (MDUFA IV). The enactment of the fourth authorization of MDUFA in 2017 (MDUFA IV) reauthorized medical device user fees for 5 additional years (FY 2018 through FY 2022). This is the sixteenth report on medical device user fee review performance, and the first report to reflect the more challenging goals set under MDUFA IV. FY 2018 is the first 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 during FY 2018. Preliminary performance data through September 30, 2018, 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 and 10 of 11 of the performance enhancement goals due in FY 2018.

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* submissions, 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.

Norman E. Sharpless, M.D.
Acting Commissioner of Food and Drugs

Acronyms

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 Practices

IDE – Investigational Device Exemption

IMDRF – International Medical Device Regulators Forum

IR – Interactive Review

MDUFA – Medical Device User Fee Amendments

NSE – Not Substantially Equivalent

PDP – Product Development Protocol

PMA – Premarket Approval Application

RCP – Reviewer Certification Program

RTA – Refuse to Accept

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 amends 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. This 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 meeting FY 2018 review goals under MDUFA IV and updated performance data on FY 2016 and FY 2017 review goals from MDUFA III.

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 (Public Law 115-52), both of which were signed into law in 2017.

All data presented in this report was current as of September 30, 2018.

FY 2018 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 21 of the 25 review goals in FY 2018 (19 review goals with specific target percentages and 2 shared outcome goals). Of these, as of September 30, 2018, 4 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 21 of the review goals for which FDA received submissions in FY 2018.

Performance Enhancement Goals

FDA had 11 performance enhancement goals with required completion dates in FY 2018. As of September 30, 2018, FDA has completed all 11 of these goals, 10 of which were completed on time.

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Introduction

On August 18, 2017, the President signed into law the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which included the reauthorization and expansion of the Medical Device User Fee Amendments (MDUFA) for 5 additional years (Fiscal Year (FY) 2018 through FY 2022, referred to as MDUFA IV). MDUFA IV authorizes the 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 with industry 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* submissions, 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 2018 MDUFA IV Cohort submissions.[3] This report also includes updated review goal performance information for FY 2016 and FY 2017 MDUFA III Cohort submissions (see Appendix A).

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, 2018.
- 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[4], where performance is

[1] https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf
[2] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm
[3] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452527.htm
[4] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452535.htm

reported separately for each Center. Details of which Center reviews which submission type is outlined in Appendix B of this report.

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

- Review goal performance data are based on a fiscal year receipt cohort. Until all submissions in a cohort receive a final decision or are sufficiently complete for FDA to determine whether the review goal 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. MDUFA decisions for each submission type are outlined in Appendix B of this report.

- The Original Premarket Approval Applications (PMA), Product Development Protocols (PDP), Panel-Track 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 with industry, 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 (completed within goal) and overdue (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 2018 submissions is shown as the percentage of submissions completed within goal as of September 30, 2018, 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.[5]

MDUFA Performance Enhancement Goals

For the purposes of this report, performance enhancement goals are defined as any non-review goal identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the applicable fiscal year. Performance information on the FY 2018 performance enhancement goals is located in Appendix E and Appendix F of this report.

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

Additional Performance Data

On May 5, 2017, the Consolidated Appropriations Act, 2017 (P.L. 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* requests, requests for information about classification, regulatory requirements applicable to a device type under 513(g), and postmarket device surveillance plan submissions (also known as a "section 522 plan"). This data is contained in Appendix C of this report.

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amends 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" (§903) and specified analyses of the use of funds (§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 makes recommendations for improvements, or identifies which commitment letter goals were not met in MDUFA IV for the applicable fiscal year (§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 of 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 would 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 premarket approval applications.

- **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 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 premarket application 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 process** – The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide 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 [510(k)] submissions.

- **Premarket Notification (510(k))** - A premarket submission made to FDA to demonstrate that a device to be marketed is at least as safe and effective as, that is, substantially equivalent to, a legally marketed device that is not subject to the PMA review process. Submitters must compare their 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 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** – 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, a single premarket submission meeting both the definitions of a premarket notification 510(k) and a CLIA waiver by application.

- **Pre-Submissions** - A formal written request from an applicant for feedback from FDA which 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 intended submission of an IDE or marketing application. The request should include specific questions regarding review issues relevant to a planned IDE or marketing application.

- **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/Drugs/InformationOnDrugs/ucm079436.htm

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 is defined by number of submissions, not percentage of submissions, that meet the Review-Time Goal, but is included for ease of reference.

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						
Decision	150 FDA days	50%	55%	60%	65%	70%

Submission Type	Review-Time Goal	Commitment Target				
		FY 18	FY 19	FY 20	FY 21	FY 22
510(k) Premarket Notifications						
Substantive Interaction	60 calendar days	95%	95%	95%	95%	95%
Decision	90 FDA days	95%	95%	95%	95%	95%
CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	90%	90%	90%	90%	90%
Decision with no Advisory Committee input	150 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee input	320 FDA days	90%	90%	90%	90%	90%
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	90%	90%	90%	90%	90%
Decision with no Advisory Committee input	180 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee input	320 FDA days	90%	90%	90%	90%	90%
Pre-Submissions						
Provide Written Feedback*	70 calendar days or 5 days prior to the meeting	1,530	1,645	1,765	1,880	1,950

*This goal is defined by 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 Supplements					
Total Time to Decision Goal (Days)	320	315	310	300	290
510(k)					
Total Time to Decision Goal (Days)	124	120	116	112	108

FY 2018 Preliminary 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 preliminary MDUFA IV review goal performance in FY 2018.

In total, FDA has 25 MDUFA IV review goals: 23 review goals with specific target percentages (including one Pre-Submission written feedback goal) and 2 shared outcome goals. In FY 2018, FDA received submissions in 21 of the 25 review goals. Preliminary data 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.

Review Goals with Specific Target Percentages

The following table provides FDA's preliminary performance data on the 23 review goals with specific target percentages, for submissions in the FY 2018 MDUFA Cohort [A]. The table below also includes FDA's performance on the Pre-Submission written feedback goal. The Pre-Submission written feedback goal is defined by number of submissions, not a specific target percentage, but is included for ease of reference. Additional detail on FDA's review goal performance can be found in the MDUFA IV Quarterly Performance Reports posted on FDA's website.[6]

Additional information about the performance provided below 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, 2018, that met the MDUFA goal.
- *Completed Overdue [C]* = the number of submissions with a MDUFA action as of September 30, 2018, 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, 2018.
- *Pending Overdue [E]* = the number submissions without a MDUFA action that are past the goal as of September 30, 2018.
- *Review Goal [F]* = the target percentage of FY 2018 MDUFA Cohort submissions that are required to meet the review-time goal (also referred to

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

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]* represents the scenario where all pending submissions within goal are completed within 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].

FDA had 23 review goals with specific target percentages (including 1 Pre-Submission written feedback goal) in FY 2018. In FY 2018, FDA received at least one submission for 19 of those 23 goals and did not receive any submissions for 4 of them. Of the 19 goals for which FDA received at least one submission, 17 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 two goals for which FDA received at least one submission because the MDUFA cohorts have only “Pending” (and no “Completed”) submissions.

In 4 of the 19 review goals with specific target percentages for which FDA received at least one submission, the FY 2018 cohorts are sufficiently complete to determine the outcome. These goals (and the final performance) are shown in **bold** text in the table below. For all four of these goals (CLIA Waiver by Application Substantive Interaction, Pre-Submission Written Feedback, Class 1 Original BLA and BLA Efficacy Supplement Resubmissions, and Class 2 Original BLA and BLA Efficacy Supplement Resubmissions), the goal was met.

FY 2018 Preliminary Review Goal 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	62	45	1	16	0	95%	98%	98%
Decision with No Advisory Committee Input	61	20	0	41	0	90%	100%	100%
Decision with Advisory Committee Input	1	0	0	1	0	90%	N/A	100%
180-Day PMA Supplements								
Substantive Interaction	200	160	3	35	2	95%	97%	98%
Decision	198	96	0	102	0	95%	100%	100%
Real-Time PMA Supplements								
Decision	339	272	0	67	0	95%	100%	100%
De Novo								
Decision	56	13	1	41	1	50%	87%	96%
510(k) Premarket Notifications								
Substantive Interaction	2,929	2,494	37	396	2	95%	98%	99%
Decision	2,905	1,740	6	1,158	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	1	0	3	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	7	0	4	0	90%	100%	100%
Decision with No Advisory Committee Input	11	5	0	6	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	0	90%	*	*
Pre-Submissions								
Provide Written Feedback	2,164	**2,044**	120	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 Preliminary Review Goal 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	3	0	11	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	94	16	0	78	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	8	0	0	8	0	90%	N/A	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	5	5	0	0	0	90%	**100%**	100%

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

Shared Outcome Goals

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

As of September 30, 2018, neither the 510(k) nor the PMA cohorts for FY 2018 have met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2018 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 Supplements					
Total Time to Decision Goal (Days)	320	315	310	300	290
Current Performance (Days)	*				
510(k)					
Total Time to Decision Goal	124	120	116	112	108
Current Performance	*				

* As of September 30, 2018, FY 2018 cohorts have not met the decision threshold to calculate performance.

MDUFA Review Workloads: FY 2014 through FY 2018

The table below compares review workloads for submission types with MDUFA review goals for a 5-year period (FY 2014 to FY 2018).

- 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.
- The 5-year averages and comparisons are only calculated for submission types that had MDUFA review goals in the entire 5-year period. Review workload is reported as "n/a" for years when a submission type did not have MDUFA review goals.
- Review workload numbers may differ from the MDUFA Cohort numbers presented in other tables, since submissions closed without MDUFA decisions are not included in the MDUFA Cohort.

Review workload in FY 2018 could be calculated for 13 of the 15 workload categories where data was available to calculate a 5-year average. The other two submission types were new to MDUFA IV and do not have the 5-year historical data. Of the 13 submission types, 2 did not receive any workload for FY 2018. Therefore, they are showing a 100 percent change from 2018 as compared to the 5-year average. However, for these two submission types—Priority Original BLAs and Priority BLA Efficacy Supplements—the change was from 1 to 0 and from 3 to 0 respectively. Given the small number of submissions, the percent change may not be meaningful. The submission type with a noted reduced workload is Class II Original BLA and BLA Efficacy Supplement Resubmissions. In comparison, submission types with noted increased workloads include Dual 510(k) and CLIA Waiver by Applications and BLA Manufacturing Supplements Requiring Prior Approval.

Review Workload* by Submission Type

Submission Type	FY 14	FY 15	FY 16	FY 17	FY 18	5-Year Average (FY 14 to FY 18)	FY 18 Compared to 5-Year Average
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	49	75	74	70	78	69	13.0%
180-Day PMA Supplements	177	203	210	276	200	213	-6.1%
Real-Time PMA Supplements	341	340	329	338	341	338	0.9%
510(k) Premarket Notifications	3,818	3,781	3,677	4,098	3,591	3,793	-5.3%
De Novo Requests †	n/a	n/a	n/a	n/a	56	n/a	n/a
CLIA Waiver by Applications	14	11	9	7	4	9	-55.6%
Dual 510(k) and CLIA Waiver by Applications	1	3	1	6	11	4	175.0%
Pre-Submissions †	n/a	n/a	n/a	n/a	2780	n/a	n/a
BLAs							
Priority Original BLAs	0	2	1	0	0	1	-100.0%
Standard Original BLAs	10‡	2	26	1	14	11	27.3%
BLA Manufacturing Supplements Requiring Prior Approval	6	19	47	38	94	41	129.3%
Priority BLA Efficacy Supplements	17	0	0	0	0	3	-100.0%
Standard BLA Efficacy Supplements	17	1	1	1	8	6	33.3%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	6	1	2	1	1	2	-50.0%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2	16	28	40	5	18	-72.2%

* Due to change in the definition of “workload,” these numbers are slightly different from what was presented in previous reports.
† Due to lack of MDUFA review goals in some years, no 5-year average is available.
‡The FY 2014 report showed 12, but 2 were placeholders for lot release.

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. FDA met all but one of the FY 2016 review goals and remains on target to meet all of the FY 2017 review goals.

MDUFA III Review-Time Goals and Commitments

In total, FDA has 23 MDUFA III review goals: 21 review goals with specific target percentages and 2 shared outcome goals. The 21 review goals with specific target percentages are summarized below; the 2 shared outcome goals are summarized separately, alongside the updated shared outcome performance below.

The tables below summarize the 21 review goals agreed to in MDUFA III 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 2013 through FY 2017. Many of the review goal targets progressively increase to account for new hires being brought on board and trained during the first 4 years of MDUFA III.

Review-Time Goals and Commitment Targets

Submission Type	Review-Time Goal	Commitment Target				
		FY 13	FY 14	FY 15	FY 16	FY 17
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	90 calendar days	65%	75%	85%	95%	95%
Decision with No Advisory Committee Input	180 FDA days	70%	80%	80%	90%	90%
Decision with Advisory Committee Input	320 FDA days	50%	70%	80%	80%	90%
180-Day PMA Supplements						
Substantive Interaction	90 calendar days	65%	75%	85%	95%	95%
Decision	180 FDA days	85%	90%	90%	95%	95%
Real-Time PMA Supplements						
Decision	90 FDA days	90%	90%	95%	95%	95%
510(k) Premarket Notifications						
Substantive Interaction	60 calendar days	65%	75%	85%	95%	95%
Decision	90 FDA days	91%	93%	95%	95%	95%
CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision with No Advisory Committee Input	180 FDA days	95%	95%	95%	95%	95%
Decision with Advisory Committee Input	330 FDA days	95%	95%	95%	95%	95%
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	90 calendar days	95%	95%	95%	95%	95%
Decision with No Advisory Committee Input	210 FDA days	90%	90%	90%	90%	90%
Decision with Advisory Committee Input	330 FDA days	95%	95%	95%	95%	95%

Review-Time Goals and Commitment Targets (continued)

Submission Type	Review-Time Goal	Commitment Target				
		FY 13	FY 14	FY 15	FY 16	FY 17
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 I Original BLA and BLA Efficacy Supplement Resubmissions	2 calendar months	90%	90%	90%	90%	90%
Class II Original BLA and BLA Efficacy Supplement Resubmissions	6 calendar months	90%	90%	90%	90%	90%

Updated MDUFA III Review Goal Performance

The tables below summarize FDA's updated MDUFA III performance for the 21 review goals with specific target percentages (for FY 2016 and FY 2017) and 2 shared outcome goals (for FY 2013 through FY 2017).

Review Goals with Specific Target Percentages (FY 2017)

The table below presents FDA's updated MDUFA III performance for the 21 review goals with specific target percentages for FY 2017. Further details can be found in the MDUFA III Quarterly Performance Reports posted on FDA's website.[7]

Additional information about the performance provided below is as follows:

- *Review Progress* presents (a) the number of submissions that had actions taken before the end of FY 2018, plus submissions pending but overdue as of September 30, 2018, and unable to meet the MDUFA goal out of (b) the number of submissions in the FY 2017 MDUFA Cohort (i.e., *Review Progress* = (a) of (b)).
- *Review Goal* presents the target percentage of FY 2017 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).

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

- *Current Review Goal Performance* presents the percentage of actions that FDA completed within the review-time goal.
- *Highest Possible Review Goal Performance* represents the scenario where all non-overdue pending submissions are completed within goal.

FDA had 21 review goals with specific target percentages in FY 2017. In FY 2017, FDA received at least one submission for 17 of those 21 goals and did not receive any submissions for 4 of them. As of September 30, 2018, the FY 2017 cohorts for all 17 review goals with specific target percentages for which FDA received at least one submission are sufficiently complete to determine the outcome, so this will be FDA's final update for this cohort. These goals (as well as the final "Current Review Goal Performance") are shown in **bold** text in the table below. For all 17 of these goals, the goal was met.

FY 2017 Updated Review Goal Performance Data

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports				
Substantive Interaction	67 of 67	95%	**96%**	96%
Decision with No Advisory Committee Input	57 of 61	90%	**100%**	100%
Decision with Advisory Committee Input	4 of 5	80%	**100%**	100%
180-Day PMA Supplements				
Substantive Interaction	275 of 275	95%	**97%**	100%
Decision	266 of 271	95%	**98%**	99%
Real-Time PMA Supplements				
Decision	331 of 331	95%	**99%**	99%
510(k) Premarket Notifications[†]				
Substantive Interaction	3785 of 3788	95%	**97%**	97%
Decision	3385 of 3443	95%	**99%**	99%
CLIA Waiver by Applications[‡]				
Substantive Interaction	4 of 4	95%	**100%**	100%
Decision with No Advisory Committee Input	7 of 7	95%	**100%**	100%
Decision with Advisory Committee Input	0 of 0	95%	*	*

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
Dual 510(k) and CLIA Waiver by Applications				
Substantive Interaction	6 of 6	95%	**100%**	100%
Decision with No Advisory Committee Input	6 of 6	90%	**100%**	100%
Decision with Advisory Committee Input	0 of 0	95%	*	*

* No submissions were received in FY 2017, so no performance can be reported.
† 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.
‡ Three applications were withdrawn prior to the Substantive Interaction.

FY 2017 Updated Review Goal Performance Data (continued)

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
BLAs				
Priority Original BLAs	0 of 0	90%	*	*
Standard Original BLAs	1 of 1	90%	**100%**	100%
BLA Manufacturing Supplements Requiring Prior Approval	38 of 38	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0	90%	*	*
Standard BLA Efficacy Supplements	1 of 1	90%	**100%**	100%
Class I Original BLA and BLA Efficacy Supplement Resubmissions	1 of 1	90%	**100%**	100%
Class II Original BLA and BLA Efficacy Supplement Resubmissions	40 of 40	90%	**100%**	100%

*No submissions were received in FY 2017, so no performance can be reported.

Review Goals with Specific Target Percentages (FY 2016)

The table below presents FDA's updated MDUFA III performance for the 21 review goals with specific target percentages for FY 2016. Further details can be found in the MDUFA III Quarterly Performance Reports posted on FDA's website.[8]

- *Review Progress* presents (a) the number of submissions that had actions taken before the end of FY 2018, plus submissions pending but overdue as of September 30, 2018, and unable to meet the MDUFA goal, out of (b) the number

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

of submissions in the FY 2016 MDUFA Cohort (i.e., *Review Progress* = (a) of (b)).

- *Review Goal* presents the target percentage of FY 2016 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* presents the percentage of actions that FDA completed within the review-time goal. Performance for submission types that are meeting or exceeding the goal as of September 30, 2018, is shown in **bold** text.
- *Highest Possible Review Goal Performance* represents the scenario where all non-overdue pending submissions are completed within goal.

FDA had 21 review goals with specific target percentages in FY 2016. In FY 2016, FDA received at least one submission for 18 of those 21 goals and did not receive any submissions for 3 of them. As of September 30, 2018, the FY 2016 cohorts for all 18 review goals with specific target percentages for which FDA received at least one submission are sufficiently complete to determine the outcome so this will be FDA's final update for this cohort. 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 goal was met.

FY 2016 Updated Review Goal Performance Data

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
Original PMA, PDPs, Panel-Track PMA Supplements, and Premarket Reports				
Substantive Interaction	73 of 73	95%	**100%**	100%
Decision with No Advisory Committee Input	70 of 72	90%	**100%**	100%
Decision with Advisory Committee Input	1 of 1	80%	**100%**	100%
180-Day PMA Supplements				
Substantive Interaction	207 of 207	95%	**98%**	100%
Decision	199 of 199	95%	**99%**	99%
Real-Time PMA Supplements				
Decision	324 of 324	95%	**100%**	100%
510(k) Premarket Notifications[†]				
Substantive Interaction	3421 of 3421	95%	**96%**	96%
Decision	3045 of 3051	95%	**98%**	98%

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
CLIA Waiver by Applications				
Substantive Interaction	9 of 9	95%	**100%**	100%
Decision with no Advisory Committee input	9 of 9	95%	**100%**	100%
Decision with Advisory Committee Input	0 of 0	95%	*	*
Dual 510(k) and CLIA Waiver by Applications				
Substantive Interaction	1 of 1	95%	**100%**	100%
Decision with No Advisory Committee Input	1 of 1	90%	**100%**	100%
Decision with Advisory Committee Input	0 of 0	95%	*	*

*No submissions were received in FY 2016, so no performance can be reported.
† 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

FY 2016 Updated Review Goal Performance Data (continued)

Submission Type	Review Progress	Review Goal	Current Review Goal Performance	Highest Possible Review Goal Performance
BLAs				
Priority Original BLAs	1 of 1	90%	**100%**	100%
Standard Original BLAs	26 of 26	90%	**100%**	100%
BLA Manufacturing Supplements Requiring Prior Approval	47 of 47	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0	90%	*	*
Standard BLA Efficacy Supplements	1 of 1	90%	**100%**	100%
Class I Original BLA and BLA Efficacy Supplement Resubmissions	2 of 2	90%	**100%**	100%
Class II Original BLA and BLA Efficacy Supplement Resubmissions	28 of 28	90%	**100%**	100%

*No submissions were received in FY 2016, so no performance can be reported.

Shared Outcome Goals (FY 2013 - FY 2017)

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 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, 2018, is shown in **bold** text.

As of September 30, 2018, the 510(k) and PMA cohorts for FY 2013, 2014, 2015, and 2016 have met the decision threshold to calculate the average TTD; the FY 2017 cohorts have not yet met the decision threshold. The average TTD for the FY 2013, FY 2014, FY 2015, and FY 2016 cohorts are listed below. FDA did not meet the shared outcome goal for 510(k)s in FY 2015 and FY 2016 but met all the PMA and other 510(k) shared outcome goals. The 510(k) goal was missed by 1 day in FY 2015 and 8 days in FY 2016. FDA will report the average TTD for 510(k) and PMA for FY 2017 in future reports, once the cohort has met the decision threshold.

MDUFA III Shared Outcome Goals

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

* As of September 30, 2018, FY 2017 cohorts have not met the decision threshold to calculate performance.

† Numbers were corrected since the last annual report.

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 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 (PHS) 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.

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 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 • Not Approvable

Submission Type	MDUFA Decisions
510(k)s	• Substantially Equivalent (SE) • Not Substantially Equivalent (NSE)
De Novo Requests	• Grant • Withdrawal (including Deletions) • Decline
CLIA Waiver by Applications	• Approval • Withdrawal (including Deletions) • Denial
Dual 510(k) and CLIA Waiver by Applications	• Substantially Equivalent (SE)/Approval • Substantially Equivalent (SE)/Withdrawal • Substantially Equivalent (SE)/Denial • Withdrawal (including Deletions) • Not Substantially Equivalent (NSE)/Denial
Pre-Submissions	• Email Reply • Email Feedback Sent Before Meeting
Biologics License Applications (BLAs) and 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 which 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; however, 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 Q-Submission:

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

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

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

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 the following items only (or combinations of these items):

(a) Final printed labeling
(b) Draft labeling
(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
(d) Stability updates to support provisional or final dating periods
(e) Commitments to perform Phase 4 studies, including proposals for such studies
(f) Assay validation data
(g) Final release testing on the last 1-2 lots used to support approval
(h) A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class 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 (P.L. 115-31), was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year ending September 30, 2017. Senate Report 114-259 directed FDA to provide performance information related to medical devices including the extent to which the Agency's responses meet statutory timeframes. Specifically, FDA was directed to report the number of De Novo requests under section 513(f)(2) for which FDA met the statutory requirement and the total number of De Novo requests submitted; the total number of requests for classification under section 513(g) and the number that met the statutory requirement; and, 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 requests received include those that passed eCopy requirements (FY14-17) 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 2014 and FY 2018, FDA met statutory timelines for issuing a final decision on a De Novo request 43 to 66 percent of the time; responded to 513(g) requests within the statutory timeframe 27 to 33 percent of the time; and met the statutory timeframe for responding to a section 522 plan 10 to 79 percent of the time.

Performance Data for Submissions with Statutory Timeframes

Submission Type	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
De Novo Requests Under 513(f)(2)					
Number received that passed applicable administrative requirements	42	60	54	101	56
Number completed with a Granted, Declined, or Withdrawn decision	42	60	53	90	14
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory timeframe of 120 days*	21	26	32	59	9
Percent that met the statutory timeframe†	50%	43%	60%	66%	64%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)					
Number received that passed applicable administrative requirements	95	104	109	133	115

Submission Type	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Number to which FDA responded within the statutory timeframe of 60 days	26	30	36	37	32
Percent that met the statutory timeframe‡	27%	29%	33%	28%	28%
Postmarket Surveillance Plans					
Number received	51	40	43	14	13
Number of FDA responses within 60 days of receipt	5	16	22	11	5
Percent that met the statutory timeframe	10%	40%	51%	79%	38%

* Other De Novo final decisions include Jurisdiction Transferred.

† This metric is defined as the number of De Novos with a Granted/Declined/Withdrawn decision within 120 FDA days, as a percentage of the sum of the number of De Novos with a Granted/Declined/Withdrawn decision plus the number of De Novos pending 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 amends 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 (§903). Specifically, section 903(b)(2) of FDARA requires the MDUFA annual performance report include the following (for only CDRH and starting in FY 2018):

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

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

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

The information below fulfills these requirements.

Number of Premarket Applications Filed and Reports Submitted

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

Relevant information about the 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 is consistent with the interpretation of identical statutory language in section 904 of FDARA and 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, 2018. This is consistent with the interpretation of

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

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

- Consistent with other parts of this report, the MDUFA Cohort is based on a fiscal year receipt cohort. Until all submissions in a cohort are closed, a preliminary number is provided for that cohort and is subject to change.
- Also consistent with other parts of this report, submissions that were closed without a MDUFA decision are not included in the MDUFA Cohort and, therefore, are not included in the table below. For the number of submissions received that have passed applicable, preliminary administrative requirements (e.g., eCopy, User Fee) regardless of whether closed with or without a MDUFA decision, please refer to the review workload tables in other sections of this report.
- As stipulated in FDARA, the numbers below only include 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 2018 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 Supplements, and Premarket Reports													
Substantive Interaction	60	3	19	4	1	11	8	1	5	1	0	6	1
Decision with No Advisory Committee Input	59	3	18	4	1	11	8	1	5	1	0	6	1
Decision with Advisory Committee Input	1	0	1	0	0	0	0	0	0	0	0	0	0
180-Day PMA Supplements													
Substantive Interaction	191	8	94	14	1	16	10	11	11	3	8	13	2
Decision	189	8	93	13	1	16	10	11	11	3	8	13	2
Real-Time PMA Supplements													
Decision	336	9	154	16	17	19	16	11	28	18	38	8	2
510(k)													
Substantive Interaction	2883	487	303	184	551	124	275	349	118	42	82	7	361
Decision	2860	485	313	178	535	125	270	337	105	42	78	6	386

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 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, 2018, in the FY2018 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 only include designation requests reviewed by CDRH and do not include those reviewed by CBER.

Cohort	Number of Breakthrough Device Designations
FY 2018	*51
FY 2019	†
FY 2020	†
FY 2021	†
FY 2022	†

*As of 9/30/2018, the FY 2018 cohort is 71% closed.

† As of 9/30/2018, fiscal year has not yet begun; will include in future reports.

Appendix E: Analysis of Use of Funds

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amends 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, and a determination of causes affecting the ability to meet goals; FDARA also 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) analysis of performance goals, and (III) a determination of causes affecting the ability to meet goals. These data are contained below.

Differences Between Aggregate Numbers

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

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

The table below provides the data required above for FY 2018 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, 2018. “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, 2018. This is consistent with the interpretation of identical statutory language in section 903 of FDARA and addressed in other sections of this report.

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

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

- *Completed [B]* = the number of submissions with a MDUFA action as of September 30, 2018. 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 agency,” representing 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 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)	
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, 2018.
- *Pending Overdue [H]* = the number of Pending [F] submissions that have not met the goal as of September 30, 2018.
- *Overdue [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 the Medical Device User Fee Amendments of 2017 for the applicable fiscal year" and represents the number of submissions that did not meet the MDUFA goal as of September 30, 2018. Overdue [I] includes both Completed Overdue [D] and Pending Overdue [H] submissions ([I] = [D] + [H]).

FY 2018 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	62	46	45	1	23	16	16	0	1
Decision with No Advisory Committee Input	61	20	20	0	5	41	41	0	0
Decision with Advisory Committee Input	1	0	0	0	0	1	1	0	0
180-Day PMA Supplements									
Substantive Interaction	200	163	160	3	88	37	35	2	5
Decision	198	96	96	0	26	102	102	0	0
Real-Time PMA Supplements									
Decision	339	272	272	0	12	67	67	0	0
510(k)									
Substantive Interaction*	2,929	2,531	2,494	37	1,584	398	396	2	39
Decision*	2,905	1,746	1,740	6	36	1,159	1,158	1	7

* 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 the Medical Device User Fee Amendments of 2017 for the applicable fiscal year.

For the 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 (FY 2018) are summarized below.

In summary, FDA had 11 performance enhancement goals with required completion dates in FY 2018. All 11 goals have been completed; 10 of 11 goals were completed on time.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Infrastructure[1]				
Quality Management – 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.	9/30/2018	Y	1/31/2018	FDA and industry communicated about areas of interest for its ongoing audit plan in Quarter 1 of FY 2018. By Quarter 2 of FY 2018, FDA incorporated this feedback, along with other information, and identified two areas to audit. The audit of the quality management system (QMS) of CDRH's Quality Management program was completed on 03/07/2018 and the audit on the effectiveness of Least Burdensome training was completed (with a report to Congress) on 6/8/2018.(https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM610577.pdf)
Program and Process Implementation[2]				
Pre-Submissions - Agency will update the Guidance on "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff."	10/1/2018	Y	6/7/2018	FDA issued a draft guidance with the required content, titled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program", on June 7, 2018 (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM609753.pdf)
CLIA Waiver by Applications - Hold CLIA Waiver Vendor Day	9/30/2018	Y	3/22/2018	
Deficiency Letters – The Agency will publish a level 2 update to the final guidance "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final Guidance for Industry and FDA Staff."	10/1/2017	Y	9/29/2017	FDA issued a final guidance, titled "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions", on September 29, 2017 (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf)
Deficiency Letters – FDA will train staff and managers on this process improvement and the updated guidance.	10/1/2017	Y	10/01/2017	
Enhanced Use of Consensus Standards – Conduct a Public Workshop to discuss objectives for the establishment of Accrediting Bodies and to accredit Test Laboratories.	9/30/2018	Y	5/22/2018	FDA held a 2-day workshop May 22-23, 2018, entitled "Accreditation Scheme for Conformity Assessment (ASCA)" (https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm)
Enhanced Use of Consensus Standards - Hold educational sessions with stakeholders about the purpose of the Accreditation Scheme for Conformity Assessment (ASCA) Program.	9/30/2018	Y	9/30/2018	Starting January 2017, FDA held 46 outreach sessions with internal and external stakeholders (24 in FY 2017, 22 in FY 2018)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Date Goal Met	Comments
Third Party Review – Establish a plan for eliminating routine re-review by FDA of Third Party reviews.	9/30/2018	Y	9/13/2018	FDA posted the plan on September 13, 2018 (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/UCM620308.pdf)
Third Party Review – Issue draft guidance outlining criteria for reaccreditation of 3rd Parties and the suspension or withdrawal of accreditation of a Third Party.	9/30/2018	Y	9/14/2018	FDA issued a draft guidance, titled "510(k) Third Party Review Program: Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations," on September 14, 2018 (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm339697.pdf)
Real World Evidence - The Agency will establish criteria for streamlining MDR requirements. For most, if not all, device procodes, FDA will permit manufacturers of such devices in those procodes to report malfunctions on a quarterly basis and in a summary MDR format. FDA will publish the list of eligible device procodes within 12 months of receiving a proposed list from Industry. The list will include, among other device procodes, Class II implantable and Class III devices, as appropriate, and will reflect FDA's consideration of Industry's proposed list. In addition, FDA will establish a mechanism at the time it publishes the list of eligible devices under 3(a) that permits stakeholders to request device procodes be added to the list.	8/18/2018*	Y	8/17/2018	
Program and Process Assessments[3]				
Independent Assessment of Review Process Management - FDA and the industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment shall be conducted in two phases under contract to FDA by a private, independent consulting firm, and "for Phase 1, FDA will award the contract by the end of CY2017."	12/27/2017	N	Jan 2018	

* Target goal date not explicitly defined commitment letter, but implied based on another commitment happening first.

[1] Performance enhancement goals described in Section III ("Infrastructure") of the MDUFA Commitment letter.

[2] Performance enhancement goals described in Section II ("Review Performance Goals") and IV ("Process Improvements") of the MDUFA Commitment letter.

[3] Performance enhancement goals described in Section V ("Independent Assessment of Review Process Management") of the MDUFA Commitment letter.

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 the Medical Device User Fee Amendments of 2017.

In total, FDA has 36 MDUFA goals for FY 2018: 25 review goals and 11 performance enhancement goals. In FY 2018, FDA received submissions in 21 of the 25 review goals. As indicated in other sections of this report, preliminary data indicate that FDA has met, or has the potential to meet, all 21 of the review goals (19 review goals with specific target percentages and 2 shared outcome goals) for which FDA received submissions in FY 2018. FDA also had 11 performance enhancement goals with required completion dates in FY 2018. In FY 2018, FDA completed all 11 goals, 10 of which were completed on time. With only 1 missed goal (of 36 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 2018 Corrective Action Report

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amends 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 2018 Review Goal Performance

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 4 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 2018 review goals for which FDA received submissions. However, with submissions still pending, it is too soon to determine final performance for the full FY 2018 cohort of review goals.	FDA will provide corrective actions for any missed FY 2018 review goals in subsequent corrective action reports.

FY 2018 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Program and Process Assessments	The goal to award a contract for the Phase 1 assessment by December 31, 2017, was missed by 12 days due to some difficulties encountered in coordinating final details during a time when communications were hampered by annual leave schedules. This slight delay did not adversely impact the quality and timeliness of the assessment; hence these circumstances did not have an impact on FDA's ability to meet the underlying requirement to publish a final report by December 31, 2018.	FDA conducted a root cause analysis and concluded that there were no systemic issues with the process used to award the contract. Hence, a corrective action is not needed to prevent future reoccurrences. The contract was awarded on January 12, 2018, in plenty of time to allow FDA to meet the underlying commitment to publish the assessment report by December 31, 2018. The only other commitment of this type under MDUFA IV is to award the Phase 2 assessment contract by March 31, 2020. That milestone comes at a time of the year that does not present the same kind of workload coordination and personnel availability challenges that existed around the time of the Phase 1 contract award milestone target.

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 during FY 2018, 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 2018 cohort.

FY 2018 Review Goal Performance

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 met 4 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. While preliminary data indicate FDA has the potential to meet the remaining 17 review goals for which FDA received submissions in FY 2018, with submissions still pending it is 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 on any missed goals in future reports.

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 during FY 2018.

This section presents performance enhancement goals with required completion dates in FY 2018 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 2019 through FY 2022 will be covered in subsequent corrective action reports.

FDA had 11 performance enhancement goals with required completion dates in FY 2018. In FY 2018, FDA completed all 11 goals, 10 of which were completed on time. Details on the one missed goal are provided below.

Program and Process Assessments

A. Summary of Performance:

FDA missed awarding a contract to conduct an Independent Assessment for Review Process Management. The contract was awarded on January 12, 2018, 12 days after the commitment milestone target.

B. Justification:

The goal to award a contract for the Phase 1 Independent Assessment for Review Process Management by December 31, 2017, was missed by 12 days due to some difficulties encountered in coordinating final details of the procurement package during a time when communications were hampered by annual leave schedules. This slight delay in the contract award date did not adversely impact the quality and timeliness of the assessment study, which was planned to take about a year. Consequently, these circumstances did not have an impact on FDA's ability to meet the underlying requirement to publish a final report by December 31, 2018.

C. FY 2019 Corrective Actions:

FDA conducted a root cause analysis and concluded there were no systemic issues with the process used to award the contract. Hence, a corrective action is not needed to prevent future reoccurrences. The contract was awarded on January 12,

2018, in plenty of time to allow FDA to meet the underlying commitment to publish the assessment report by December 31, 2018. The only other commitment of this type under MDUFA IV is to award the Phase 2 assessment contract by March 31, 2020. That milestone comes at a time of the year that does not present the same kind of workload coordination and personnel availability challenges that existed around the time of the Phase 1 contract award milestone target.

Department of Health and Human Services
Food and Drug Administration

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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