FY 2017

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee Amendments

Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA or the Agency) Fiscal Year (FY) 2017 Performance Report to Congress for the Medical Device User Fee Amendments (MDUFA). The enactment of the third authorization of MDUFA in 2012 (MDUFA III) reauthorized medical device user fees for 5 additional years (FY 2013 through FY 2017). This is the fifteenth report on medical device user fee review performance, and the fifth report to reflect the more challenging goals set under MDUFA III. Fiscal Year 2017 is the fifth and final year of MDUFA III. The first year of MDUFA IV began on October 1, 2017 (FY 2018).

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 III 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 2017, even with FY 2017's performance goals reaching their highest performance level for the 5-year period of MDUFA III. Preliminary data for performance goals through September 30, 2017, including completed and pending reviews, indicate that FDA has met, or has the potential to meet, all 17 of the performance goals for which FDA received submissions in FY 2017. FDA is currently exceeding all of the 18 performance goals for which FDA received submissions in FY 2016.

We believe the actions that FDA has taken under MDUFA III, such as establishing a structured pre-submission program and submission acceptance criteria, had a positive impact on the medical device review process. Additional process improvements the Agency has completed can be found in the attached report. These completed actions demonstrate our continued commitment to strengthening our medical device review programs, providing predictable medical device review processes, and increasing the efficiency with which medical devices are developed and made available to patients.

Scott Gottlieb, M.D.
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

ELP – Experiential Learning Program

FDA – Food and Drug Administration

FDASIA – Food and Drug Administration Safety and Innovation Act

FY – Fiscal Year (October 1 to September 30)

GMP – Good Manufacturing Practice

IDE – Investigational Device Exemption

IMDRF – International Medical Device Regulators Forum

IR – Interactive Review

MDUFA – Medical Device User Fee Amendments

NSE – Not Substantially Equivalent

PMA – Premarket Approval Application

RCP – Reviewer Certification Program

RTA – Refuse to Accept

SE – Substantially Equivalent

SI – Substantive Interaction

Executive Summary

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which included the reauthorization and expansion of the Medical Device User Fee Amendments (MDUFA) for 5 additional years (Fiscal Year (FY) 2013 through FY 2017, referred to as MDUFA III).

This report presents updated data on FDA's success in meeting FY 2016 review performance goals and preliminary data on meeting FY 2017 review performance goals and commitments under MDUFA III as of September 30, 2017.

FY 2016 Performance

As of September 30, 2017, FDA received submissions in 18 of the 21 goal categories for FY 2016. FDA has met 17 of the 18 performance goals with submissions and has the potential to meet the one pending performance goal.

FY 2017 Performance

As of September 30, 2017, FDA received submissions in 17 of the 21 goal categories for FY 2017. Preliminary data, including completed and pending reviews, indicate that FDA has met, or has the potential to meet, all 17 of the performance goals for which FDA received submissions in FY 2017. FDA made decisions in 14 of the goal categories in FY 2017. There are 2,073 submissions still pending within the MDUFA III goal date, representing 27 percent of the total FY 2017 cohort.

MDUFA III Process Improvements

Under MDUFA III, FDA committed to a variety of process improvements. Major process improvement accomplishments during FY 2017 include:

- Assessed 4,030 product codes and finalized the exemption of over 70 class I device types and over 1,000 class II device types.
- Introduced "Smart" review memoranda and written feedback templates for voluntary use during Pre-Submission review.
- Conducted 510(k) pilot programs to explore different approaches intended to facilitate efficiency and timeliness in the review process.
- Issued final guidance on "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)"
- Published the CDRH FY 2018 Proposed Guidance Development plan, including listing of final guidance documents for retrospective review.
- Conducted first patient Engagement Advisory Committee meeting and issued final guidance on including patient preference information in premarket approval

applications, Humanitarian Device Exemption applications, de novo requests, and device labeling.

MDUFA III Closeout

We believe the actions that FDA has taken under MDUFA III, such as establishing a structured pre-submission program and submission acceptance criteria, had a positive impact on the medical device review process. Additional process improvements the Agency has completed are described later in this report. These completed actions along with our achievements in meeting MDUFA III performance goals demonstrate our continued commitment to strengthening our medical device review programs, providing predictable medical device review processes, and increasing the efficiency with which medical devices are developed and made available to patients.

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Introduction

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which included the reauthorization and expansion of the Medical Device User Fee Amendments (MDUFA) for 5 additional years (fiscal year (FY) 2013 through FY 2017, referred to as MDUFA III). MDUFA III 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 performance goals and shared outcome goal commitments. [1]

Some of the notable changes to MDUFA III include: FDA's facilitation of earlier, more transparent, and predictable interactions with industry; more rigorous premarket review performance goals; and outcome goals that are shared by both industry and FDA. Additional information on the history of MDUFA I and MDUFA II can be found on FDA's website.[2]

Performance Presented in This Report

In any given year, FDA performance includes reviews of submissions pending from previous fiscal years and submissions received during the current fiscal year. This report presents updated performance information for FY 2016 MDUFA III cohort submissions and preliminary performance for FY 2017 MDUFA III cohort submissions.[3]

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

- Only performance goals with specific target percentages (e.g., 80 percent) are presented in this report. Information on performance goals without target percentages can be found in the MDUFA III Quarterly Performance Reports located on FDA's website.[4]

- Review performance statistics 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 performance goal was met, a preliminary performance assessment is provided for that cohort. The MDUFA III cohort performance for each submission type is therefore subject to change until that cohort is closed.

[1] www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.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

- FDA MDUFA III decisions for Original Premarket Approval Applications (PMAs) and Panel-Track Supplements are placed in six categories: *approval*, *approvable*, *approvable pending current good manufacturing practice (CGMP) inspection*, *not approvable*, *acceptance of withdrawal*, or *denial*. The decision categories for 180-day PMA Supplements are *approval*, *approvable*, *approvable pending current CGMP inspection*, and *not approvable*. Decision categories for Real-Time PMA Supplements are *approval*, *approvable*, and *not approvable*. The decisions for 510(k) Submissions are *substantially equivalent (SE)* or *not substantially equivalent (NSE)*. Decisions for Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications are approval, withdrawn, or denial. The decision categories for Biologics License Applications (BLAs) are *complete response* and *approval*. BLAs have many application categories: Priority Original, Standard Original, Priority Efficacy Supplements, Standard Efficacy Supplements, Manufacturing Supplements Requiring Prior Approval, Class 1 Original BLA and BLA Efficacy Supplement Resubmissions, and Class 2 Original BLA and BLA Efficacy Supplement Resubmissions.

- The Original PMAs, Panel-Track Supplements, and Premarket Report Applications performance section includes PMAs that are filed for priority review (previously referred to as expedited).

- Submissions that were closed without an FDA MDUFA III decision are not included in the MDUFA III cohort and, therefore, are not included in the statistics used to measure MDUFA III performance. However, the total number of submissions received is noted in the workload tables when the number differs from the number of MDUFA cohort submissions. Examples of this include when applications do not meet the acceptance criteria or are withdrawn by a sponsor.

- 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 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 review* indicates that action was completed within the number of days specified by the review-time goal.

- Performance is based on the number of submissions reviewed on time (acted on within goal) or overdue (acted on past the performance goal or pending past the performance goal) and is presented as *on-time performance percentage*.

- The *on-time performance percentage* refers to the percent of reviews where FDA met a review-time goal for a given type of submission. FDA's on-time performance percentage for a given type of submission is used to determine whether FDA met or exceeded the MDUFA III performance goals.
- When determining FDA performance, 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.
- MDUFA review-time goals range from 60 days to 330 days. To meet MDUFA review performance goals, FDA must meet the various review-time goals from 80 to 95 percent of the time, depending on the particular goal and fiscal year.
- Preliminary performance for FY 2017 submissions is shown as the percentage of submissions reviewed on time as of September 30, 2017, excluding any that have not yet reached their due date. The highest possible percent of reviews that may be completed on time is shown as the highest possible performance.
- Unless otherwise noted, all performance data are as of September 30, 2017.

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 and regulatory requirements applicable to a device type under 513(g), and postmarket device surveillance plan submissions (also known as a "section 522 plan"). These data are contained in Appendix F of this report.

Submission Types Included in This Report

- **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.

- **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.

- **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.

- **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.

- **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, i.e., is substantially equivalent to, a legally marketed device that is not subject to the PMA review process (a predicate device). Sponsors must compare their device to one or more similar legally marketed devices and support their substantial equivalency claims.

- **CLIA Waiver** - A categorization issued by FDA allowing a laboratory test 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.

- **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.

- **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 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 1 resubmissions, the new information may include matters related to product labeling, safety updates, and other minor clarifying information. For Class 2 resubmissions, the new information could warrant presentation to an advisory committee or a re-inspection of the manufacturer's device establishment.

- **Investigational Device Exemption (IDE)** - A device, including a transitional device that is the object of an investigation. IDE refers to the regulations under 21 CFR 812. An approved IDE means that the Institutional Review Board (and FDA, for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.

MDUFA III Performance Goals and Commitments

The following tables present 21 goal timelines and the target percentage of submissions required to meet the goal for all the various submission types for each year from FY 2013 through FY 2017. Many of the performance goal targets progressively increase to account for new hires being brought on board and trained during the first 4 years of MDUFA III.

Performance Goals and Commitment Targets

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

Performance Goals and Commitment Targets (continued)

Submission Type	Review-Time Goal	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 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%

FY 2016 Updated Review Performance

The table below presents updated FY 2016 MDUFA performance. Further details can be found in the MDUFA III Quarterly Performance Reports posted on FDA's website.[5] Updates on previous years' review performance are provided in Appendix C.

- *Review Progress* presents the number of submissions that had actions taken before the end of FY 2017, plus submissions pending, but overdue as of September 30, 2017, and unable to meet the MDUFA goal.
- *Current 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, 2017, is shown in bold text. Appendix A contains additional information on the completed reviews.
- *Highest Possible Performance* represents the scenario where all non-overdue pending submissions are reviewed on time.

As of September 30, 2017, FDA received submissions in 18 of the 21 goal categories for FY 2016. FDA has met 17 of the 18 performance goals with submissions and has the potential to meet the one pending performance goal.

[5] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452527.htm

FY 2016 Updated Review Performance Percentages

Submission Type	Review Progress	Performance Goal	Current Performance	Highest Possible Performance
PMA, Panel-Track PMA Supplements, and Premarket Reports				
Substantive Interaction	73 of 73 complete	95%	**99%**	99%
Decision with No Advisory Committee Input	61 off 72 complete	90%	**100%**	100%
Decision with Advisory Committee Input	1 of 1 complete	80%	**100%**	100%
180-Day PMA Supplements				
Substantive Interaction	206 of 206 complete	95%	**98%**	98%
Decision	197 of 199 complete	95%	**99%**	99%
Real-Time PMA Supplements				
Decision	324 of 324 complete	95%	**99%**	99%
510(k) Premarket Notifications				
Substantive Interaction	3,407 of 3,411 complete	95%	**96%**	96%
Decision	3,024 of 3,071 complete	95%	**98%**	98%
CLIA Waiver by Applications				
Substantive Interaction	9 of 9 complete	95%	**100%**	100%
Decision with no Advisory Committee Input	9 of 9 complete	95%	**100%**	100%
Decision with Advisory Committee Input	0 of 0 complete	95%	--*	--

*No actions in this submission type were taken in FY 2016, so no performance can be reported.

FY 2016 Updated Review Performance Percentages (continued)

Submission Type	Review Progress	Goal Percentage	Current Performance	Highest Possible Performance
Dual 510(k) and CLIA Waiver by Applications				
Substantive Interaction	1 of 1 complete	95%	**100%**	100%
Decision with No Advisory Committee Input	1 of 1 complete	90%	**100%**	100%
Decision with Advisory Committee Input	0 of 0 complete	95%	--*	--
BLAs				
Priority Original BLAs	1 of 1 complete	90%	**100%**	100%
Standard Original BLAs	26 of 26 complete	90%	**100%**	100%
BLA Manufacturing Supplements Requiring Prior Approval	47 of 47 complete	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0 complete	90%	--*	--
Standard BLA Efficacy Supplements	1 of 1 complete	90%	**100%**	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	2 of 2 complete	90%	**100%**	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	28 of 28 complete	90%	**100%**	100%

* No actions in this submission type were taken in FY 2016, so no performance can be reported.

FY 2017 Preliminary Review Performance

The table below presents preliminary FY 2017 MDUFA performance. Further details can be found in the MDUFA III Quarterly Performance Reports posted on FDA's website.[6]

- *Review Progress* presents the number of submissions that had actions taken before the end of FY 2017, plus submissions pending, but overdue as of September 30, 2017, and unable to meet the MDUFA goal.
- *Current 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, 2017, is shown in bold text. Appendix B contains additional information on the completed reviews.
- *Highest Possible Performance* represents the scenario where all non-overdue pending submissions are reviewed on time.

As of September 30, 2017, FDA received submissions in 17 of the 21 goal categories for FY 2017. Preliminary data, including completed and pending reviews, indicate that FDA has met, or has the potential to meet, all 17 of the performance goals for which FDA received submissions in FY 2017. FDA made decisions in 14 of the goal categories in FY 2017. There are 2,073 submissions still pending within the MDUFA III goal date, representing 27 percent of the total FY 2017 cohort.

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

FY 2017 Preliminary Review Performance Percentages

Submission Type	Review Progress	Performance Goal	Current Performance	Highest Possible Performance
PMA, Panel-Track PMA Supplements, and Premarket Reports				
Substantive Interaction	48 of 59 complete	95%	94%	95%
Decision with No Advisory Committee Input	24 of 56 complete	90%	**100%**	100%
Decision with Advisory Committee Input	0 of 3 complete	80%	--*	100%
180-Day PMA Supplements				
Substantive Interaction	217 of 280 complete	95%	**96%**	97%
Decision	169 of 280 complete	95%	**99%**	99%
Real-Time PMA Supplements				
Decision	267 of 331 complete	95%	**99%**	99%
510(k) Premarket Notifications				
Substantive Interaction	2,897 of 3,333 complete	95%	**97%**	97%
Decision	1,918 of 3,287 complete	95%	**99%**	99%
CLIA Waiver by Applications				
Substantive Interaction	3 of 4 complete	95%	**100%**	100%
Decision with No Advisory Committee Input	5 of 7 complete	95%	**100%**	100%
Decision with Advisory Committee Input	0 of 0 complete	95%	--*	**--**

*No actions in this submission type were taken in FY 2017, so no performance can be reported.

FY 2017 Preliminary Review Performance Percentages (continued)

Submission Type	Review Progress	Goal Percentage	Current Performance	Highest Possible Performance
Dual 510(k) and CLIA Waiver by Applications				
Substantive Interaction	5 of 6 complete	95%	**100%**	100%
Decision with No Advisory Committee Input	0 of 6 complete	90%	--*	100%
Decision with Advisory Committee Input	0 of 0 complete	95%	--*	**--**
BLAs				
Priority Original BLAs	0 of 1 complete	90%	--*	100%
Standard Original BLAs	0 of 2 complete	90%	--*	100%
BLA Manufacturing Supplements Requiring Prior Approval	32 of 37 complete	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0 complete	90%	--*	--
Standard BLA Efficacy Supplements	0 of 0 complete	90%	_*	--
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1 of 1 complete	90%	**100%**	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	12 of 40 complete	90%	**100%**	100%

* No actions in this submission type were taken in FY 2017, so no performance can be reported.

MDUFA Review Workloads: FY 2012 through FY 2017

The table below compares the review workloads for the period FY 2012 to FY 2017. Workload in FY 2017 was equal to or greater than the previous 5-year average for 5 of the 10 workload categories where submissions were received in FY 2017 and for which there was data to calculate a 5-year average. The submission type with a noted reduced workload is Standard Original BLAs. In comparison, submission types with noted increased workloads include PMAs, Panel-Track PMA Supplements, Premarket Reports, and 180 Day PMA Supplements. The submission types which have been identified as a MDUFA Cohort only include submissions which have been accepted by FDA and/or have received a MDUFA decision. All other submission types have no difference between a received cohort and a MDUFA cohort.

Workload by Submission Type

Submission Type	FY12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 12 to FY 16 5-Year Avg.	FY 17 Compared to 5-Year Avg.
PMAs, Panel-Track PMA Supplements, and Premarket Reports – MDUFA Cohort*	38	45	48	71	73	59	55	+ 7%
180-Day PMA Supplements – MDUFA Cohort	203	177	172	193	199	280	189	+ 48%
Real-Time PMA Supplements – MDUFA Cohort	297	301	333	325	324	331	316	- 5%
510(k) Premarket Notifications – MDUFA Cohort	3,392	3,383	3,195	3,187	3,071	3,287	3,246	+ 1%
De Novo Requests†	--	48	42	60	54	101	-- †	--
CLIA Waiver by Applications – Receipts†	--	3	14	11	9	7	-- †	--
Dual 510(k) and CLIA Waiver by Applications – Receipts†	--	0	1	3	1	6	-- †	--
BLAs								
Priority Original BLAs	0	0	0	2	1	1	1	0%
Standard Original BLAs	13	9	10‡	2	26	2	12	- 83%
BLA Manufacturing Supplements	28	20	6	19	47	37	24	+54%

Requiring Prior Approval*								
Priority BLA Efficacy Supplements	0	0	0	0	0	0	0	-- §
Standard BLA Efficacy Supplements	1	0	17	1	1	0	4	- 100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions*	5	10	6	1	2	1	5	- 80%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	1	0	2	16	28	40	9	+ 78%

* New reporting requirement combines Original PMAs and Expedited PMAs and represents the receipt cohort.
† Due to changing reporting requirements, no 5-year average is available.
‡The FY 2015 report showed 12, but two were placeholders for lot release.
§The percent change cannot be calculated as no submissions were received in FY 2017 or 5-year average is zero.

Report on Additional MDUFA III Performance Commitments

Under MDUFA III, FDA made several commitments related to the medical device review process in addition to performance goals. These commitments include maintaining performance in areas not covered by explicit performance goals, applying the interactive review program, using informal and formal meetings to advance medical device reviews, providing quarterly reports on performance, continuing to focus on reviewer training, and developing guidance documents. Additional information on these commitments is included in Appendix D.

Total Time to Final Decision

FDA committed to report the average total time to final decision once decisions were made for 95 percent of the PMA cohort and 99 percent of the 510(k) cohorts. The PMA and 510(k) cohort calculations are based on the methodology prescribed in the MDUFA III commitment letter. The average total time to decision for the FY 2013, FY 2014, and FY 2015 cohorts are listed below. At this point in time, the threshold for closure of the FY 2016 and FY 2017 cohorts has not been met. FDA did not meet the shared outcome goal for 510(k)s in FY 2015; this goal was missed by 1 day. Once the required percentage of each open cohort has been reached, FDA will report the average time to final decision in future reports.

MDUFA III Shared Outcome Goal
Total Time to Decision (Days)

Submission Type	FY 13	FY 14	FY 15	FY 16	FY 17
PMAs					
Performance Goal	395	395	390	390	385
Current Performance	378	258	293	*	*
510(k)					
Performance Goal	135	135	130	130	124
Current Performance	124	125	131	*	*

* As of September 30, 2017, FY 2016 and FY 2017 cohorts have not met the decision threshold to calculate performance.

Training

As part of the MDUFA III agreement, CDRH committed to applying user fee revenue to supplement management training for Branch Chiefs and Division Directors, MDUFA III training for all staff, a Reviewer Certification Program (RCP) for new CDRH reviewers, and specialized training to provide continuous learning for all staff. During FY 2017, CDRH provided 574 learning events that addressed reviewer training; new scientific technologies; law, regulation, and guidance updates; and leadership and professional development. In addition, CDRH enhanced the RCP curriculum training that addresses Regulatory Basics, Standards, and the Medical Device Ecosystem. Additionally, the program was expanded to provide training for premarket review staff beyond the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR), in support of the Center's efforts regarding Total Product Lifecycle. In FY17, a total of 141 CDRH review staff participated in RCP. CDRH continued to expand the Experiential Learning Program (ELP), through which academia, industry, and clinical facilities host FDA review staff to provide real-world experience with regulated products. In FY 2017, 218 medical device review staff participated in ELP, visiting a total of 23 sites. CDRH also conducted training in preparation for MDUFA IV (MIV), including a MIV Introduction module for all Center staff and targeted training for staff involved in premarket review. CDRH also hosted three vendor days to provide staff with an opportunity to interact with industry and gain experience with regulated products. More information on CDRH training is available on the FDA website.

The Center for Biologics Evaluation and Research (CBER) provided training for medical device reviewers once again by providing a 3-day Medical Device Reviewer Training Course. Six Device Review Update sessions were held covering topics

such as “Update on ISO14155,” “Bundling of Multiple Medical Device Submissions,” “Medical Device Provisions of the 21st Century Cures Act,” “Overview of CLIA Complexity Categorization,” “Overview of Convenience Kits,” “MDUFA IV Updates” (2 sessions), “CBER’s New Device Submission Tracking System (DST),” and “Overview of MDUFA Guidance Documents.” Training was also provided on “Interactive Review” and “Documentation Basics.”

Process Improvement Accomplishments

FDA’s accomplishments for the process improvement commitments agreed to by FDA for MDUFA III are summarized below. Please see Appendix E for details about the process improvement commitments.

Performance Areas with Process Improvement Agreements	*MDUFA III Accomplishments FY 2012-FY 2016*	*FY 2017 Updates*
Pre-Submissions: FDA will institute a structured process for managing Pre-Submissions. Pre-Submissions subject to this process are defined in Section VIII, Definitions and Explanations of Terms. The Agency will continue to improve the Pre-Submission process as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. FDA will issue a draft guidance document and final guidance document on Pre-Submissions	• CDRH/CBER began implementing the Pre-Submission program on 10/1/12 (i.e., the start of MDUFA III). FDA devised a structured process for managing Pre-Submissions which included defining the scope of the Pre-Submission program; guidelines for timely completion of Pre-Submission review; and developing the IT infrastructure to manage submission receipt, processing, and workload management. • FDA issued the "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" final guidance document on 2/18/14. The guidance outlined the principles of the Pre-Submission program, as specified in the commitment letter. • CDRH conducted several evaluations of the Pre-Submission program to gain a greater understanding of how the Pre-Submission program is utilized by industry, the timeliness of completion of Pre-Submissions, and the impact of Pre-Submissions in the medical device product premarket lifecycle. These evaluations were conducted largely in FY16 and were utilized during the MDUFA IV negotiations to drive key areas for future improvements and performance commitments.	CDRH introduced "smart" review memoranda and written feedback templates for voluntary use during Pre-Submission review. These tools are used by premarket review staff and intended to improve Pre-Submission review consistency and further enhance a structured process for managing Pre-Submissions. These tools are periodically reviewed and refined as appropriate to reflect updates to internal best review practices and to reflect updates to guidance.

Performance Areas with Process Improvement Agreements	*MDUFA III Accomplishments FY 2012-FY 2016*	*FY 2017 Updates*
Submission Acceptance Criteria: To facilitate a more efficient and timely review process, FDA will implement revised submission acceptance criteria. The Agency will publish guidance outlining electronic copy of submissions (e-Copy) and objective criteria for revised "refuse to accept/refuse to file" checklists. FDA will publish draft and final guidance prior to implementation.	• 510(k) Refuse to Accept (RTA) policy guidance update issued August 4, 2015, and implemented on October 1, 2015. **Link:** www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm315014.pdf • The RTA criteria for 510(k) and PMA is a checklist of objective criteria for screening out submissions that lack basic requirements. If a submission is refused for acceptance, the review clock does not start until FDA receives a revised submission that meets the established acceptance criteria. This approach provides a more efficient strategy for ensuring that safe and effective medical devices are cleared for marketing as quickly as possible. **Link:** www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf • The Q-Submission (Pre-Submission) program established at the start of MDUFA III includes an acceptance review. The acceptance review occurs within the first 15 calendar days of receipt. FDA review staff utilize the acceptance checklist included in the "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" final guidance document. The acceptance review serves two purposes; 1) to determine the type Q-Submission that is submitted and 2) to determine if the Q-Submission is administratively complete.	No formal process improvements were made to the submission acceptance criteria in FY17 for the 510(k) and PMA programs. CDRH continued to implement the policies for submission acceptance review as outlined in the respective program guidance documents. The iterative process improvements made between FY12-FY16 for the 510(k) program have led to increased rates of first-round submission acceptance. In FY17, CDRH began piloting different approaches intended to facilitate efficiency and timeliness in the review process. CDRH review staff frequently identify substantive review issues during the 510(k)-acceptance review. However, the acceptance review policy prevents review staff from communicating these issues within the acceptance checklist. In an effort to enhance transparency and encourage early resolution of such issues, CDRH is piloting a policy that permits review staff to communicate these issues via an "RTA addendum." Preliminary results from this pilot suggest this approach can contribute to reduced number of deficiencies and can reduce FDA's time to final decision. CDRH intends to expand the pilot and will implement policies that achieve the fundamental principles of acceptance review.

Performance Areas with Process Improvement Agreements	*MDUFA III Accomplishments FY 2012-FY 2016*	*FY 2017 Updates*
Interactive Review: The Agency will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and applicants. As described in the guidance document, Interactive Review for Medical Device Submissions: 510(k)s, Original [Premarket Approvals] PMAs, PMA Supplements, Original BLAs, and BLA Supplements, both FDA and industry believe that an interactive review process for these types of premarket medical device submissions should help facilitate timely completion of the review based on accurate and complete information. Interactive review is intended to facilitate the efficient and timely review and evaluation by FDA of premarket submissions. The interactive review process contemplates increased informal interaction between FDA and applicants, including the exchange of scientific and regulatory information	• In FY 2016, CDRH and CBER review staff received training on best practices for interactive review during the review of 510(k) submissions. The training focused on how and when to use interactive review during each phase of the 510(k) review process. The training introduced the new policies and practices on the use of interactive review during the RTA review. The training provided guidelines on how staff can use their discretion to determine whether to work interactively during the RTA review to resolve issues efficiently rather than issuing an RTA decision and discussed the suggested time frame to allow sponsors to respond. Staff was also encouraged to utilize interactive review during the pre-Substantive Interaction (SI) review phase. The training discussed examples of the types of questions that should be communicated during the pre-Substantive Interaction window, such as requesting information to ensure the complete understanding of the device. Staff was given instructions on the procedures for requesting information interactively and guidelines on the timing of requests. The training also focused on appropriate documentation of Interactive Review (IR) for the administrative record. The training was intended to create a more consistent approach to the use of IR. • Final guidance was issued in April 2014 ("Types of Communication during the Review of Medical Device Submissions"), and FDA has implemented process and policy improvements consistent with the interactive review section of the MDUFA III commitment letter. **Link:** www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm341948.pdf	Established internal procedures and policies regarding best practices for incorporating interactive review in each phase of the 510(k) review process. These procedures and policies are incorporated into work instructions and other job aids. In FY17, CDRH began piloting several approaches intended to incorporate more interactions and greater transparency with 510(k) applicants. Specifically, CDRH began piloting a "10 day check-in" policy. Review staff have been offering 510(k) applicants the opportunity to have an informal conversation within 10 days of the issuance of a request for additional information letter. The pilot program is intended to encourage applicants to discuss their questions and get clarification from CDRH review staff on the submitted deficiencies. Early feedback from these interactive conversations suggests applicants gain a greater understanding of CDRH's perspective and the fundamental issues driving the requests.

Performance Areas with Process Improvement Agreements	MDUFA III Accomplishments FY 2012-FY 2016	FY 2017 Updates
Guidance Document Development: FDA will apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents. The Agency will continue to develop guidance documents and improve the guidance development process as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. FDA will update its website in a timely manner to reflect the following: The Agency's review of previously published device guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency; A list of prioritized device guidance documents (an "A-list") that the Agency intends to publish within 12 months of the date this list is published each fiscal year; and A list of device guidance documents (a "B-list") that the Agency intends to publish, as the Agency's guidance-development resources permit, each fiscal year. ***The Agency will establish a process allowing stakeholders an opportunity to:*** Provide meaningful comments and/or propose draft language for proposed guidance topics in the "A" and "B" lists; provide suggestions for new or different guidance documents; and comment on the relative priority of topics for guidance.	• CDRH FY 2016 Proposed Guidance Development as well as a listing of final guidance documents for retrospective review can be found at the following **Link:** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm467223.htm • CDRH FY 2017 Proposed Guidance Development as well as a listing of final guidance documents for retrospective review can be found at the following **Link:** https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm • CDRH has also developed "leapfrog" guidances to provide initial recommendations regarding the type of information that would be appropriate in the review of emerging technologies. These guidances seek early stakeholder feedback prior to publication of the draft guidance. In FY 2016, CDRH updated or issued a number of leapfrog guidances, including: "Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf); "Radiation Biodosimetry Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427866.pdf); "Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices	CDRH has published the 2018 Proposed Guidance Document Development plan and a listing of final guidance documents for retrospective review. These documents can be found at the following **Link:** https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm580172.htm ***Summary of Guidance Document Activities Accomplished in 2017***: CDRH issued nine guidance documents from the respective 2017 "A" and "B" priority lists. To ensure the available guidance documents reflect FDA's current thinking, CDRH conducted a retrospective review of guidance documents issued in 2007, 1997, and 1987 and solicited comments from the public. CDRH withdrew 32 guidance documents in response to the comments and because the documents no longer reflect the Agency's current thinking. CDRH has received feedback that stakeholders desire earlier involvement in the guidance process and has taken steps to create a mechanism to address this request. In FY 2016, in anticipation of guidance documents expected to be developed, CDRH sought stakeholder input regarding electromagnetic compatibility of electrically powered medical devices and regarding utilizing animal studies to evaluate the safety of organ preservation devices and solutions. Demonstrating commitment to incorporating stakeholder input, CDRH issued a draft guidance in FY17 on utilizing animal studies to evaluate the safety of organ

	Targeting Disease Progression and Clinical Outcomes" (www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm489111.pdf) and "Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails" (www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM431312.pdf).	preservation devices, progressing toward issuance of draft policies reflecting early stakeholder input as appropriate (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm575922.pdf).

Performance Areas with Process Improvement Agreements	MDUFA III Accomplishments FY 2012-FY 2016	FY 2017 Updates
Third-Party Review: The Agency will continue to support the third-party review program and agrees to work with interested parties to strengthen and improve the current program while also establishing new procedures to improve transparency. The Agency will continue to improve the third-party review program as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.	• On 9/12/2016, FDA issued draft guidance on the "510(k) Third Party Review Program." • CDRH updated its internal IT systems to more accurately reflect its internal policy on the timely completion of 510(k) third-party submissions.	**Guidance:** In January 2017, FDA received feedback from external stakeholders and decided to re-issue the draft guidance. The draft guidance is scheduled to be released by September 2018. The draft guidance outlines the criteria for reaccreditation, suspension or withdrawal of third parties, and expands the product code eligibility criteria to reflect the changes made in FDARA. **Process Improvements:** CDRH established and trained staff on new review templates and SOPs for third-party submissions. These templates and SOPs were introduced with the goal of improving efficiency and standardization in the program. CDRH also initiated a training program to improve 510(k) review and documentation by accredited third parties. These sessions were led by subject matter experts and will continue in FY 2018 to target different device types and cross-cutting topics.

Performance Areas with Process Improvement Agreements	MDUFA III Accomplishments FY 2012-FY 2016	FY 2017 Updates
***Patient Safety and Risk Tolerance**:* FDA will fully implement final guidance on the factors to consider when making benefit-risk determinations in medical device premarket review. This guidance will focus on factors to consider in the premarket review process, including patient tolerance for risk, magnitude of the benefit, and the availability of other treatments or diagnostic tests. Over the period of MDUFA III, FDA will meet with patient groups to better understand and characterize the patient perspective on disease severity or unmet medical need. In addition, FDA will increase its utilization of FDA's Patient Representatives as Special Government Employee consultants to CDRH to provide patients' views early in the medical product development process and ensure those perspectives are considered in regulatory discussions. Applicable procedures governing conflicts of interest and confidentiality of proprietary information will be utilized for these consultations	• FDA issued draft guidance in July 2014 on "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics" **Link:** www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm282958.htm • FDA issued final guidance in April 2015 on "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" **Link:** www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393994.pdf • FDA issued draft guidance in June 2015 on "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)" **Link:** www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm451440.pdf • FDA issued draft guidance in May 2015 on "Patient Preference Information – Submission, Review in PMAs, HDE Application and De Novo Requests, and Inclusion in Device Labeling" **Link:** www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm446680.pdf • CDRH launched the Patient Engagement Advisory Committee in September 2015 as part of the Patient Preference Initiative **Link:** www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/default.htm • FDA issued final guidance in January 2017 on "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)" **Link:** https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm451440.pdf • FDA issued final guidance in August 2016 on "Patient Preference Information – Submission, Review in PMAs, HDE Application and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling" **Link:** www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm446680.pdf • FDA issued final guidance in December 2016 on "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance and Enforcement Decisions' **Link:**	FDA issued final guidance in January 2017 on "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)." The first Patient Engagement Advisory Committee was held October 11-12, 2017. The purpose was for the committee to discuss and make recommendations on the topic of patient input into medical device clinical trials.

	https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm506679.pdf	

Performance Areas with Process Improvement Agreements	***MDUFA III Accomplishments FY 2012-FY 2016***	***FY 2017 Updates***
Low Risk Medical Device Exemptions: By the end of FY 2013, FDA will propose additional low risk medical devices to exempt from premarket notification. Within 2 years of such proposal, FDA intends to issue a final rule exempting additional low risk medical devices from premarket notification.	• The draft guidance "Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements" was issued and announced in the *Federal Register* on August 1, 2014. The final guidance was issued on July 1, 2015, with a revision on August 14, 2015. The guidance is final and being implemented at this time. **Link**: www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm407292.pdf • Exemptions through the regulatory process may require a panel meeting, rulemaking, or issuance of administrative order. • Section 3054 of the 21st Century Cures Act required that FDA publish two *Federal Register* notices (FRNs) expressly related to exemptions from 510(k) for both Class I & II devices.	In FY17, CDRH (ODE and OIR) and CBER developed a decision-making framework, systematically assessed 4,030 product codes, and finalized the exemption of over 70 class I device types and over 1,000 class II device types. As the Cures Act requires FDA to perform this exercise at least once every 5 years, CDRH and CBER collaborated to establish processes and tools to complete this recurring activity with consistency, predictability, and transparency. The impact of this action (and future actions) include decreasing regulatory burdens on the medical device industry and FDA, reducing private costs and expenditures required to comply with federal regulation, increasing patient access to now-exempt devices, and reallocating FDA premarket resources toward riskier and/or innovative device types.

Performance Areas with Process Improvement Agreements	*MDUFA III Accomplishments FY 2012-FY 2016*	*FY 2017 Updates*
Emerging Diagnostics: FDA will work with industry to develop a transitional in vitro diagnostics (IVD) approach for the regulation of emerging diagnostics	CDRH held a series of meetings with industry regarding emerging diagnostics. At CDRH's suggestion, industry developed a proposal that applies the principles included in the CDRH guidance "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" to both PMAs and De Novo applications for emerging diagnostics. Using Industry's proposal as a guide, FDA agreed to pilot four emerging diagnostics proposed by industry (one in each IVD division); industry submitted three proposals, but decided not to proceed. FDA is waiting for industry to submit additional proposals to pilot, however, the Agency believes the breakthrough provisions of 21st Century Cures have sufficiently addressed this need.	FDA has continued to highlight the emerging diagnostics pilot, as well as the breakthrough program, at meetings with IVD developers. While there have been several breakthrough designations and one approval of a breakthrough IVD device, there have been no additional proposals for the emerging diagnostics pilot.

Performance Areas with Process Improvement Agreements	MDUFA III Accomplishments FY 2012-FY 2016	FY 2017 Updates
Independent Assessment: As committed, a third-party consulting firm contract assessing the devices program's review process, management systems, IT infrastructure, workload management tools, reviewer training programs, and staff turnover.	The study was done in two phases. Phase 1 focused on identifying review process improvements opportunities and Phase 2 on evaluating CDRH's progress toward implementing the consulting firm's Phase 1 recommendations and on the impact of CDRH's actions on review outcomes. **Phase 1:** The Phase 1 report affirmed that the devices program was on a path to meeting many of the challenges that were flagged in the months leading up to the enactment of MDUFA III, including such topics as sponsor communication, IT infrastructure, reviewer training, reviewer attrition, and submission quality. The report provided 11 recommendations intended to further improve the medical device review process by reducing total review times and improving predictability, consistency, and transparency. As required, following the issuance of the Phase 1 recommendations, CDRH published a Plan of Action outlining the actions the center was planning to take to address the specific recommendations (Stage 1 actions). CDRH's Plan of Action also identified long-term actions that looked beyond the Phase 1 recommendations to further improve CDRH processes (Stage 2 actions). **Phase 2:** CDRH formed 14 working groups to implement the CDRH Plan of Action and committed to completing all Stage 1 actions by December 31, 2015. The Center successfully completed all Stage 1 actions and some Stage 2 actions by its self-imposed due date. The consulting firm issued the Phase 2 report, an evaluation of the actions taken by CDRH, on February 2016 (report available at https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM484146.pdf). The report acknowledged that "CDRH successfully completed each project in its Plan of Action to address Booz Allen's recommendations, which represents a significant accomplishment by the Center across a broad range of areas in its medical device review program, and satisfies FDA's commitment to fulfill the recommendations from the Independent Assessment."	To date, CDRH has implemented and completed Stage 2 actions for each of the 11 recommendations. Of note, CDRH has completed the following: Document Control System (DCS): The DCS serves as a repository for internal documents (e.g., SOPs, Work Instructions, review tools). The DCS ensures CDRH staff utilize the correct and most current policies and procedures. The DCS includes templates for SOPs and Work Instructions that are intended to standardize the format and ensure each document contains the appropriate level of information. The DCS is an important component of the Quality Management System. Decision Making Consistency process improvements: CDRH has issued a Critical Control Points SOP that identifies the critical components of premarket review documentation and decision making. CDRH has also issued "smart" review memorandum templates for the 510(k), De Novo, and Pre-Submission programs. These memorandum templates are intended to standardize the documentation for each submission type. The templates are periodically updated to ensure consistency with guidance documents and current review practice. Additionally, CDRH implemented the Focal Point pilot program. The Focal Point program is intended to identify and utilize subject matter experts on cross-cutting topics such as biocompatibility. The Focal Point experts train staff on baseline competencies for the respective topic and serve as consultants for the premarket review should the content exceed the lead reviewer's knowledge. CDRH has begun its internal assessment of the implementation activities in preparation for the Independent Assessment that is committed to occur in MDUFA IV.

Appendices

Appendix A: FY 2016 Updated Review Performance Details

The following table provides additional performance detail on FY 2016 applications worked on under the MDUFA III performance goals, otherwise known as the MDUFA Cohort [A]. When calculating Current Performance [E], the numerator is the number reviewed On Time [B] divided by Total MDUFA Cohort [A] minus all submissions Pending within Goal [D]. Therefore, Current Performance [E] = [B] / ([A] - [D]).

Highest Possible Performance represents the scenario where all pending applications are reviewed within their goal dates. [F] is calculated by adding all the reviews Pending within Goal [D] to those already reviewed On Time [B] divided by the Total MDUFA Cohort [A]. Therefore, Highest Possible Performance [F] = ([B] + [D]) / [A].

FY 2016 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
PMA, Panel-Track PMA Supplements, and Premarket Reports							
Substantive Interaction	73	72	1	0	95%	99%	99%
Decision with no Advisory Committee Input	72	61	0	11	90%	100%	100%
Decision with Advisory Committee Input	1	1	0	0	80%	100%	100%
180-Day PMA Supplements							
Substantive Interaction	207	202	5	0	95%	98%	98%
Decision	199	195	2	2	95%	99%	99%
Real-Time PMA Supplements							
Decision	321	320	1	0	95%	99%	99%
510(k) Premarket Notifications							
Substantive Interaction	3,411	3,270	137	4	95%	96%	96%
Decision	3,071	2,951	73	47	95%	98%	98%
CLIA Waiver by Applications							
Substantive Interaction	9	9	0	0	95%	100%	100%
Decision with No Advisory Committee Input	9	9	0	0	95%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	--*	--
Dual 510(k) and CLIA Waiver by Applications							
Substantive Interaction	1	1	0	0	95%	100%	100%

Decision with No Advisory Committee Input	1	1	0	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	--*	--

* No actions in this submission type were completed in FY 2016; therefore, no performance can be reported.

FY 2016 Updated Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
BLAs							
Priority Original BLAs	1	1	0	0	90%	100%	100%
Standard Original BLAs	26	26	0	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	47	47	0	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	1	1	0	0	90%	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	2	2	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	28	28	0	0	90%	100%	100%

* No actions in this submission type were completed in FY 2016; therefore, no performance can be reported.

Appendix B: FY 2017 Preliminary Review Performance Details

The following table provides additional performance detail on FY 2017 applications worked on under the MDUFA III performance goals, otherwise known as the MDUFA Cohort [A]. When calculating Current Performance [E], the numerator is the number reviewed On Time [B] divided by Total MDUFA Cohort [A] minus all submissions Pending within Goal [D]. Therefore, Current Performance [E] = [B] / ([A] - [D]).

Highest Possible Performance represents the scenario where all pending applications are reviewed within their goal dates. [F] is calculated by adding all of the reviews Pending within Goal [D] to those already reviewed On Time [B] divided by the Total MDUFA Cohort [A]. Therefore, Highest Possible Performance [F] = ([B] + [D]) / [A].

FY 2017 Preliminary Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
PMA, Panel-Track PMA Supplements, and Premarket Reports							
Substantive Interaction	59	45	3	11	95%	94%	95%
Decision with No Advisory Committee Input	57	24	0	33	90%	100%	100%
Decision with Advisory Committee Input	2	0	0	2	90%	*	100%
180-Day PMA Supplements							
Substantive Interaction	280	209	8	63	95%	96%	97%
Decision	280	168	1	111	95%	99%	99%
Real-Time PMA Supplements							
Decision	302	299	2	1	95%	99%	99%
510(k) Premarket Notifications							
Substantive Interaction	3,333	2,813	84	436	95%	97%	97%
Decision	3,287	1,913	5	1368	95%	99%	99%
CLIA Waiver by Applications							
Substantive Interaction	4	3	0	1	95%	100%	100%
Decision with No Advisory Committee Input	7	5	0	2	95%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*
Dual 510(k) and CLIA Waiver by Applications							
Substantive Interaction	6	5	0	1	95%	100%	100%
Decision with No Advisory Committee Input	6	0	0	6	90%	*	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*

*No actions in this submission type were completed in FY 2017; therefore, no performance can be reported.

† Three applications were withdrawn prior to Substantive Interaction.

FY 2017 Preliminary Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
BLAs							
Priority Original BLAs	1	0	0	1	90%	*	100%
Standard Original BLAs	2	0	0	2	90%	*	100%
BLA Manufacturing Supplements Requiring Prior Approval	37	32	0	5	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	0	0	0	0	90%	*	*
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	40	12	0	28	90%	100%	100%

* No actions in this submission type were completed in FY 2017; therefore, no performance can be reported.
† One application was switched from No Advisory Committee input to Advisory Committee input.

Appendix C: MDUFA III Updates on Previous Years' Review Performance

The following tables provides additional performance detail on application cohorts worked on prior to (and including) FY 2015 under the MDUFA III performance goals, otherwise known as the MDUFA Cohort [A]. When calculating Current Performance [F], the numerator is the number reviewed On Time [B] divided by Total MDUFA Cohort [A] minus all submissions pending within Goal [D]. Therefore, Current Performance [F] = [B] / ([A] - [D]).

Highest Possible Performance represents the scenario where all pending applications are reviewed within their goal dates. Highest Possible Performance [G] is calculated by adding all of the reviews Pending within Goal [D] to those already reviewed On Time [B] divided by the Total MDUFA Cohort [A]. Therefore, Highest Possible Performance [G] = ([B] + [D]) / [A].

FY 2013 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
PMA, Panel-Track PMA Supplements, and Premarket Reports							
Substantive Interaction	45	41	4	0	65%	91%	91%
Decision with no Advisory Committee Input	27	25	2	0	70%	93%	93%
Decision with Advisory Committee Input	18	16	0	2	50%	89%	89%
180-Day PMA Supplements							
Substantive Interaction	184	171	13	0	65%	93%	93%
Decision	177	172	5	0	85%	97%	97%
Real-Time PMA Supplements							
Decision	301	299	2	0	90%	99%	99%
510(k) Premarket Notifications							
Substantive Interaction	3,767	3,539	228	0	65%	94%	94%
Decision	3,383	3,315	68	0	91%	98%	98%
CLIA Waiver by Applications							
Substantive Interaction	3	2	1	0	95%	67%	67%
Decision with no Advisory Committee Input	3	3	0	0	95%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*
Dual 510(k) and CLIA Waiver by Applications							
Substantive Interaction	0	0	0	0	95%	*	*
Decision with No Advisory Committee Input	0	0	0	0	90%	*	*

Decision with Advisory Committee Input	0	0	0	0	95%	*	*

* No submissions in this submission type were received in FY 2013; therefore, no performance can be reported.
† One application was switched from No Advisory Committee input to Advisory Committee input.

FY 2013 Updated Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
BLAs							
Priority Original BLAs	0	0	0	0	90%	*	*
Standard Original BLAs	9	9	0	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	20	20	0	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	0	0	0	0	90%	*	*
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	10	10	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	90%	*	*

* No submissions in this submission type were received in FY 2013; therefore, no performance can be reported.

FY 2014 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
PMA, Panel-Track PMA Supplements, and Premarket Reports							
Substantive Interaction	48	46	2	0	75%	96%	96%
Decision with No Advisory Committee Input	42	41	1	0	80%	98%	98%
Decision with Advisory Committee Input	6	6	0	0	70%	100%	100%
180-Day PMA Supplements							
Substantive Interaction	177	168	9	0	75%	95%	95%
Decision	172	172	0	0	90%	100%	100%
Real-Time PMA Supplements							
Decision	333	329	4	0	90%	99%	99%
510(k) Premarket Notifications							
Substantive Interaction	3,557	3,451	106	0	75%	97%	97%
Decision	3,195	3,142	53	6	93%	98%	98%
CLIA Waiver by Applications							
Substantive Interaction	13	13	0	0	95%	100%	100%
Decision with No Advisory Committee Input	14	14	0	0	95%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*
Dual 510(k) and CLIA Waiver by Applications							
Substantive Interaction	1	1	0	0	95%	100%	100%
Decision with No Advisory Committee Input	1	1	0	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*

* No actions in this submission type were completed in FY 2014; therefore, no performance can be reported.

† One application was withdrawn prior to Substantive Interaction.

FY 2014 Updated Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
BLAs							
Priority Original BLAs	0	0	0	0	90%	*	*
Standard Original BLAs	10	10	0	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	6	6	0	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	17	17	0	0	90%	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	6	6	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2	2	0	0	90%	100%	100%

* No actions in this submission type were completed in FY 2014; therefore, no performance can be reported.

FY 2015 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
PMA, Panel-Track PMA Supplements, and Premarket Reports							
Substantive Interaction	71	67	4	0	85%	94%	94%
Decision with No Advisory Committee Input	66	64	2	0	80%	97%	97%
Decision with Advisory Committee Input	5	4	0	1	80%	100%	100%
180-Day PMA Supplements							
Substantive Interaction	197	186	11	0	85%	94%	94%
Decision	194	194	0	0	90%	100%	100%
Real-Time PMA Supplements							
Decision	325	320	5	0	95%	98%	98%
510(k) Premarket Notifications							
Substantive Interaction	3,529	3,444	85	0	85%	98%	98%
Decision	3,187	3,083	103	1	95%	97%	97%
CLIA Waiver by Applications							
Substantive Interaction	10	10	0	0	95%	100%	100%
Decision with No Advisory Committee Input	11	11	0	0	95%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*
Dual 510(k) and CLIA Waiver by Applications							
Substantive Interaction	3	3	0	0	95%	100%	100%
Decision with No Advisory Committee Input	3	3	0	0	90%	100%	100%
Decision with Advisory Committee Input	0	0	0	0	95%	*	*

* No actions in this submission type were completed in FY 2015; therefore, no performance can be reported.

† One application was withdrawn prior to Substantive Interaction.

FY 2015 Updated Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Performance Goal [E]	Current Performance [F]	Highest Possible Performance [G]
BLAs							
Priority Original BLAs	2	2	0	0	90%	100%	100%
Standard Original BLAs	2	2	0	0	90%	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	19	19	0	0	90%	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	90%	*	*
Standard BLA Efficacy Supplements	1	1	0	0	90%	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	0	0	90%	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	16	16	0	0	90%	100%	100%

* No actions in this submission type were completed in FY 2015; therefore, no performance can be reported.

Appendix D: MDUFA III Process Improvement Commitments

This section presents selected portions of the MDUFA commitment letter that explain commitments related to process improvements. The complete commitment letter for MDUFA III can be found on FDA's website.[7]

I. Process Improvements

A. Submission Acceptance Criteria

To facilitate a more efficient and timely review process, FDA will implement revised submission acceptance criteria. The Agency will publish guidance outlining electronic copy of submissions (e-Copy) and objective criteria for revised "refuse to accept/refuse to file" checklists. FDA will publish draft and final guidance prior to implementation.

B. Guidance Document Development

FDA will apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents. The Agency will continue to develop guidance documents and improve the guidance development process as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. FDA will update its website in a timely manner to reflect the following:

1. The Agency's review of previously published device guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency;
2. A list of prioritized device guidance documents (an "A-list") that the Agency intends to publish within 12 months of the date this list is published each fiscal year; and
3. A list of device guidance documents (a "B-list") that the Agency intends to publish, as the Agency's guidance-development resources permit, each fiscal year.

The Agency will establish a process allowing stakeholders an opportunity to:

1. Provide meaningful comments and/or propose draft language for proposed guidance topics in the "A" and "B" lists;
2. Provide suggestions for new or different guidance documents; and
3. Comment on the relative priority of topics for guidance.

C. Third Party Review

The Agency will continue to support the third-party review program and agrees to work with interested parties to strengthen and improve the current program while also establishing new procedures to improve transparency. The Agency will continue to

[7] www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452538.htm

improve the third-party review program as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.

D. Patient Safety and Risk Tolerance

FDA will fully implement final guidance on the factors to consider when making benefit-risk determinations in medical device premarket review. This guidance will focus on factors to consider in the premarket review process, including patient tolerance for risk, magnitude of the benefit, and the availability of other treatments or diagnostic tests. Over the period of MDUFA III, FDA will meet with patient groups to better understand and characterize the patient perspective on disease severity or unmet medical need. In addition, FDA will increase its utilization of FDA's Patient Representatives as Special Government Employee consultants to CDRH to provide patients' views early in the medical product development process and ensure those perspectives are considered in regulatory discussions. Applicable procedures governing conflicts of interest and confidentiality of proprietary information will be utilized for these consultations.

E. Low Risk Medical Device Exemptions

By the end of FY 2013, FDA will propose additional low risk medical devices to exempt from premarket notification. Within 2 years of such proposal, FDA intends to issue a final rule exempting additional low risk medical devices from premarket notification.

F. Emerging Diagnostics

FDA will work with industry to develop a transitional in vitro diagnostics approach for the regulation of emerging diagnostics.

G. Training

Prior to the commencement of MDUFA III, CDRH will implement its Reviewer Certification Program. FDA commits to holding a minimum of two medical device Vendor Days each year. CDRH will apply user fee revenues to supplement the following training programs:

1) Management training for Branch Chiefs and Division Directors.
2) MDUFA III Training Program for all staff.
3) Reviewer Certification Program for new CDRH reviewers. FDA will publish the curriculum of this program and other course offerings. FDA will consider comments from stakeholders when making updates to courses and determining course offerings.
4) Specialized training to provide continuous learning for all staff.

Appendix E: Definitions of Key Terms

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

- PMA under section 515;
- a premarket notification under section 510(k);
- an application for an IDE under section 520(g);
- 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 paper 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 filed (PMA). FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted (510(k)) or filed (PMA).

D. MDUFA Decisions: Original PMAs: Decisions for Original PMAs are Approval, Approvable, Approvable Pending GMP Inspection, Not Approvable, Withdrawal, and Denial. 180-Day PMA Supplements: Decisions for 180-Day PMA Supplements include Approval, Approvable, and Not Approvable. Real-Time PMA Supplements: Decisions for Real-Time PMA supplements include Approval, Approvable, and not Approvable. 510(k)s: Decisions for 510(k)s are SE or NSE. CLIA Waiver by Applications: Decisions for CLIA Waiver by Applications are Approval, Withdrawn, and Denial. Decisions for BLAs are complete response and approval. BLAs have many application categories: Priority Original, Standard Original, Priority Efficacy Supplements, Standard Efficacy Supplements, Manufacturing Supplements Requiring Prior Approval, Class 1 Original BLA and BLA Efficacy Supplement Resubmissions, and Class 2 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 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, if the requested feedback meets the criteria for a Pre-Submission, outlined above, FDA will contact the sponsor, and with the concurrence of the sponsor, may convert the request to a Pre-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. 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 prior to the Substantive Interaction goal date will qualify as a Substantive Interaction. If substantive issues that would warrant 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.

G. 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 1 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 1 category)
(i) Other minor clarifying information (determined by the Agency as fitting the Class 1 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 2 resubmitted applications – resubmissions that include any other items, including any item that would require presentation to an advisory committee.

Appendix F: 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 the Food and Drug Administration (FDA or the Agency) 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 and regulatory requirements applicable to a device type under 513(g), and postmarket device surveillance plan submissions (also known as a "section 522 plan"). FDA reports that, between FY 2013 and FY 2017, FDA met statutory timelines for issuing a final decision on a De Novo request 37 to 65 percent of the time; responded to 513(g) requests within the statutory timeframe 27 to 38 percent of the time; and met the statutory timeframe for responding to a section 522 plan 39 to 79 percent of the time.

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.

De Novo Requests Under 513(f)(2)	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Total number of De Novo requests submitted	48	42	60	54	101
Total number of De Novo requests with a Granted, Declined, or Withdrawn decision	41	36	52	43	25
Number on which FDA made a Granted, Declined, or Withdrawn decision within the statutory timeframe of 120 days*	24	18	19	27	21
Percent that met the statutory timeframe†	59%	50%	37%	56%	62%
Requests for Information About Classification and Regulatory Requirements Applicable to a Device Type Under 513(g)	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
Total number of requests for classification under 513(g)	102	95	103	110	134
Number to which FDA responded within the statutory timeframe of 60 days	39	26	30	36	29
Percent that met the statutory timeframe‡	38%	27%	29%	33%	26%
Postmarket Surveillance Plans	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
Total number of postmarket surveillance plans submitted	214	51	40	43	14
Number of FDA responses within 60 days of receipt	84	38	16	22	11
Percent that met the statutory timeframe	39%	75%	40%	51%	79%

* Other De Novo final decisions include Deleted and Jurisdiction Transferred.

† This metric is defined as the number of De Novos with a Granted/Declined/Withdrawn decision with 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 of longer than 120 FDA days as of the cutoff date.

‡ This metric 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.

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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