FY 2015

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee Amendments

Food and Drug Administration
Department of Health and Human Services

Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA's) Fiscal Year (FY) 2015 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 thirteenth report on medical device user fee review performance, and the third report to reflect the more challenging goals set under MDUFA III.

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. MDUFA III represents a commitment between the U.S. medical device industry and FDA to increase the efficiency of regulatory processes in order 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 2015, the third year of MDUFA III. Preliminary data for performance goals through September 30, 2015, including completed and pending reviews, indicate that FDA has met, or has the potential to meet, all 18 of the performance goals for which FDA received submissions in FY 2015. The steps FDA is taking to continue to improve predictability, consistency, and transparency in the device review process are listed on FDA's website.[1]

We believe the actions that FDA has taken and plans to take under MDUFA III will have a positive impact on the device review process. These completed and planned 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.

Robert M. Califf, M.D.
Commissioner of Food and Drugs

[1] www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm239448.htm

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

IMDRF – International Medical Device Regulators Forum

MDUFA – Medical Device User Fee Amendments

NSE – Not Substantially Equivalent

PMA – Premarket Approval Application

RCP – Reviewer Certification Program

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 (FY 2013 through FY 2017, referred to as MDUFA III).

This report presents updated data on FDA's success in meeting FY 2014 review performance goals and preliminary data on meeting FY 2015 review performance goals and commitments under MDUFA III as of September 30, 2015.

FY 2014 Performance

FDA saw continued high review performance on the new goals under MDUFA III in FY 2014. As of September 30, 2015, FDA had completed actions in 17 of the 21 goal categories. For the first time, FDA received submissions in the categories of Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application, Standard Biologics License Application (BLA) Efficacy Supplement, and Class 2 Original BLA and BLA Efficacy Supplement Resubmission. FDA is currently exceeding all 17 performance goals where actions were taken, but there are 5 open cohorts. The only open cohort with performance still pending is the Premarket Approval Application (PMA), Panel-Track PMA Supplement, and Premarket Report Decision with Advisory Input cohort. The other four open cohorts will definitely exceed their performance goals.

FY 2015 Performance

FDA saw a continual improvement in performance in FY 2015. As of September 30, 2015, FDA had completed actions in 18 of the 21 goal categories. One additional goal category, Priority Original PMAs, received submissions in FY 2015. FDA is currently exceeding all 14 performance goals where actions were taken. With 2,088 submissions still pending within the MDUFA III goal date, representing 29 percent of the total cohort, FDA has the potential to meet or exceed all applicable performance goals for FY 2015. Of the 18 open cohorts, 5 will definitely exceed their performance goals and the other 13 cohorts' performances are still pending.

MDUFA III Process Improvements

Under MDUFA III, FDA committed to a variety of process improvements. Major process improvement accomplishments during FY 2015 include:

- The updated guidance on Refuse to Accept criteria for 510(k)s was issued and implemented during FY 2015.
- FDA completed a review of previously published device guidance documents.
- FDA launched the Patient Engagement Advisory Committee.
- FDA has completed Stage 1 for 7 of the 11 recommendations identified in Booz Allen Hamilton's MDUFA II/III Evaluation, including all 4 projects under the Quality Management recommendation. All Stage 1 actions were met by December 2015. Resources permitting, FDA will continue to implement Stage 2 actions.

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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 (FY 2013 through FY 2017, referred to as MDUFA III). MDUFA III authorizes the Food and Drug Administration (FDA) 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 commitments.

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 2014 MDUFA III cohort submissions and preliminary performance for FY 2015 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.

[2] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm
[3] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452527.htm
[4] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452535.htm

- FDA MDUFA III decisions for Original PMAs and Panel-Track Supplements are placed in six categories: approval, approvable, approvable pending current good manufacturing practice (GMP) inspection, not approvable, acceptance of withdrawal, or denial. The decision categories for 180-day PMA Supplements are approval, approvable, approvable pending current GMP 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 CLIA Waiver by Applications are withdrawn, approval, or denial. The decision categories for BLAs are approval, approvable, and not approvable. 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 decision are not included in the MDUFA 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 are refused acceptance by FDA or are withdrawn by a sponsor.

- As agreed upon with industry, all references to *FDA days* are those calendar days when a submission is considered to be 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 rounded down to 99 percent.

- *Filing status* refers to whether the review committee has made a determination 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.

- Preliminary performance for FY 2015 submissions is shown as the percentage of submissions reviewed on time as of September 30, 2015, 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, 2015.

Submission Types Included in This Report

- **Premarket Approval Application (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, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.
- **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, that is, substantially equivalent, to a legally marketed device that is not subject to the PMA review process. 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 so 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** – There are two options for de novo classification for new devices of low to moderate risk that are not substantially equivalent to an existing class I or class II device and for which general or general and special controls are sufficient to ensure a reasonable assurance of safety and effectiveness.
    - Option 1: Any sponsor who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a de novo request for FDA to make a risk-based evaluation for classification of the device into Class I or II.
    - Option 2: Any sponsor who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a de novo request for FDA to make a risk-based classification of the device into Class I or II, without first submitting a 510(k) and receiving an NSE determination.
- **Biologics License 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, it's 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.
- **IDE**: A device, including a transitional device that is the object of an investigation. Investigational Device Exemption (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.

Sources:

BLAs – http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm

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

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

MDUFA III Performance Goals and Commitments

The following tables present 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 PMAs filed submissions with no Advisory Committee input	180 FDA days	70%	80%	80%	90%	90%
Decision for PMAs 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 2014 Updated Review Performance

The table below presents updated FY 2014 MDUFA performance. Further details can be found in the MDUFA III Quarterly Performance Reports posted on FDA's website.[5]

- *Review Progress* presents the number of submissions that had actions taken before the end of FY 2015, plus submissions pending but overdue as of September 30, 2015, whether or not they met the MDUFA goal date.
- *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, 2015, is shown in bold text. Of the 21 goal categories, 17 received submissions for the FY 2014 cohort. Actions were taken in all 17 of these categories, and FDA is currently exceeding all 17 performance goals, with the potential to meet or exceed all 17 performance goals. 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.

FY 2014 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	48 of 48 complete	75%	**96%**	96%
Decision with no Advisory Committee input	41 of 42 complete	80%	**98%**	98%
Decision with Advisory Committee input	4 of 6 complete	70%	**75%**	83%
180-Day PMA Supplements				
Substantive Interaction	178 of 178 complete	75%	**95%**	95%
Decision	168 of 175 complete	90%	**100%**	100%
Real-Time PMA Supplements				
Decision	333 of 333 complete	90%	**99%**	99%
510(k) Premarket Notifications				
Substantive Interaction	3,553 of 3,554 complete	75%	**97%**	97%
Decision	3,165 of 3,215 complete	93%	**98%**	98%
CLIA Waiver by Applications				
Substantive Interaction	14 of 14 complete	95%	**100%**	100%
Decision with no Advisory Committee input	14 of 14 complete	95%	**100%**	100%
Decision with Advisory Committee input	0 of 0 complete	95%	--*	**--**

* No submissions were completed in FY 2014, so no performance can be reported.

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

FY 2014 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	95%	**100%**	100%
Decision with Advisory Committee input	0 of 0 complete	95%	--*	**--**
BLAs				
Priority Original BLAs	0 of 0 complete	90%	--*	--
Standard Original BLAs	10 of 10 complete	90%	**100%**	100%
BLA Manufacturing Supplements Requiring Prior Approval	6 of 6 complete	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0 complete	90%	--*	--
Standard BLA Efficacy Supplements	17 of 17 complete	90%	**100%**	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	6 of 6 complete	90%	**100%**	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2 of 2 complete	90%	**100%**	100%

* No actions were taken in FY 2014, so no performance can be reported.

FY 2015 Preliminary Review Performance

The table below presents preliminary FY 2015 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 in FY 2015 plus submissions pending but overdue as of September 30, 2015, whether or not they met the MDUFA goal date.
- *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, 2015, is shown in bold text. Of the 21 goal categories, 18 received submissions in FY 2015. Actions were taken in 14 of these categories, and FDA is currently exceeding all 14 performance goals, with the potential to meet or exceed all 18 performance goals. 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.

FY 2015 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	49 of 65 complete	85%	**92%**	94%
Decision with no Advisory Committee input	16 of 64 complete	80%	**81%**	95%
Decision with Advisory Committee input	0 of 1 complete	80%	--*	100%
180-Day PMA Supplements				
Substantive Interaction	149 of 199 complete	85%	**94%**	95%
Decision	88 of 199 complete	90%	**100%**	100%
Real-Time PMA Supplements				
Decision	265 of 326	95%	**99%**	99%
510(k) Premarket Notifications				
Substantive Interaction	2,757 of 3,187 complete	85%	**98%**	98%
Decision	1,817 of 3,159 complete	95%	**99%**	99%
CLIA Waiver by Applications				
Substantive Interaction	10 of 11 complete	95%	**100%**	100%
Decision with no Advisory Committee input	5 of 11 complete	95%	**100%**	100%
Decision with Advisory Committee input	0 of 0 complete	95%	--*	**--**
Dual 510(k) and CLIA Waiver by Application				
Substantive Interaction	1 of 3 complete	95%	100%	100%

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

Decision with no Advisory Committee input	0 of 3 complete	95%	--*	100%
Decision with Advisory Committee input	0 of 0 complete	95%	--*	**--**
BLAs				
Priority Original BLAs	2 of 2 complete	90%	**100%**	100%
Standard Original BLAs	2 of 2 complete	90%	**100%**	100%
BLA Manufacturing Supplements Requiring Prior Approval	18 of 18 complete	90%	**100%**	100%
Priority BLA Efficacy Supplements	0 of 0 complete	90%	--*	--
Standard BLA Efficacy Supplements	0 of 1 complete	90%	--*	100%
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	0 of 16 complete	90%	--*	100%

* No actions were taken in FY 2015, so no performance can be reported.

MDUFA Review Workloads: FY 2010 through FY 2015

The table below compares the review workloads for the period FY 2010 to FY 2015. Workload in FY 2015 was equal to or greater than the previous 5-year average for 7 of the 13 workload categories where submissions were received in FY 2015 and a 5-year average was calculable. Submission types with reduced workloads generally had low numbers of submissions, even in earlier years.

Workload by Submission Type

Submission Type	FY10	FY 11	FY 12	FY 13	FY 14	FY 15	FY 10 to FY 14 5-Year Average	FY 15 Compared to 5-Year Average
PMAs, Panel-Track PMA Supplements, and Premarket Reports*								
PMAs, Panel-Track PMA Supplements, and Premarket Reports – Total Accepted	60	52	38	45	48	65	49	+ 33%
PMAs, Panel-Track PMA Supplements, and Premarket Reports – MDUFA Cohort	59	52	38	45	48	65	48	+ 35%
180-Day PMA Supplements								
180-Day PMA Supplements – Total Accepted	164	156	223	186	179	206	182	+ 13%
180-Day PMA Supplements – MDUFA Cohort	139	139	203	178	175	199	167	+ 19%
Real-Time PMA Supplements								
Real-Time PMA Supplements – Total Accepted	271	246	308	311	341	340	295	+ 15%
Real-Time PMA Supplements – MDUFA Cohort	259	236	297	301	333	326	285	+ 14%
510(k) Premarket Notifications								
510(k) Premarket Notifications – Total Accepted[§]	3,935	3,877	4,045	3,914	3,655	3,278	3,885	- 16%
510(k) Premarket Notifications – MDUFA Cohort	3,187	3,231	3,392	3,412	3,215	3,159	3,287	- 4%
***De Novo* Requests**								
De Novo Requests[†]	--	--	--	48	42	60	-- [‡]	--
CLIA Waiver by Applications								
CLIA Waiver by Applications – Receipts[†]	--	--	--	3	14	11	-- [‡]	--
Dual 510(k) and CLIA Waiver by Applications								
Dual 510(k) and CLIA Waiver by Applications – Receipts[†]	--	--	--	0	1	3	-- [‡]	--

* New reporting requirement combines Original PMAs and Expedited PMAs and represents the receipt cohort.
† Total Receipts and MDUFA cohort are equal.
‡ Due to changing reporting requirements, no 5-year average is available.
§ Submissions received on or before September 30, 2015, but that are accepted after this date will increase the counts of accepted submissions and affect the workload comparisons. The numbers of accepted submissions for FYs 2014 and 2015 are likely to increase.

Workload by Submission Type (continued)

Submission Type	FY 10	FY 11	FY 12	FY 13	FY 14	FY 15	FY 10 to FY 14 5-Year Average	FY 15 Compared to 5-Year Average
BLAs								
Priority Original BLAs*	0	0	0	0	0	2	0	-- †
Standard Original BLAs*	0	1	13	9	10‡	2	7	- 71%
BLA Manufacturing Supplements Requiring Prior Approval*	83	37	28	20	6	18	35	- 49%
Priority BLA Efficacy Supplements*	0	0	0	0	0	0	0	-- †
Standard BLA Efficacy Supplements*	1	1	1	0	17	1	4	- 75%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions*	0	0	5	10	6	1	4	- 75%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions*	1	4	1	0	2	16	2	+ 700%

* Total Receipts and MDUFA cohort are equal.
† The percent change cannot be calculated as no submissions were received in FY 2015 or 5 year average is zero.
‡ The 2014 report showed 12, but two were placeholders for lot release

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) cohort. FDA has not met the decision threshold for the FY 2013, FY 2014, and FY 2015 PMA cohorts. The average total time to decision for the FY 2013 510(k) cohort is 124 total days based on the prescribed calculation methods for the Shared Outcome Goal. FDA has not met the decision threshold for the FY 2014 and FY 2015 510(k) cohorts. 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	*	*	*	*	*
510(k)					
Performance Goal	135	135	130	130	124
Current Performance	124	*	*	*	*

* As of September 30, 2015, these cohorts have not met the decision threshold to calculate performance

Training

As part of the MDUFA III agreement, the Center for Devices and Radiological Health (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 2015, CDRH provided 499 learning events that addressed: reviewer training; new scientific technologies; law, regulation, and guidance updates; and leadership and professional development. In addition, CDRH updated the RCP curriculum to include training

on 510(k) Program guidance. In FY 2015, a total of 177 CDRH review staff participated in RCP training. 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 2015, 290 medical device review staff participated in ELP, visiting a total of 24 sites. 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.[7] The Center for Biologics Evaluation and Research (CBER) continued the Device Review Updates sessions intended to provide to CBER reviewers monthly updates regarding the latest guidance documents published and other issues related to review of medical device submissions handled by CBER. CBER also developed and presented detailed training on the 510(k) process. The training consisted of three sessions in which all device reviewers conducting reviews for 510(k)s and their supervisors were required to participate.

[7] http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109210.htm#

Process Improvement Accomplishments

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

Performance Area	Process Improvement Agreements	MDUFA III Accomplishments
Pre-Submissions	Institute a structured process for managing Pre-Submissions, and to continue to improve the Pre-Submission process as resources permit.	• Final guidance issued February 2014 ("Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff"). That guidance established such a structured process with clear recommendations for sponsors who submit Pre-Submissions, and for FDA staff and managers involved in their review, as well as expected timeframes for scheduling meetings. • Link: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf
Submission Acceptance Criteria	Implement revised submission acceptance criteria.	• 510(k) Refuse to Accept policy guidance update issued August 4, 2015 and implemented on October 1, 2015. • Link: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm315014.pdf • The Refuse to Accept 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: http://ww.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf

Performance Area	Process Improvement Agreements	MDUFA III Accomplishments
Interactive Review	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.	• 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: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm341948.pdf

Performance Area	Process Improvement Agreements	MDUFA III Accomplishments

Guidance Document Development	Apply user fees (as resources permit) to improve the process of developing, reviewing, tracking, issuing, and updating guidance documents.	• CDRH FY 2015 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/Overview/MDUFAIII/ucm321367.htm
		• FDA established and implemented a process, including the establishment of a public docket (FDA-2012-N-1021), allowing stakeholders to provide comments on the priority of topics for guidance, and/or propose draft language for proposed guidance topics, provide suggestions for new or different guidance documents, and comment on the applicability of guidance documents previously issued.
		• On June 5, 2014, CDRH held an all-day Public Workshop on Guidance Development and Prioritization. In response to feedback received at the workshop, CDRH has done the following:
		  • Revised its templates for new draft guidance documents by adding the watermark "DRAFT" to all pages in order to more conspicuously mark the guidance as not for implementation
		  • Listed draft guidances separately from final guidances on CDRH's guidance website, to more clearly distinguish draft from final guidances
		  • Committed to performance goals for current and future draft guidance documents to ensure timely finalization of draft guidance
		  • Obtained early stakeholder input on guidances in development
		  • Performed a retrospective review of published final guidances (ongoing) in 10 year increments to help ensure guidances remain relevant
		• 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 2015, CDRH issued two leapfrog draft guidances, "Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices" (http://ww.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm433165.pdf) and "Radiation Biodosimetry Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427866.pdf).

Performance Area	Process Improvement Agreements	MDUFA III Accomplishments
Third Party Review	Support the third party review program and to work with interested parties to strengthen and improve the current program (as resources permit) while also establishing new procedures to improve transparency.	• The number of Third Party submissions increased slightly from 84 in FY 2014 to 85 in FY 2015. The median FDA review time for closed submissions that have been reviewed by a Third Party decreased from 29 days in FY 2014 to 25.5 days in FY 2015.
Patient Safety and Risk Tolerance	Fully implement final guidance on the factors to consider when making benefit-risk determinations in medical device premarket review.	• FDA issued final guidance in April 2015 on "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval." • Link: • http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393994.pdf://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: http://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: http://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: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/default.htm
Low Risk Medical Device Exemptions	By the end of FY 2015, FDA intends to issue a final guidance on exemption criteria from premarket notification for low risk medical devices.	• The draft guidance "Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements" issued and was announced in the Federal Register on August 1, 2014. The final guidance issued on July 1, 2015, with a revision on August 14, 2015. The guidance is final and being implemented at this time. • Link: http://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.

Performance Area	Process Improvement Agreements	MDUFA III Accomplishments
Emerging Diagnostics	FDA will work with industry to develop a transitional In Vitro Diagnostics 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 (1 in each IVD division); industry submitted two proposals. One proposal was subsequently withdrawn by the sponsor and FDA is currently working with the remaining sponsor on their submission.

Independent Assessment of the Premarket Review Process	Participate, with the device industry, in a comprehensive assessment of the process for the review of device applications.	• A third party consulting firm assessed the Devices Program's review process, management systems, IT infrastructure, workload management tools, reviewer training programs and staff turnover.
		• CDRH's Plan of Action was released in June 2014.
		• Link: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm400674.pdf
		• The Final Report on Findings and Recommendations, released in June 2014, affirms that the Devices Program is 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.
		• Final report link: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm400676.pdf
		• Phase 2 of this contract was awarded in July 2014.
		• CDRH released its final Plan of Action on December 2014 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM426392.pdf
		  • FDA has completed Stage 1 for 7 of the 11 recommendations identified in Booz Allen Hamilton's MDUFA II/III Evaluation, including all 4 projects under the Quality Management recommendation. All Stage 1 actions were met by December 2015.
		  • Resources permitting, FDA will continue to implement Stage 2 actions.

Appendices

Appendix A: FY 2014 Updated Review Performance Details

The following table provides additional performance detail on FY 2014 applications worked on, to 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 2014 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Current Performance [E]	Highest Possible Performance [F]
PMA, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	48	46	2	0	96%	96%
Decision with no Advisory Committee input	42	40	1	1	98%	98%
Decision with Advisory Committee input	6	3	1	2	75%	83%
180-Day PMA Supplements						
Substantive Interaction	178	169	9	0	95%	95%
Decision	175	168	0	7	100%	100%
Real-Time PMA Supplements						
Decision	333	330	3	0	99%	99%
510(k) Premarket Notifications						
Substantive Interaction	3,554	3,442	111	1	97%	97%
Decision	3,215	3,115	50	50	98%	98%
CLIA Waiver by Applications						
Substantive Interaction	14	14	0	0	100%	100%
Decision with no Advisory Committee input	14	14	0	0	100%	100%
Decision with Advisory Committee input	0	0	0	0	--*	--
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	1	1	0	0	100%	100%
Decision with no Advisory Committee input	1	1	0	0	100%	100%
Decision with Advisory Committee input	0	0	0	0	--*	--

* No actions 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]	Current Performance [E]	Highest Possible Performance [F]
BLAs						
Priority Original BLAs	0	0	0	0	--*	--
Standard Original BLAs	10†	10	0	0	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	6	6	0	0	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	--*	--
Standard BLA Efficacy Supplements	17	17	0	0	100%	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	6	6	0	0	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	2	2	0	0	100%	100%

* No actions were completed in FY 2014; therefore no performance can be reported.
† The 2014 report showed 12, but two were placeholders for lot release

Appendix B: FY 2015 Preliminary Review Performance Details

The following table provides additional performance detail on FY 2015 applications worked on, to 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 2015 Preliminary Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Current Performance [E]	Highest Possible Performance [F]
PMA, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	65	45	4	16	92%	94%
Decision with no Advisory Committee input	64	13	3	48	81%	95%
Decision with Advisory Committee input	1	0	0	1	--*	100%
180-Day PMA Supplements						
Substantive Interaction	199	140	9	50	94%	95%
Decision	199	88	0	111	100%	100%
Real-Time PMA Supplements						
Decision	326	262	3	61	99%	99%
510(k) Premarket Notifications						
Substantive Interaction	3,187	2,698	59	430	98%	98%
Decision	3,159	1,791	26	1,342	99%	99%
CLIA Waiver by Applications						
Substantive Interaction	11	10	0	1	100%	100%
Decision with no Advisory Committee input	11	5	0	6	100%	100%
Decision with Advisory Committee input	0	0	0	0	--*	--
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	3	1	0	2	100%	100%
Decision with no Advisory Committee input	3	0	0	3	--*	100%
Decision with Advisory Committee input	0	0	0	0	--*	--

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

FY 2015 Preliminary Review Performance Details (continued)

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Current Performance [E]	Highest Possible Performance [F]
BLAs						
Priority Original BLAs	2	2	0	0	100%	100%
Standard Original BLAs	2	2	0	0	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	18	18	0	0	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	--*	--
Standard BLA Efficacy Supplements	1	0	0	1	--*	100%
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	1	1	0	0	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	16	0	0	16	--*	100%

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

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

The following table provides additional performance detail on applications worked on prior to FY 2014, to 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 2013 Updated Review Performance Details

Submission Type	Total MDUFA Cohort [A]	On Time [B]	Overdue [C]	Pending within Goal [D]	Current Performance [E]	Highest Possible Performance [F]
PMA, Panel-Track PMA Supplements, and Premarket Reports						
Substantive Interaction	45	41	3	1	93%	93%
Decision with no Advisory Committee input	27†	25	1	1	96%	96%
Decision with Advisory Committee input	18	15	1	2	94%	94%
180-Day PMA Supplements						
Substantive Interaction	182	171	11	0	94%	94%
Decision	175	171	4	0	98%	98%
Real-Time PMA Supplements						
Decision	301	299	2	0	99%	99%
510(k) Premarket Notifications						
Substantive Interaction	3,772	3,538	234	0	94%	94%
Decision	3,382	3,314	68	0	98%	98%
CLIA Waiver by Applications						
Substantive Interaction	3	2	1	0	67%	67%
Decision with no Advisory Committee input	3	3	0	0	100%	100%
Decision with Advisory Committee input	0	0	0	0	--*	--
Dual 510(k) and CLIA Waiver by Applications						
Substantive Interaction	0	0	0	0	--*	--
Decision with no Advisory Committee input	0	0	0	0	--*	--
Decision with Advisory Committee input	0	0	0	0	--*	--

* No submissions 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]	Current Performance [E]	Highest Possible Performance [F]
BLAs						
Priority Original BLAs	0	0	0	0	--*	--
Standard Original BLAs	9	9	0	0	100%	100%
BLA Manufacturing Supplements Requiring Prior Approval	20	20	0	0	100%	100%
Priority BLA Efficacy Supplements	0	0	0	0	--*	--
Standard BLA Efficacy Supplements	0	0	0	0	--*	--
Class 1 Original BLA and BLA Efficacy Supplement Resubmissions	10	10	0	0	100%	100%
Class 2 Original BLA and BLA Efficacy Supplement Resubmissions	0	0	0	0	--*	--

* No submissions were received in FY 2013; 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.[8]

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 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

[8] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452538.htm

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 two 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:

- an application for premarket approval under section 515;
- a premarket notification under section 510(k);
- an application for investigational device exemption 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 (e-Copy): 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 Withdrawn, Approval, and Denial. 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 investigational device exemption (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 in order 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 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.

G. BLA-related Definitions:

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

Class 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

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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