FY 2015

PERFORMANCE REPORT TO CONGRESS

for the

Prescription Drug User Fee Act

Food and Drug Administration
Department of Health and Human Services

Commissioner's Report

I am pleased to present to the President and Congress the Food and Drug Administration's (FDA or the Agency) Fiscal Year (FY) 2015 Prescription Drug User Fee Act (PDUFA) Performance Report. This report marks the 23rd year of PDUFA and the third year of PDUFA V (FY 2013 through FY 2017).

This report presents updated data on FDA's progress in meeting FY 2014 performance goals, preliminary data on meeting FY 2015 review performance goals, and other commitments under PDUFA V as of September 30, 2015.

One of the key programs under PDUFA V has been the new molecular entity (NME) review program. As of September 30, 2015, FDA has received more than 160 applications through this program since its inception, which involves more communication and transparency between the applicant and FDA review team during review of the marketing application. The FY 2014 program cohort is nearly closed, with 96 percent of applications acted on within the goal date. The FY 2015 program cohort has received 59 applications and, as of the end of FY 2015, 100 percent of actions taken on applications within this cohort met the goal date. FDA will continue to focus on these highly innovative products that represent important new medicines for the American people.

We are committed to meeting all PDUFA performance goals related to human drug review. FDA continued improving performance for procedural goals in FY 2015, and the Agency will continue to strengthen efforts to improve performance in these areas while maintaining a focus on ensuring that safe, effective, and high-quality new drugs and biologics are reviewed in an efficient and predictable time frame.

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

Acronyms

BLA – Biologics License Application

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

ETASU – Elements to Assure Safe Use

FAERS – FDA Adverse Event Reporting System

FBIS – FAERS Business Intelligence Solution

FDA – Food and Drug Administration

FDASIA – Food and Drug Administration Safety and Innovation Act

FY – Fiscal Year (October 1 to September 30)

ICH – International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

IND – Investigational New Drug

MedDRA – Medical Dictionary for Regulatory Activities

NDA – New Drug Application

NIH – National Institutes of Health

NME – New Molecular Entity

PDUFA – Prescription Drug User Fee Act

PEPFAR – President's Emergency Plan for AIDS Relief

PFDD – Patient-Focused Drug Development

PMC – Postmarketing Commitment

PMR – Postmarketing Requirement

PRISM – Post-licensure Rapid Immunization Safety Monitoring

PROMPT – Prospective Routine Observational Monitoring Program Tools

REMS – Risk Evaluation and Mitigation Strategy

VAERS – Vaccine Adverse Event Reporting System

Executive Summary

PDUFA was enacted in 1992 and authorized the Food and Drug Administration (FDA or the Agency) to collect user fees from pharmaceutical and biotechnology companies for the review of certain human drug and biological products. In return, FDA commits to certain review performance goals as well as procedural and processing goals and other commitments which are part of the Agency's agreement with the regulated industry.

PDUFA must be reauthorized by Congress every 5 years. The fifth and most recent authorization (known as PDUFA V) occurred on July 9, 2012, when the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA). As directed by Congress in the FDA Amendments Act of 2007, FDA developed proposed enhancements for PDUFA V in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. These discussions led to the current set of performance goals for the FY 2013-2017 period, detailed in a document commonly known as the PDUFA Commitment Letter.[1]

This report summarizes FDA's performance in meeting PDUFA goals and commitments for FY 2014 and FY 2015, the second and third years under PDUFA V. Specifically, it updates performance data for submissions received in FY 2014 (initially reported in the FY 2014 PDUFA Performance Report) and presents preliminary data on FDA's progress in meeting FY 2015 goals. Updates on FDA's accomplishments related to additional PDUFA V commitments for FY 2015 and historical review trend data are also included. Details of FY 2014 and FY 2015 performance, review cycle data on all original NDAs and BLAs approved during FY 2015, the number and characteristics of applications filed by review division, and definitions of key terms used in this report are presented in the appendices. Descriptions of the various submission types are included on page 4.

Achievements in FY 2015

Among the changes made under PDUFA V, FDA established a modified review program (the Program) for NME NDAs and original BLAs received from October 1, 2012, through September 30, 2017. The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval by providing (1) new opportunities for communication between applicants and the FDA review team during the Agency's review of the application and (2) additional review time for FDA and applicants to address review activities that occur late in the review cycle for these highly complex applications. In FY 2014, 57 applications were received through the Program. As of September 30, 2015, 96 percent (53 of 55) of these applications were acted on within goal and two applications are pending within goal. During FY 2015, 59 applications were received and will be

[1] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

reviewed under the Program. As of September 30, 2015, 5 of these applications had been reviewed and acted on, and all of the reviews were completed on time. The remaining 54 applications are pending within their PDUFA goal dates. Additional quality metrics related to the Program and an update on the independent assessment of the Program are included in this report.

FDA's estimated[2] median approval times for standard NDA and BLA applications received in FY 2014 decreased compared to estimated median approval times in FY 2013, while priority application estimated median approval time remained the same. The preliminary data shows that the percentage of priority and standard applications filed in FY 2014 and approved during the first review cycle were 92 percent and 60 percent, respectively.

Review Performance

The FY 2014 cohort had a workload of 2,563 review actions. FDA met or exceeded the 90 percent performance level for 11 of 12 of the review performance goals.

As of September 30, 2015, FDA had completed 1,429 review actions for the FY 2015 cohort. FDA is currently meeting or exceeding 11 of 12 review performance goals for FY 2015. With 1,326 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed all 12 review performance goals for FY 2015.

Procedural and Processing Performance

FDA's workload for actions related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2014 cohort was 7,904. FDA met or exceeded the 90 percent performance level for 12 of 18 of the procedural and processing goals, with the remaining 6 goals were met with having 70 percent or higher on-time performance.

FDA is currently meeting or exceeding 11 of 18 procedural and processing goals for the FY 2015 cohort. With 1,108 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 12 of 18 procedural and processing goals for FY 2015, with 2 additional goals that could potentially exceed 86 percent on-time performance. All 18 goals have the potential to exceed 70 percent on-time performance.

Additional PDUFA V Commitments

During FY 2015, FDA made significant progress implementing other important PDUFA V commitments, including enhancing regulatory science and expediting drug development, enhancing benefit-risk assessment in regulatory decision making, enhancing and modernizing the

[2] Median approval time is estimated because an application can receive an approval after multiple review cycles, thus impacting median approval time for all applications in a given receipt cohort.

FDA drug safety system, and improving the efficiency of human drug review through required electronic submissions and standardization of electronic drug application data. These achievements, as well as information about FDA's information technology accomplishments and hiring commitment progress are included in this report.

Table of Contents

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Introduction

On July 9, 2012, the President signed Food and Drug Administration Safety and Innovation Act (FDASIA) into law, which included the reauthorization of the Prescription Drug User Fee Act (PDUFA) for FY 2013 through FY 2017, known as PDUFA V. PDUFA V continues to provide the Food and Drug Administration (FDA or the Agency) with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biologics. In return for additional resources, FDA agreed to certain review performance goals, such as reviewing and acting on NDA and BLA submissions within predictable timeframes.

Since the implementation of PDUFA I in 1992, FDA has used PDUFA resources to significantly reduce the time it takes to evaluate new drugs and biologics without compromising its rigorous standards for demonstration of safety, efficacy, and quality of new drugs and biologics before approval. The efficiency gains under PDUFA have revolutionized the drug review process in the United States and enabled FDA to ensure more timely access to innovative and important new therapies for patients.

More information on the history of PDUFA is available on the FDA website.[3]

Information Presented in This Report

This report presents PDUFA performance and workload information for two different types of goals: (1) review of applications and other submissions pertaining to human drugs and biologics and (2) meeting management and other procedural goals related to responses and notifications in the human drug review process. PDUFA workload information for these goals is included in the tables that follow on pages 5 and 8. Significant additional components of PDUFA workload that are not captured by PDUFA goals and therefore not presented in this report include review of investigational new drug (IND) applications, labeling supplements, annual reports, and the ongoing monitoring of drug safety in the postmarket setting.

PDUFA performance information related to achieving the two types of goals includes reviews of submissions pending from the previous fiscal year as well as reviews of submissions received during the current fiscal year. This report presents final performance for FY 2014 cohort submissions based on actions completed in FY 2014 and FY 2015. In addition, it includes preliminary performance for FY 2015 cohort submissions that had actions completed or due for completion in FY 2015. Final performance for FY 2015 cohort submissions will be presented in the FY 2016 PDUFA Performance Report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2015.

[3] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm

Among other changes made under PDUFA V, FDA established a modified review program (the Program) for NME NDAs and original BLAs received from October 1, 2012, through September 30, 2017. The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval by providing (1) new opportunities for communication between applicants and the FDA review team during FDA's review of the application and (2) additional review time for FDA and applicants to address review activities that occur late in the review cycle for these highly complex applications. More information on FDA's achievements related to other PDUFA V commitments can be found on pages 14 through 27 of this report.

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

- The following terminology is used throughout this document:
  - *Application* means a new, original application.
  - *Supplement* means a supplement to an approved application.
  - *Resubmission* means a resubmitted application or supplement in response to a complete response, approvable, not approvable, or tentative approval letter
  - *NME* refers only to NMEs that are NDAs (not BLAs).
  - *Submission* applies to all of the above.
  - *Review Action* refers to an FDA decision on any of the above, including an approval, a tentative approval, a complete response, or withdrawal of the submission by the sponsor.

- Under PDUFA V, the preliminary counts of NMEs in workload tables for the current fiscal year may not be discrete filed NMEs. FDA often receives multiple submissions for the same NME (e.g., different dosage forms). All are initially designated as NMEs, and once FDA approves the first of the multiple submissions, the others will be designated as non-NMEs and workload numbers will be appropriately updated in later years.

- The IND data presented in this report do not include biosimilar INDs. These data are presented in the annual BsUFA Performance Reports located on the FDA website.[4]

- FDA only files applications that are sufficiently complete to permit a substantive review. The Agency makes a filing decision within 60 days of an original application's receipt. FDA's review of an application begins once the application is received. For NME NDAs and original BLAs reviewed under the PDUFA V NME Review Program (see the PDUFA V Commitment Letter[5] for more information), the PDUFA clock begins after the conclusion of the 60-day filing period. For all other submissions, the PDUFA clock begins upon FDA's receipt of the application.

- FDA reports PDUFA performance data annually for each fiscal year receipt cohort

[4] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm
[5] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

(defined as submissions filed from October 1 to September 30 of the following year). In each fiscal year, FDA receives submissions that will have associated goals due in the following fiscal year. In these cases, FDA's performance will be reported in subsequent fiscal years, either after the Agency takes an action or when the goal becomes overdue, whichever comes first.

- Submission types (e.g., responses to clinical holds) with shorter (e.g., 30 day) review-time goals tend to have a larger percentage of reviews completed by the end of the fiscal year, and their preliminary performance is a more reliable indicator of their final performance. However, submission types (e.g., standard efficacy supplement submissions) with longer (e.g., 10 month) review-time goals tend to have a smaller percentage of reviews completed, and their preliminary performance is a less reliable indicator of their final performance.

- Final performance for FY 2014 submissions is shown as the percentage of submissions that were reviewed within the specified goal timeline. Submission types with 90 percent or more submissions reviewed by the goal date are shown as having met the goal.

- Preliminary performance for FY 2015 submissions is shown as the percentage of submissions reviewed on time as of September 30, 2015, excluding actions pending within the PDUFA goal date. Submission types with 90 percent or more submissions reviewed by the goal date are shown as currently meeting the goal. The highest possible percent of reviews that may be completed on time (highest possible performance) if all non-overdue pending reviews are completed within goal is also shown.

- FY 2015 workload and performance figures include applications that are identified as *undesignated*, which means they are still within the 60-day filing date and have not yet had a review designation, standard or priority, made.

- For resubmitted applications, the applicable performance goal is determined by the fiscal year in which the resubmission is received, rather than the year in which the original application was submitted.

- Unless otherwise noted, all performance data are as of September 30, 2015.

- Definitions of key terms used throughout this report can be found in Appendix E.

Submission Types Included in This Report

- **NDA –** When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States.
- **NME –** A new molecular entity (NME) is a drug for which the active ingredient has never before been approved or marketed in the United States in any form.
- **BLA –** A biologics license application (BLA) is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the clinical effects of a biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.
- **Resubmission –** A resubmitted original application or supplement is a complete response to an FDA action letter that addresses all identified deficiencies.
- **Supplement –** A supplement is an application to allow a company to make changes in a product that already has an approved NDA or to seek FDA approval for new uses of an approved drug. CDER must approve all major NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.
- **Source:** www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm

PDUFA Review Goals

Review Workload: FY 2010 to FY 2015

In the table below, preliminary review workload numbers from FY 2015 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements. FDA received no applications for Class 1 resubmitted NDA and BLA efficacy supplements in FY 2015, and Class 2 resubmitted NDA and BLA efficacy supplements continued to trend downward. Original priority NME and BLA submissions in FY 2015 increased 61 percent compared to the 5 year average, and original priority non-NME NDA submissions increased 75percent in FY 2015.

Workload for original applications (priority and standard) will appear different from workload reported in reports prior to FY 2013 due to different reporting requirements under PDUFA V. Definitions of Class 1 and Class 2 resubmissions and other terms are found in Appendix E.

Review Workload for Applications and Submissions

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
Original Priority NMEs and BLAs	11	14	18	19	28	29†	18	61%
Original Standard NMEs and BLAs	18	23	32	35	21	30	26	15%
Original Priority non-NME NDAs	8	8	8	8	10	14†	8	75%
Original Standard non-NME NDAs	66	56	72	76	72	78	68	15%
Class 1 Resubmitted NDAs and BLAs	12	9	6	11	7	7	9	-22%
Class 2 Resubmitted NDAs and BLAs	41	53	36	38	35	37	41	-10%
Priority NDA and BLA Efficacy Supplements	19	23	39	29	40	58‡	30	93%
Standard NDA and BLA Efficacy Supplements	125	118	108	123	165	116	128	-9%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	17	13	4	2	7	0	9	-100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	17	24	19	10	10	8	16	-50%
NDA and BLA Manufacturing Supplements requiring prior approval	967	809	872	873	776	769	859	-10%
NDA and BLA Manufacturing Supplements not requiring prior approval	1,524	1,771	1,566	1,542	1,392	1,609	1559	3%

* FY 2014 numbers were changed to reflect updates to data presented in the FY 2014 PDUFA Performance Report.
† FY 2015 numbers are preliminary. Two NME NDAs and five non-NME NDAs are included in the 'priority' rows above have an undesignated review priority as of September 30, 2015, and will be updated in the FY 2016 PDUFA Performance Report.
‡ FY 2015 numbers are preliminary. Seven efficacy supplements included in the 'priority' row above have an undesignated review priority as of September 30, 2015, and will be updated in the FY 2016 PDUFA Performance Report.

Final FY 2014 Review Performance

Final FY 2014 review goal performance is presented in the table below. Final performance for submission types that met the goal (90 percent or more reviews completed by the goal date) is shown in bold text. Applications reviewed under the Program have review goals starting from the 60-day filing date, while other submissions have goals starting from the submission receipt date. FDA met or exceeded the 90 percent performance level for 11 of 12 of the review performance goals in FY 2014. More detailed information on performance is available in Appendix A.

Submission Type	Goal: Review 90 percent within	FY 2014 Performance
Original Priority NMEs and BLAs	6 months from filing date	**96%**
Original Standard NMEs and BLAs	10 months from filing date	**95%**
Original Priority non-NME NDAs	6 months	80%
Original Standard non-NME NDAs	10 months	**97%**
Class 1 Resubmitted NDAs and BLAs	2 months	**100%**
Class 2 Resubmitted NDAs and BLAs	6 months	**97%**
Priority NDA and BLA Efficacy Supplements	6 months	**100%**
Standard NDA and BLA Efficacy Supplements	10 months	**92%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	**90%**
NDA and BLA Manufacturing Supplements requiring prior approval	4 months	**95%**
NDA and BLA Manufacturing Supplements not requiring prior approval	6 months	**96%**

Preliminary FY 2015 Review Performance

Preliminary FY 2015 review goal performance is presented in the table below.

- The review progress (the number of reviews completed or pending overdue) and the total number of submissions received for each submission type are shown in the second column. Current performance for submission types with a greater proportion of reviews completed will be more representative of final performance. Appendix B contains additional information on the completed reviews.
- Applications reviewed under the Program have review goals starting from the 60-day filing date, while other submissions have goals starting from the submission receipt date.
- Current performance for submission types that are meeting the performance goal (90 percent or more reviews completed by the goal date) as of September 30, 2015, is shown in bold text. FDA is meeting or exceeding the 90 percent performance level for 11 of 12 of the review performance goals. For FY 2015, FDA did not receive any Class 1 Resubmitted NDA and BLA Efficacy Supplements.
- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance presented in the Highest Possible Final Performance column. FDA has the potential to meet or exceed the 90 percent performance level for all 12 review performance goals.

Submission Type	Review Progress	Goal: Review 90 percent within	FY 2015 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	4 of 27 complete	6 months from filing date	**100%**	100%
Original Standard NMEs and BLAs	2 of 30 complete	10 months from filing date	**100%**	100%
Original Priority non-NME NDAs	3 of 9 complete	6 months	**100%**	100%
Original Standard non-NME NDAs	6 of 78 complete	10 months	83%	99%
Class 1 Resubmitted NDAs and BLAs	7 of 7 complete	2 months	**100%**	100%
Class 2 Resubmitted NDAs and BLAs	21 of 37 complete	6 months	**100%**	100%
Priority NDA and BLA Efficacy Supplements	18 of 51 complete	6 months	**94%**	98%
Standard NDA and BLA Efficacy Supplements	30 of 116 complete	10 months	**100%**	100%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	0 of 0 complete	2 months	**--**	--
Class 2 Resubmitted NDA and BLA Efficacy Supplements	0 of 8 complete	6 months	**--**	100%
NDA and BLA Manufacturing Supplements requiring prior approval	499 of 769 complete	4 months	**93%**	96%
NDA and BLA Manufacturing Supplements not requiring prior approval	839 of 1609 complete	6 months	**95%**	97%

PDUFA Procedural and Processing Goals and Commitments

Procedural and Processing Workload: FY 2010 to FY 2015

FY 2015 procedural and processing workload, which includes actions related to meeting management, procedural responses, and procedural notifications, is compared to the previous 5-year averages in the table below. FY 2015 workload varied moderately from past 5-year averages, with the largest increase seen in Type C Meeting Requests (up 47 percent) and the largest decrease in major dispute resolutions (down 35 percent), both continuing trends in changing workloads. Meeting type definitions and other terms can be found in Appendix E.

Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request 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
Type A Meeting Requests	234	204	184	140	160	173	184	-6%
Type B Meeting Requests	1,305	1,331	1,322	1,394	1,467	1,632	1,364	20%
Type C Meeting Requests	718	715	785	932	995	1,216	829	47%
Type A Meetings Scheduled	216	184	168	118	145	162†	166	-2%
Type B Meetings Scheduled	1,199	1,263	1,261	1,189	1,154	1,204	1,213	-1%
Type C Meetings Scheduled	613	646	725	611	543	612	628	-3%
Type B Written Response	--	--	--	153	249	364	--‡	--
Type C Written Response	--	--	--	281	393	526	--‡	--
Meeting Minutes	1,580	1,526	1,585	1,486	1,503	1,605	1,536	4%
Responses To Clinical Holds	204	176	178	161	148	161	173	-7%
Major Dispute Resolutions	7	18	32	25	33	15	23	-35%
Special Protocol Assessments	309	313	288	222	201	234	267	-12%
Review of Proprietary Names Submitted During IND Phase	102	128	164	161	170	180	145	24%
Review of Proprietary Names Submitted with NDA/BLA	207	186	216	224	209	220	208	6%
First-Cycle Filing Review Notifications: NDAs and BLAs	105	101	126	138	131	150	120	25%
First-Cycle Filing Review Notifications: Efficacy Supplements	112	95	96	99	136	117	108	8%
Notification of Planned Review Timelines: NDAs and BLAs	--	101	126	138	131	150	--‡	--
Notification of Planned Review Timelines: Efficacy Supplements	--	--	96	99	136	117	--‡	--

* FY 2014 numbers were changed to reflect updates to data presented in the FY 2014 PDUFA Performance Report.
† Includes meetings denoted as undesignated in the database.
‡ Due to changing reporting requirements, no past year average is presented for this area.

Final FY 2014 Procedural and Processing Performance

The table below presents final performance for FY 2014 submissions in meeting goals related to meeting management, procedural responses, and procedural notifications. Final performance for submission types that met the goal (90 percent or more reviews completed by the goal date) is shown in bold text. FDA exceeded the 90 percent performance level for 12 of 18 of the procedural and processing goals in FY 2014 and exceeded 70 percent performance in all categories. More detailed information on performance is available in Appendix A.

Submission/Request Type	Goal: Review 90 percent within	FY 2014 Performance
Type A Meeting Requests	14 days	**90%**
Type B Meeting Requests	21 days	**91%**
Type C Meeting Requests	21 days	88%
Type A Meetings Scheduled	30 days	73%
Type B Meetings Scheduled	60 days	71%
Type C Meetings Scheduled	75 days	80%
Type B Written Response	60 days	79%
Type C Written Response	75 days	86%
Meeting Minutes	30 days	**90%**
Responses to Clinical Holds	30 days	**93%**
Major Dispute Resolutions	30 days	**97%**
Special Protocol Assessments	45 days	**98%**
Review of Proprietary Names Submitted During IND Phase	180 days	**99%**
Review of Proprietary Names Submitted with NDA/BLA	90 days	**98%**
First-Cycle Filing Review Notifications: NDAs and BLAs	74 days	**98%**
First-Cycle Filing Review Notifications: Efficacy Supplements	74 days	**97%**
Notification of Planned Review Timelines: NDAs and BLAs	74 days	**100%**
Notification of Planned Review Timelines: Efficacy Supplements	74 days	**99%**

Preliminary FY 2015 Procedural and Processing Performance

The table below presents preliminary performance for FY 2015 submissions in achieving goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA V.

- The review progress (the number of reviews completed or pending overdue) and the total number of submissions received for each submission type are shown in the second column. More detailed information on the completed reviews is available in Appendix B.
- FDA is currently meeting or exceeding 11 of 18 procedural and processing goals with 60 percent or higher performance in all goal categories.
- If all pending submissions are reviewed on time, FDA has the potential to meet 12 of 18 goals, as seen in the Highest Possible Final Performance column.

Submission/Request Type	Review Progress	Goal: Review 90 percent within	FY 2015 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	130 of 173 complete	14 days	87%	90%
Type B Meeting Requests	1579 of 1632 complete	21 days	**91%**	91%
Type C Meeting Requests	1193 of 1216 complete	21 days	86%	87%
Type A Meetings Scheduled	109 of 162 complete	30 days	60%	73%
Type B Meetings Scheduled	1135 of 1204 complete	60 days	71%	73%
Type C Meetings Scheduled	571 of 612 complete	75 days	80%	81%
Type B Written Response	307 of 364 complete	60 days	75%	79%
Type C Written Response	427 of 526 complete	75 days	82%	86%
Meeting Minutes	1176 of 1605 complete	30 days	**90%**	93%
Responses to Clinical Holds	139 of 161 complete	30 days	**94%**	94%
Major Dispute Resolutions	12 of 15 complete	30 days	**100%**	100%
Special Protocol Assessments	204 of 234 complete	45 days	**96%**	97%
Review of Proprietary Names Submitted During IND Phase	119 of 180 complete	180 days	**100%**	100%
Review of Proprietary Names Submitted with NDA/BLA	183 of 220 complete	90 days	**99%**	100%
First-Cycle Filing Review Notifications: NDAs and BLAs	126 of 150 complete	74 days	**96%**	97%
First-Cycle Filing Review Notifications: Efficacy Supplements	97 of 117 complete	74 days	**94%**	95%
Notification of Planned Review Timelines: NDAs and BLAs	126 of 150 complete	74 days	**100%**	100%
Notification of Planned Review Timelines: Efficacy Supplements	97 of 117 complete	74 days	**99%**	99%

Meeting Planned Review Timeline Target Dates

FDA has committed to inform applicants of the planned timeline for feedback related to labeling and postmarketing requirements (PMRs) and postmarketing commitments (PMCs). This timeline must be included in a letter sent within 14 days of the 60-day filing date (known as a 74-day letter).

FDA committed to report performance in meeting the planned review timelines for communication of labeling comments and PMR/PMC requirements/requests though there is no PDUFA-related goal. This commitment includes reporting on the number and percentage of applications for which the planned target dates for communication of labeling comments and PMRs/PMCs were met. If FDA receives a major amendment after issuing the 74-day letter, the target date included is no longer applicable.

Final FY 2014 Cohort Performance

Application Type	Number of 74 Day Letters With Timelines	Target Date Inapplicable	Target Date Met	Target Date Not Met	Withdrawn	Percent of Applications Target Date Met
NDAs and BLAs	131†	6	82*	42	1	**66%**
Efficacy Supplements	135†	4	96	35	0	**73%**

* Target dates for six NDAs/BLAs and one efficacy supplement were met by communicating deficiencies.

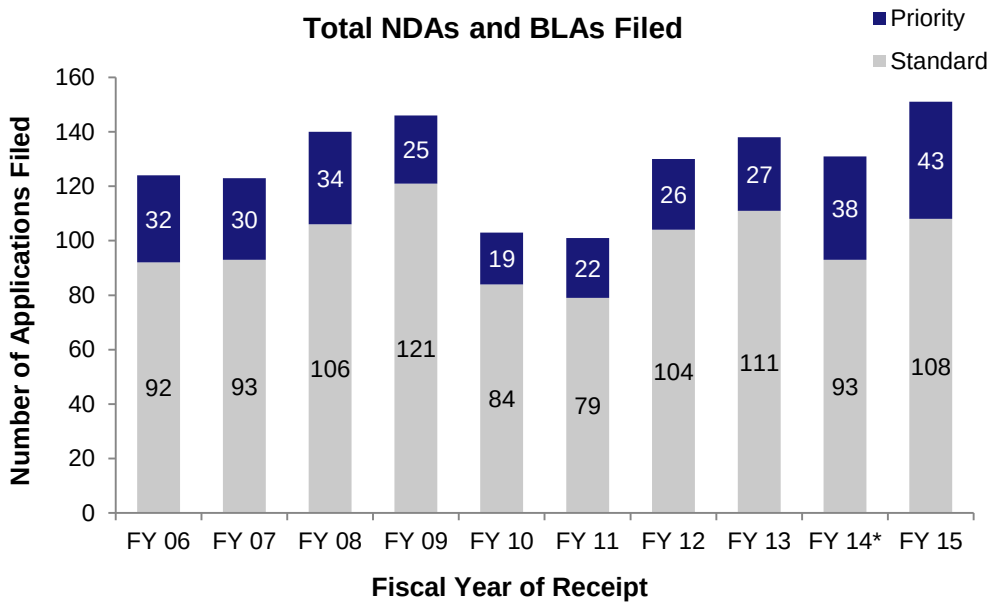
† FY 2014 numbers were changed to reflect updates to data presented in the FY 2014 PDUFA Performance Report.

Preliminary FY 2015 Cohort Performance

Application Type	Number of 74 Day Letters With Timelines	Target Date Inapplicable	Target Date Met	Target Date Not Met	Applications Pending within Target Date	Withdrawn	Percent of Applications Target Date Met
NDAs and BLAs	126	10	29	11	76	0	**73%**
Efficacy Supplements	96	3	32	14	47	0	**70%**

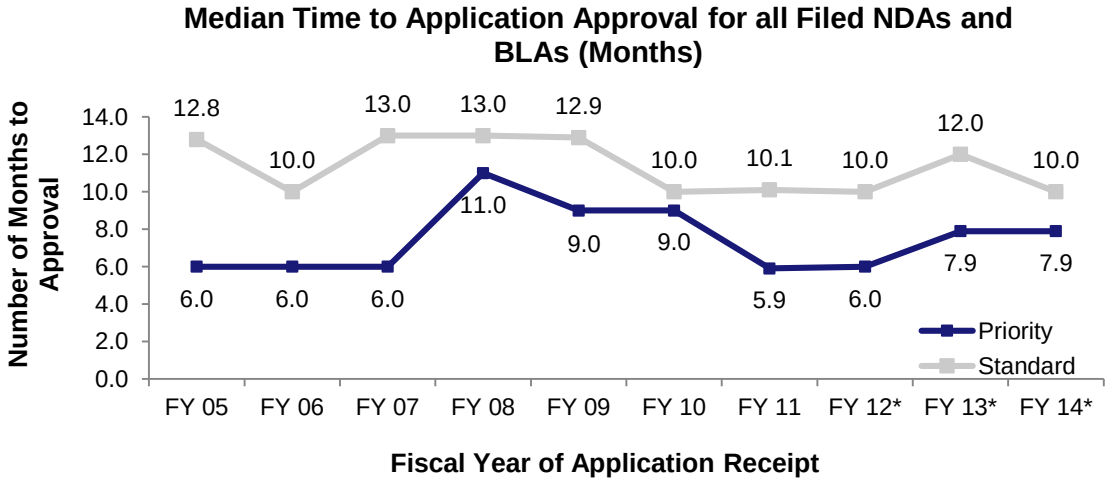
PDUFA Trend Graphs

The number of NDAs and BLAs filed from FY 2006 to FY 2015 is presented in the graph below. The total number of priority and standard applications of NDAs and BLAs filed in FY 2015 increased compared to the number filed in FY 2014.



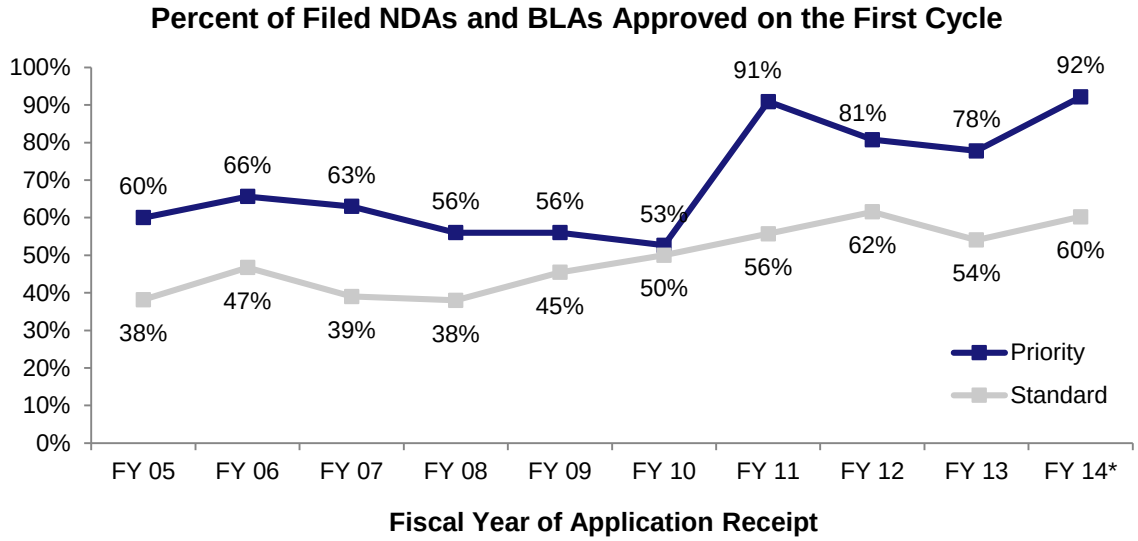
*FY 2014 numbers were changed to reflect updates to data presented in the FY 2014 PDUFA Performance Report.

Median total time to approval for priority and standard applications for FY 2005 through FY 2014 are presented in the graph below. After an increase in median approval time in FY13 compared to FY 12 and FY 11, FY14 median approval times are unchanged for priority applications and decreased to 10 months for standard applications. FY 2015 data are too preliminary to estimate the median approval time.



* The median approval times for the three most recent years are estimated.

The percentages of first-cycle approvals for priority and standard NDAs and BLAs filed from FY 2005 to FY 2014 are presented in the graph below. Standard applications saw a steady increase in first-cycle approvals from FY 2009 to FY 2012, reaching a 10-year high in FY 2012 with 62 percent of applications approved on the first cycle. Thus far for the FY 2014 cohort, which is still preliminary, 60 percent of standard applications have been approved on the first cycle. First-cycle approvals for priority NDAs and BLAs reached a new high in FY 2014, with 92 percent of applications approved on the first cycle. The FY 2015 data are too preliminary to estimate the percent of first-cycle approvals.



* First cycle approvals are still possible for FY 2014 standard applications, so the data are preliminary.

Additional PDUFA V Commitments

Section XIII of the PDUFA Commitment Letter requires FDA to report progress on the additional program enhancements identified in the following sections of the Commitment Letter:[6]

- Section IX: Enhancing Regulatory Science and Expediting Drug Development
- Section X: Enhancing Benefit-Risk Assessment in Regulatory Decision-Making
- Section XI: Enhancement and Modernization of the FDA Drug Safety System
- Section XII: Improving the Efficiency of Human Drug Review through Required Electronic Submissions and Standardization of Electronic Drug Application Data

These enhancements are designed to improve the efficiency of both drug development and the human drug review process. Section 104 of FDASIA further requires FDA to report on the Agency's plans for meeting the PDUFA V commitments. At the beginning of PDUFA V, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) convened a steering committee to oversee the implementation of PDUFA V. The committee meets approximately quarterly to review current progress and plans for future work in each area to ensure timely completion of FDA's commitments.

The progress reports in this section discuss the work FDA performed in FY 2015 on commitments in sections IX-XII of the commitment letter. Commitments that were met and reported in the FY 2014 PDUFA Performance Report are not repeated here. FDA is also including an update on accomplishments under Section XIV: Information Technology Goals. Each accomplishment includes a reference to the specific section of the commitment letter. References are also provided to published guidances, meeting summaries, and other pertinent information.

FDA is dedicated to the goals outlined in these sections of the commitment letter. Where applicable, for each section, additional information is included on other activities FDA has conducted that are not specifically required but further the goals outlined in the commitment letter.

[6] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

Section IX: Enhancing Regulatory Science and Expediting Drug Development

Commitment Title	FY15 Accomplishments

IX.A Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• FDA's enhanced communication functions are located in CDER's Office of New Drugs and CBER's Manufacturing Assistance and Technical Training Branch. During FY 2015, CDER's Enhanced Communication Team responded to 135 contacts regarding the drug development process, referred 88 contacts regarding other issues to the appropriate resources, and received 0 requests for facilitation of issues with review divisions. (IX.A.1-.6)
	
	• Identified best practices for communicating with sponsors were incorporated into existing training curricula. This training material will be updated as additional best practices are developed. A CDER working group drafted a training plan for the implementation of the principles and practices established in the draft guidance for review staff and industry describing best practices for communication between FDA and IND sponsors during drug development. This training plan will be implemented upon publication of the draft guidance. (IX.A.7)
	
	• FDA's working group developed a draft guidance for review staff and industry describing best practices for communication between FDA and IND sponsors during drug development. (IX.A.8)
	
	• Office of New Drugs (OND) published ten final guidances and 13 draft guidances. Notable new guidances include (IX.A.8):
	  ○ Alcoholism: Developing Drugs for Treatment, February 2015, draft guidance
	  ○ Abuse Deterrent Opioids: Evaluation and Labeling, April 2015, final guidance
	  ○ Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatments, June,2015, draft guidance, which was the result of a thoughtful process of CDER's engagement with the Duchenne Muscular Dystrophy patient community
	  ○ Rare Diseases: Common Issues in Drug Development, August 2015, draft guidance
	
	• FDA published an interim assessment of the Program for Enhanced Review Transparency and Communication in March 2015 and held a public meeting on this report in May 2015. (IX.A.8)
	
	• FDA-American Association for Cancer Research (AACR) workshop Dose-finding of Small Molecule Oncology Drugs in May 2015. (IX.A.1-6)
	
	• Held a public meeting in collaboration with the Brookings Institute entitled, "Improving productivity in pharmaceutical research and development: The role of clinical pharmacology and experimental medicine" on July 28, 2015. (IX.A.1-6)

IX.B. Advancing the Science of Meta-Analysis Methodologies	• FDA continued efforts in FY 2015 to recruit and hire additional statistical, epidemiological, and medical reviewers to evaluate and conduct meta-analyses to explore safety signals. (IX.B.1). • Development of a draft guidance on meta-analyses of randomized controlled clinical trials (RCTs) to evaluate safety and FDA's intended approach for the use of meta-analyses in regulatory decision-making continues through FY 2015. FDA anticipates concluding these efforts by mid FY 2016, through the publication of this draft guidance, clarifying FDA's intended approach for the use of meta-analyses in regulatory decision-making. (IX.B.2 and 3)

IX.C. Advancing the Use of Biomarkers and Pharmacogenomics	• FDA continued recruitment efforts to hire subject matter experts (SMEs) under this enhancement. Recent new hires include individuals with expertise in pharmacogenomics, molecular oncology, and biomarker development. Staff capacity is being applied in IND/NDA/BLA review through consultation with Genomics and Targeted Therapy Staff and other Clinical and Biostatistics experts in pharmacogenomics and biomarkers. (IX.C.1) • CDER conducted its second 2-day continuing education program entitled *Clinical Genomics: Scientific and Regulatory Aspects* to train review staff on various drug and diagnostic guidances that are applicable to the review of biomarkers in the investigational drug development context. This will continue to be held annually and recorded for new employees. FDA also hosted numerous internal educational lectures provided by visiting scientists and expert FDA staff on topics related to pharmacogenomics, personalized medicine, and biomarker development. (IX.C.2)
IX.D. Advancing Development of Patient Reported Outcomes (PROs) and Other Endpoint Assessment Tools	• CDER sponsored a meeting with the Brookings Institution on "Advancing Development and Use of Patient-Reported Outcomes in Drug Development: Near-Term Opportunities" held on October 6, 2014. (IX.D.1) • CDER held a public workshop on "Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges" on April 1, 2015 that satisfied a PDUFA V commitment. Workshop included discussion of the proposed Compendium of Clinical Outcome Assessments, which is currently in the clearance process. (IX.D.2)
IX.E Advancing Development of Drugs for Rare Diseases	• The Rare Disease Program (RDP) continues to support the Data Analysis Search Host (DASH) database that provides quick access to comprehensive scientific and regulatory data that is not otherwise available from a single source. This data supports analyses of rare and common diseases, new molecular entity drug and biologic actions, and major efficacy supplements (new indications and/or new populations). The database has improved our understanding of the impact of expedited development programs, informed the expedited programs and the common issues in rare diseases drug development guidances, and formed the basis of staff training. The database has proven to be an invaluable resource for evaluation of the impact of the RDP which seeks to facilitate, support and accelerate the development of drug and biologic products for the treatment of patients with rare disorders. (IX.E.6) • Published draft guidance on Rare Diseases: Common Issues in Drug Development in August 2015 • CBER initiated a project to develop human immune model for better understanding of factor VIII inhibitor development among Hemophilia A patients receiving FVIII prophylactic treatment. The goal is to help personalize the treatment for Hemophilia A patients and improve the clinical outcome. (IX.E.3) • CBER initiated a project on advancing safety and efficacy evaluation of novel pharmacokinetic-based dosing approaches for clotting proteins used in hemophilia A patients. (IX.E.3) • FDA added Chagas' disease and neurocysticercosis to the list of designated tropical diseases. This action now offers a priority review incentive to encourage the development of new drugs in these disease areas. • Several Patient Focused Drug Development (PFDD) related external presentations were held including, "Annual Rare Disease Scientific Workshop." Also presented "Myotonic Dystrophy Patient Centered Therapy Development" in September 2015. (X.C)

Section X. Enhancing Benefit-Risk Assessment in Regulatory Decision-Making

Commitment Title	FY15 Accomplishments
Implementation of a Structured Framework for Benefit-Risk Assessment in the New Drug and Biologic Review Process	• In FY 2015, CDER completed revision of four review or memo templates that incorporate the Benefit-Risk Framework into new drug review: a) the Clinical Review, b) the Cross-Discipline Team Leader Review, c) the Division Director Summary Review for Regulatory Action, and d) the Office Director Decisional Memo. In March 2015, CDER began a phased implementation of the revised templates in new drug review, beginning with the reviews of NME NDAs and Original BLAs submitted to the agency after March 1, 2015. Future phases of implementation of the revised templates into other areas of new drug review are planned for later in PDUFA V. (X.B) • Starting in March 2015, CDER's phased rollout of the revised templates for NME NDAs and original BLAs has been accompanied by: a) an internal website containing the templates, background on the Benefit-Risk Framework, and supplementary materials; b) a 3-hour training on use of the new templates, offered monthly; c) training and individual coaching by technical writing experts focused on completion of the Benefit-Risk Framework portion of the review; d) individual support to reviewers as needed. (X.D) • CBER developed and offers two training courses, "Introduction to Risk Assessment for Biologics" and "Introduction to Risk Management for Biologics" tor CBER staff every year. The courses introduce the concepts and new methodologies for benefit-risk assessment, and facilitate the implementation of a Structured Framework for Benefit-Risk in CBER regulatory review. (X.D) • In September 2015, CDER awarded a contract to a qualified third party to support an evaluation of the Benefit-Risk Framework implementation into new drug review, in accordance with the evaluation plan outlined in the 2013 Draft Implementation Plan. This evaluation is planned for two years and will: a) assess the degree to which the implemented Benefit-Risk Framework provides utility to reviewer deliberations and communications of benefit-risk considerations; and b) assess the degree to which the framework provides a clear explanation of FDA approval decisions to public stakeholders, including patients, healthcare professionals, and drug sponsors. (X.A) • FDA provided leadership on the International Conference on Harmonisation (ICH) M4E (R2) working group that produced "*Revision of M4E Guideline on Enhancing the Format and Structure of Benefit-Risk Information in ICH*" on August 5, 2015. • CBER provided a course on using data from patient preference studies in benefit-risk assessments.

Patient-Focused Drug Development (PFDD)	• FDA held seven PFDD meetings during FY 2015 on female sexual dysfunction, breast cancer, Chagas' disease, functional gastrointestinal disorders, Huntington's disease and Parkinson's disease, and alpha-1 antitrypsin deficiencies. (X.C) • PFDD summary reports published in FY 2015 (X.C): o In October 2014, FDA published the summary report of the February 2014 meeting on Sickle-Cell disease. o In October 2014, FDA published the summary report of the March 2014 meeting on Fibromyalgia. o In December 2014, FDA published the summary report of the May 2014 meeting on pulmonary arterial hypertension. o In February 2015, FDA published the summary report of the June 2014 meeting on neurological manifestations of inborn errors of metabolism. o In March 2015, FDA published the summary of the September 2014 meeting on Idiopathic pulmonary fibrosis. o In June 2015, FDA published the summary of the October 2014 meeting on female sexual dysfunction. o In September 2015, FDA published the summary of the April 2014 meeting on breast cancer. • In July 2015, FDA published the final list of eight disease areas to be addressed during fiscal years 2016–2017. The disease areas are: alopecia areata, autism, hereditary angioedema, non-tuberculous mycobacterial infections, patients who have received an organ transplant, psoriasis, neuropathic pain associated with peripheral neuropathy, and sarcopenia. (X.C) • In July 2015, FDA published guidelines for externally-led patient-focused drug development meetings, welcoming patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through PFDD as a model. (X.C) • Office of Biostatistics and Epidemiology (OBE) collaborated with Office of Cellular, Tissue and Gene Therapies (OCTGT) on a project on patient-focused decision analysis for treatment of Wiskott-Aldrich syndrome.

Section XI. Enhancement and Modernization of the FDA Drug Safety System

Commitment Title	FY15 Accomplishments
XI.A Measure the Effectiveness of Risk Evaluation and Mitigation Strategy (REMS) and Standardize and Better Integrate REMS into the Healthcare System	• FDA continued working to develop guidance on how FDA applies statutory criteria to determine whether REMS is necessary to ensure that the benefits of a drug outweigh the risks. (XI.A.1) • FDA developed a REMS data model and successfully balloted REMS data elements with HL7, in working towards incorporating REMS into SPL format (*Pharmacy Systems* REMS Priority Project). FDA also conducted outreach with HL7's Tech Team (Webinar: February 9, 2015) and NCPDP to further refine the REMS data model and data elements. REMS in SPL format is expected to be piloted publicly early in FY2016. (XI.A.2) • FDA continued working to develop guidance on methodologies for assessing REMS (XI.A.3): o Updates to Approved Risk Evaluation and Mitigation Strategies (REMS); o Brookings Institution summary of REMS/CME Meeting on May 18, 2015: "Incorporating Continuing Education into Single-Drug REMS: Exploring the Challenges and Opportunities"; o Webinar by the FDA Division of Drug Information (DDI): "*Introducing the REMS@FDA Website"* on June 23, 2015; o Center for Health Policy at Brookings and the FDA held a workshop on July 24, 2015 entitled, "Risk Evaluation and Mitigation Strategies (REMS): Building a Framework for Effective Patient Counseling on Medication Risks and Benefits," seeking input from stakeholders across academia, industry, health systems, and patient advocacy groups; and the REMS Integration Initiative. Input received from this meeting is helping to inform ongoing exploration of benefit/risk counseling practices (i.e. completion of a literature search) that will culminate in a report of findings as described under the *Providing Benefit/Risk Information to Patients* REMS Priority Project. • In May 2015, FDA participated in an expert workshop held by the Brookings Institution's Center for Health Policy (funded under a cooperative agreement with FDA) to discuss the opportunities and challenges to incorporating continuing medical education (CME) into single-drug REMS. This workshop is helping to inform ongoing exploration of the feasibility of incorporating CME into REMS programs, as proscribed by the Prescriber Education REMS PDUFA V Priority Project. Work continues on a report on FDA's findings, expected to be completed in FY 2016. (XI.A.2) • FDA launched a new REMS website on June 15, 2015 and held an introductory webinar on June 23. The changes to the website help address stakeholder concerns that the old website did not always have the information they needed (i.e. more information about the content of REMS programs, including what is required of specific stakeholders). The new REMS website presents key information found in the FDA-approved REMS document in a concise, user friendly summary. This completed the Practice Settings REMS PDUFA V priority project. (XI.A.2)
XI.B Sentinel as a Tool for Evaluating Drug Safety Issues That May Require Regulatory Action	• FDA held a workshop on February 5, 2015, to discuss a variety of topics on active medical product surveillance, including current and emerging Sentinel projects as well as projects that would be appropriate to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action. (XI.B.1)

	• FDA conducted a third-party interim assessment to evaluate the strengths, limitations, and the appropriate use of Sentinel for informing regulatory actions to manage safety issues. The assessment report was posted on the FDA's PDUFA V public website on September 24, 2015. (XI.B.3) • FDA initiated a pilot study of TreeSCAN utilizing PRISM data for the Gardasil 4 vaccine and a revised protocol for a pilot study of TreeSCAN utilizing PRISM data for the HPV4 Vaccine was posted to the Mini-Sentinel website on March 30, 2015. (XI.B.2.) • Posted a final report on the Sentinel website: *"Accessing the Freshest Feasible Data for Conducting Active Influenza Vaccine Safety Surveillance (PRISM)"* in April 2015. (XI.B.2) • Published a report on venous Thromboembolism (VTE) and Gardasil vaccination. This study evaluated more than 650,000 females ages 9 -23 years and more than 1.4 million doses of vaccine and found no association between the vaccine and VTE. The study report was posted on the Mini-Sentinel and FDA websites in April 2015. (XI.B.2) • Posted a protocol on the Sentinel website on *"*Conducting Vaccine Effectiveness Surveillance in Sentinel's PRISM Program" in June 2015. (XI.B.2) • Posted a protocol to the Sentinel website for Kawasaki disease following vaccination with Prevnar 13 entitled "Kawasaki Disease and PCV13 Vaccine" in September 2015. (XI.B.2) • FDA initiated an assessment of febrile seizures in children ages 6-59 months following influenza vaccination for the 2013-2014 and 2014-2015 seasons to explore the role of background rates when surveillance is not self-controlled. The protocol was posted on the Sentinel website on September 25, 2015; analysis will begin in spring 2016 so that both seasons of influenza data can be analyzed simultaneously. (XI.B.2) • Posted a protocol to the Sentinel website for IVIG and thromboembolic events following IVIG administration entitled "Thromoembolic Events after Immonuglobulin Protocol v3.0" on September 28, 2015. (XI.B.2)
XI.C Conduct and Support Activities Designed to Modernize the Process of Pharmacovigilance	• FAERS data entry modernization continued with evaluation of technologies available to expedite data entry processes. • FDA revised a draft CDER-specific requirements and guidance for acceptance of individual case safety reports using the Efficacy Topics' Data Elements for Transmission of Adverse Drug Reactions Reports (E2B(R3)) data standard adopted by the ICH. • FDA launched use of the Safety Reporting Portal as a means for smaller pharmaceutical manufacturers to submit adverse event reports in a non-E2B format. • FDA created and maintains the FAERS Manufacturer Dictionary, a repository of collected and indexed manufacturer names, synonyms, and related information, used by MedWatch Coders to match and validate reported firm names. • FDA created and maintains the FAERS Product Dictionary, a listing of FDA-regulated products and product information used by FDA for validating, mapping, and coding suspect medical products listed in FAERS adverse event reports.

	• FDA supported research on the use of social media and patient-generated data for pharmacovigilance and innovative tools and methods to increase efficiency in conducting routine drug safety surveillance. • FDA held three all-day Sentinel System trainings to continue the training and development of FDA staff. These trainings focused on: ○ Exploring the Sentinel distributed database to help define what types of questions Sentinel can address, and provide practical training on the use of Sentinel to assess Sentinel sufficiency and inform study design; ○ Basic theory and mechanics of executing propensity score safety analysis in Sentinel; and ○ Using Sentinel routine querying tools to perform comparative analyses. (XI.C.1) • Assessed Safety of Clotting Factors and potential risk factors using large databases. Article "*Clotting Factor Product Administration and Same-Day Occurrence of Thrombotic Events, as Recorded in Large Healthcare Database During 2008-2013"* was accepted in the *Journal of Thrombosis and Haemostasis,* and in the journal *Value in Health* in November 2014. (XI.C.1) • FDA held a public workshop in conjunction with University of Maryland-School of Pharmacy (M-CERSI) entitled "Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases*"* on May 4, 2015. (XI.C.1) • CBER has been developing a Decision Support Environment (DSE) to assist medical experts and epidemiologists in accomplishing their daily tasks efficiently, effectively, and rigorously. The DSE includes two tightly integrated components that allow for the extraction and standardization of meaningful information from the report narratives and the processing of big data in multiple ways. The following were published: (XI.C.1) ○ "*Can Natural Language Processing Improve the Efficiency of Vaccine Adverse Event Report Review?* In *Methods of Information in Medicine* in September 2015. ○ *"Identifying Similar Cases in Document Networks Using Cross-Reference Structures"* in *IEEE Journal of Biomedical and Health Informatics* in November 2015.

Section XII. Improving the Efficiency of Human Drug Review through Required Electronic Submissions and Standardization of Electronic Drug Application Data

Commitment Title	FY15 Accomplishments
Electronic Submissions Requirement	• Published final guidance requiring regulatory submissions in electronic format — Submissions Under Section 745A(a). This guidance describes how FDA interprets and plans to implement the requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). (XII.G) • Published final guidance requiring regulatory submissions in electronic format – Standardized Study Data. This Study Data Technical Conformance Guide provides specifications, recommendations, and general considerations on how to submit standardized study data using FDA-supported data standards located in the Data Standards Catalog. (XII.G) • Published final guidance requiring regulatory submissions in electronic common technical document (eCTD) format. This guidance described the implementation of electronic submission requirements of section 745A(a) of the FD&C Act for the electronic format of the content submitted in NDAs, abbreviated new drug applications (ANDAs), certain BLAs, and certain INDs to CDER or CBER. (XII.D&G)
Standardization of Drug Application Data	• Posted updates to the Data Standards Catalog. (XII.D-F) This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. • Posted Study Data Technical Conformance Guide. (XII.D-F) • Required Electronic Submissions using E2B (R3) for vaccines. Completed Iteration I pilot testing for all required ICH data elements and completed review of draft eVAERS guidance comments. (XII.C) • Completed review of FDA VAERS business validation rules alignment across IT tools used by FDA and CDC. (XII.C) • Required Electronic submissions using E2B (R3) for drugs and biologics. Internal review clearance of draft FAERS E2B (R3) Technical Specifications Document was completed. (XII.D&G) • Successful ISO balloting completed for ISO Draft Technical Specifications for ISO 20443 (medicinal product identification), and ISO 20451 (pharmaceutical product identification). (XII.C)
Clinical Terminology Standards	• Published annual updates to the Therapeutic Area Standards web page in July 2015. Currently 52 therapeutic areas are listed. (XII.E)

Section XIV. Information Technology Goals

Performance Goal	FY 2015 Accomplishments
Supporting Regulatory Operations	• Initiated the 2nd Generation Electronic Submissions Gateway (ESG) Modernization project which will meet critical user needs to support a significant increase in submission loads, and increase system availability and processing capabilities. (XIV.A) • Infrastructure provisioning and software license procurement for all environments in Phase 1 for 2nd Generation project were completed in May 2015. (XIV.A) • The ESG Program Governance Board (PGB) completed its first year and has initiated a review of all documents and processes to increase communication and effectiveness. (XIV.A) • The ESG PGB is performing a review of the industry-facing website to identify and implement changes that will make the website more intuitive and user-friendly. (XIV.A) • ESG PGB met with PhRMA on September 1, 2015 to discuss industry needs and requirements. (XIV.A) • Implemented automated Help Desk Ticket Software into production on August 1, 2015. (XIV.A)
Communications and Technical Interactions	• Conducted quarterly meetings with industry on the following dates: December 8, 2014, March 9, June 29, and September 1, 2015. Quarterly meetings participants discussed prospective implementation of the IT plan, progress toward the long term goal, potential impacts that future activities may have on FDA or stakeholders, and potential revisions to the IT plan. (XIV.B.2)
Metrics and Measures	• FDA will report the FY 2015 IT metrics and measures in the PDUFA IT Annual Assessment and post to the FDA webpage by the end of December 2015. (XIV.C.1)

FY 2015 Hiring and Placement of New PDUFA V Staff at FDA

In addition to the commitments previously described, FDA committed to provide reporting on the hiring and placement of new staff and use of PDUFA resources to complete this work. The table below shows the FY 2015 status of FDA's hiring and placement for the 129 FTEs agreed to in PDUFA V. At the beginning of PDUFA V, a plan was developed to allocate these FTEs among CDER's super-offices, CBER, and the Office of the Commissioner (OC). FDA has used the same allocation plan to depict the placement of the new staff in the table below. As of FY 2015, 99 of 129 (77 percent) of the FTEs have been hired.

Office	Allocated FTEs	Hired
Enhanced Communication		
CDER/Office of New Drugs	6	5
CBER	1	1
Methods for Meta-analysis		
CDER/Office of New Drugs	4	2
CDER/Office of Translational Sciences	4	3
CBER	2	0
Biomarkers and Pharmacogenomics		
CDER/Office of New Drugs	3	2
CDER/Office of Translational Sciences	10	9
CBER	2	2
Use of Patient-Reported Outcomes		
CDER/Office of New Drugs	10	6
CDER/Office of Translational Sciences	5	4
CBER	2	1
Development of Drugs for Rare Disease		
CDER/Office of New Drugs	5	5
CBER	1	1
Benefit-Risk and Patient-Focused Drug Development		
CDER/Office of New Drugs	4	3
CDER/Office of Strategic Programs	7	3
OC/Office of Health and Constituent Affairs	1	0
CBER	2	1
Standardize and Integrate REMS into the Health Care System		
CDER/Office of New Drugs	3	3
CDER/Office of Surveillance and Epidemiology	5	5
CDER/Office of Regulatory Policy	2	1
CDER/Office of the Center Director	1	0
Electronic Submissions and Data Standards		
CDER/Office of Translational Sciences	4	3
CDER/Office of Strategic Programs	6	5
Review Program Data and Systems Upgrades		
CDER/Office of Strategic Programs	3	1
PDUFA V Total Direct FTEs	**93**	**66**

Office	Allocated FTEs	Hired
PDUFA V Indirect FTEs Allocations		
CDER	32	30
CBER	4	3
OC	0	0
TOTAL PDUFA V FTEs	**129**	**99**

Additional PDUFA V Review Program Reporting

Independent Assessment of the Program

One of the key features of PDUFA V is the Program for NME NDAs and original BLAs, which involves more interaction between the FDA review team and the applicant during review of the marketing application. To understand the Program's impact on NME NDA and original BLA reviews, FDA contracted with an independent firm to evaluate the Program. The Statement of Work for this effort was published for comment on FDA's website, and the contract was awarded to Eastern Research Group (ERG). ERG is responsible for evaluating each interaction between FDA and an applicant by examining documents from both parties and by analyzing events in the review process as they occur or soon thereafter. After FDA takes action on a Program application, ERG also conducts interviews with the applicant and the FDA review team to identify best practices and opportunities for improvement of the Program. Two assessments of the Program will be published during PDUFA V: an interim assessment was published March 31, 2015, and a final assessment will be published by December 31, 2016. Section 104 of FDASIA further requires FDA to report on the status of the independent assessment of the Program in this annual PDUFA performance report.

FDA received a total of 56 applications (36 NME NDAs and 20 BLAs) for review in the Program in FY 2013. Forty of these applications were approved, 3 were withdrawn after filing by the applicant, and 13 received a complete response. FDA received 57 applications (38 NME NDAs and 19 BLAs) for review in the Program during FY 2014. Forty-seven of these applications were approved, 2 were withdrawn after filing by the applicant, and 5 received a complete response. Three remaining applications were still pending FDA first action at the end of FY 2015. FDA received 59 applications (37 NME NDAs and 22 BLAs) for review in the Program during FY 2015. Five of these applications were approved, and 54 were pending within the PDUFA goal by September 30, 2015.

In the first 3 years of the Program, ERG has evaluated numerous interactions between FDA and applicants, including 136 pre-submission meetings, 135 mid-cycle communications, and 111 late-cycle meetings. For the 115 applications that received a first-cycle FDA action by

September 30, 2015, ERG also conducted 94 post-action interviews with applicants and 103 with FDA review teams.

Program Quality Metrics

The tables below provide information on FY 2014 and FY 2015 applications that had a completed first action reviewed under the Program as of September 30, 2015. These counts capture the Program milestones completed for applications received in the listed fiscal year. Metrics for applications received in FY 2015 will be updated in the FY 2016 PDUFA Performance Report.

Quality System Metric	FY 2014	FY 2015*
Applications Filed with a First Action	54	5
Pre-NDA/BLA Meetings Held	42	5
Applications with Agreement on Complete Application	38	4
Applications with Agreement on Late Component Submission	23	4
74-Day Letters Issued	54	5
Mid-Cycle Communications	53	5
Primary Reviews Completed	547	37
Secondary Reviews Completed	196	4
Late Cycle Meeting Packages	48	5
Late Cycle Meetings Held	46	5
Discipline Review Letters Issued	1	0

*FY 2015 data are preliminary.

Disciplines Referenced in Discipline Review Letters*

	FY 2014	FY 2015**
Clinical	1	0
Clinical Pharmacology	0	0
Nonclinical	0	0
Quality	0	0
Statistical	0	0

* More than one discipline may be referenced in a single discipline review letter.
** FY 2015 data are preliminary.

Appendices

Appendix A: Final FY 2014 Cohort Performance Detail

The following tables detail the final performance for the FY 2014 cohort of submissions. These data include the number of submissions reviewed *on time* (acted on by the PDUFA goal date) or *overdue* (acted on past goal or pending past the goal date) and the final *percent on time* (final performance with no actions pending within the PDUFA goal date). The performance data presented here have been updated from the preliminary performance information reported in the FY 2014 PDUFA Performance Report.

Review Goal Performance

Products Reviewed Under PDUFA V NME Review Program

The table below represents NME NDAs and original BLAs that were reviewed under the PDUFA V NME NDA and Original BLA Review Program. Applications that were received as NME NDAs may not retain that status upon final action. For example, this can occur when an applicant submits two separate applications for the same NME at the same time or a second application while the first application is still under review. Both applications would be reviewed under the Program, though upon approval of either application as an NME, the second one would no longer be considered an NME. However, since both applications were reviewed under the Program, they are included in this table for Program analysis. In addition, although the Program only applies to NME NDAs and original BLAs, there is the potential that when there are multiple applications for the same NME, the second NME application could convert to an efficacy supplement upon approval of the first NME application. Because these applications would be reviewed under the Program, they are included as efficacy supplements in the table below. Furthermore, some applications that were submitted as original BLAs under existing FDA guidance may not be considered novel products to which the Program is targeted. In such cases, these original BLAs were not reviewed in the Program. For the reasons described in this paragraph, the figures in the table below may differ from the figures provided under the original application counts used for performance goal tracking elsewhere in this report.

There are no performance goals associated specifically with the Program, though each Program application falls under other performance goals according to its application type. As of September 30, 2015, 96 percent of FY 2014 cohort applications in the Program were reviewed within their PDUFA goal timelines.

Products Reviewed Under PDUFA V Review Program

Application Type (Final Designation)	Filed	On Time	Overdue	Pending Within Goal
Priority NDAs and BLAs	30	29	1	0
Standard NDAs and BLAs	23	20	1†	2
Priority Efficacy Supplements*	1	1	0	0
Standard Efficacy Supplements*	3	3	0	0
Total Program Performance	**57**	**53**	**2**	**2**

* Some applications that are submitted as NME NDAs may be considered efficacy supplements at the time of approval.
† One standard NDA was pending past the goal date as of September 30, 2015.

Original Applications

Original Application Type	Performance Goal: Act on 90 percent within	Filed	On Time	Overdue	Percent On Time
Priority NMEs & BLAs	6 months of filing date	28	27	1	**96%**
Standard NMEs & BLAs	10 months of filing date	21	20	1	**95%**
Priority Non-NME NDAs	6 months	10	8	2	**80%**
Standard Non-NME NDAs	10 months	72	70	2	**97%**

Resubmitted Applications

Resubmitted Application Type	Performance Goal	Filed	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	7	7	0	**100%**
Class 2	Act on 90 percent within 6 months	35	34	1	**97%**

Efficacy Supplements

Efficacy Supplement Type	Performance Goal	Filed	On Time	Overdue	Percent On Time
Priority	Act on 90 percent within 6 months	40	40	0	**100%**
Standard	Act on 90 percent within 10 months	165	151	14	**92%**

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Performance Goal	Received	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	7	7	0	**100%**
Class 2	Act on 90 percent within 6 months	10	9	1	**90%**

Manufacturing Supplements

Manufacturing Supplement Type	Performance Goal	Filed	On Time	Overdue	Percent On Time
Prior Approval Required	Act on 90 percent within 4 months	776	735	41	**95%**
Prior Approval Not Required	Act on 90 percent within 6 months	1,392	1,337	55	**96%**

Procedural and Processing Goal Performance

Meeting Management

Type	Performance Goal	Received*	On Time	Overdue	Percent On Time
Type A Meeting Requests	Review 90 percent within 14 days	160	144	16	**90%**
Type B Meeting Requests	Review 90 percent within 21 days	1,467	1,335	132	**91%**
Type C Meeting Requests	Review 90 percent within 21 days	995	876	119	**88%**
Type A Meetings Scheduled	Review 90 percent within 30 days	145	106	39	**73%**
Type B Meetings Scheduled	Review 90 percent within 60 days	1,154	817	337	**71%**
Type C Meetings Scheduled	Review 90 percent within 75 days	543	432	111	**80%**
Type B Written Response	Review 90 percent within 60 days	249	196	53	**79%**
Type C Written Response	Review 90 percent within 75 days	393	339	54	**86%**
Meeting Minutes	Review 90 percent within 30 days	1,503	1,358	145	**90%**

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

Responses to Clinical Holds

Performance Goal	Received	On Time	Overdue	Percent On Time
Respond to 90 percent within 30 days	148	138	10	**93%**

Major Dispute Resolutions

Performance Goal	Responses*	On Time	Overdue	Percent On Time
Respond to 90 percent within 30 days	33	32	1	**97%**

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. It is not representative of the number of unique appeals received that have been reviewed, as there may be more than one response to an original appeal.

Special Protocol Assessments

Performance Goal	Received	On Time	Overdue	Percent On Time
Respond to 90 percent within 45 days	201	196	5	**98%**

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Total Resubmissions
23	18	3	2	30

Drug/Biological Product Proprietary Names

Submission Type	Performance Goal	Received	On Time	Overdue	Percent On Time
Submitted During IND Phase	Review 90 percent within 180 days	170	169	1	**99%**
Submitted with NDA/BLA	Review 90 percent within 90 days	209	205	4	**98%**

First-Cycle Filing Review Notifications

Notification Type	Performance Goal	Filed	On Time	Overdue	Percent On Time
NDAs and BLAs	Act on 90 percent within 74 days	131	128	3	**98%**
Efficacy Supplements	Act on 90 percent within 74 days	136	132	4	**97%**

Notification of Planned Review Timelines

Application Type	Applications Filed*	In 74-Day Letter	Not In 74-Day Letter	Percent In 74-Day Letters
NDAs and BLAs	131	131	0	**100%**
Efficacy Supplements	136	135	1	**99%**

* The number of original applications filed in any given year may not match the number of first-cycle notifications due to the status of an application at the time the data are reported.

Appendix B: Preliminary FY 2015 Cohort Performance Detail

The following detailed performance information for FY 2015 cohort submissions includes the number of submissions filed, reviewed *on time* (acted on by the PDUFA goal date), and *overdue* (acted on past goal or pending past the goal date). The number of submissions not yet acted on but still pending within the PDUFA goal date (*pending within goal*) is also provided, along with the highest possible percent of reviews that may be completed on time.

Review Goal Performance

Products Reviewed Under PDUFA V NME Review Program

The table below represents NME NDAs and original BLAs that were reviewed under the PDUFA V NME NDA and Original BLA Review Program. Applications that were received as NME NDAs may not retain that status upon final action. For example, this can occur when an applicant submits two separate applications for the same NME at the same time or while the first application is still under review. Both applications would be reviewed under the Program, though upon approval of either application as an NME, the second one would no longer be considered an NME. However, since both applications were reviewed under the Program, they are included in this table for Program analysis. In addition, although the Program only applies to NME NDAs and original BLAs, there is the potential that when there are multiple applications for the same NME, the second NME application could convert to an efficacy supplement upon approval of the first NME application. Because these applications would be reviewed under the Program, they are included as efficacy supplements in the table below. Furthermore, some applications that were submitted as original BLAs under existing FDA guidance may not be considered novel products to which the Program is targeted. In such cases, these original BLAs were not reviewed in the Program. For the reasons described in this paragraph, the figures in the table below may differ from the figures provided under the original application counts used for performance goal tracking elsewhere in this report.

There are no performance goals associated specifically with the Program, though each Program application falls under other performance goals according to its application type. As of September 30, 2015, all FY 2015 cohort applications in the Program were reviewed within their PDUFA goal timelines

Products Reviewed Under PDUFA V Review Program

Application Type (Final Designation)	Filed	On Time	Overdue	Pending Within Goal
Priority NDAs and BLAs	27	4	0	23
Standard NDAs and BLAs	30	1	0	29
NDAs and BLAs Review Priority Undesignated*	2	0	0	2
Priority Efficacy Supplements†	0	0	0	0
Standard Efficacy Supplements†	0	0	0	0
Efficacy Supplements Review Priority Undesignated*	0	--	--	--
Total Program Performance	**59**	**5**	**0**	**54**

* These applications have not reached the 60-day filing date and have not yet received a review priority designation.
† Some applications that are submitted as NME NDAs may be considered efficacy supplements at the time of approval.

Original Applications

Application Type	Performance Goal: Act on 90 percent within	Filed	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Priority NMEs & BLAs	6 months of filing date	27	4	0	23	**100%**	**100%**
Standard NMEs & BLAs	10 months of filing date	30	2	0	28	**100%**	**100%**
Priority Non-NME NDAs	6 months	9	3	0	6	**100%**	**100%**
Standard Non-NME NDAs	10 months	78	5	1	72	**83%**	**99%**
Review Priority Undesignated*	To Be Determined	7	--	--	--	**--**	**--**

* These applications have not reached the 60-day filing date and have not yet received a review priority designation.

Resubmitted Applications

Resubmitted Application Type	Performance Goal: Act on 90 percent within	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Class 1	2 months	7	7	0	0	**100%**	**100%**
Class 2	6 months	37	21	0	16	**100%**	**100%**

Efficacy Supplements

Efficacy Supplement Type	Performance Goal: Act on 90 percent within	Filed	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Priority	6 months	51	17	1	33	**94%**	**98%**
Standard	10 months	116	30	0	86	**100%**	**100%**
Review Priority Undesignated*	To Be Determined	7	--	--	--	**--**	**--**

* These applications have not reached the 60-day filing date and have not yet received a review priority designation.

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Performance Goal: Act on 90 percent within	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Class 1	2 months	0	0	0	0	**--**	**--**
Class 2	6 months	8	0	0	8	**--**	**100%**

Manufacturing Supplements

Manufacturing Supplement Type	Performance Goal: Acton 90 percent within	Filed	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Prior Approval Required	4 months	769	465	34	270	**93%**	**96%**
Prior Approval Not Required	6 months	1,609	796	43	770	**95%**	**97%**
Review Priority Undesignated	To Be Determined	0	--	--	--	**--**	--

Procedural and Processing Goal Performance

Meeting Management

Type	Performance Goal: Review 90 percent within	Received*	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Type A Meeting Requests†	14 Days	173	113	17	43	**87%**	**90%**
Type B Meeting Requests	21 Days	1,632	1,440	139	53	**91%**	**91%**
Type C Meeting Requests	21 Days	1,216	1,031	162	23	**86%**	**87%**
Type A Meetings Scheduled†	30 Days	162	65	44	53	**60%**	**73%**
Type B Meetings Scheduled	60 Days	1,204	807	328	69	**71%**	**73%**
Type C Meetings Scheduled	75 Days	612	454	117	41	**80%**	**81%**
Type B Written Response	60 Days	364	229	78	57	**75%**	**79%**
Type C Written Response	75 Days	526	352	75	99	**82%**	**86%**
Meeting Minutes	30 Days	1,605	1,061	115	429	**90%**	**93%**

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 90 meetings (51 requests and 51 scheduling) coded as undesignated in the database as of September 30, 2015. These undesignated meetings are included as Type A meetings in the table above. Performance in all categories will change once designations are made for these requests and scheduling and will be updated in the FY 2016 PDUFA Performance Report.

Responses to Clinical Holds

Performance Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 30 days	161	130	9	22	**94%**	**94%**

Major Dispute Resolutions

Performance Goal	Responses*	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 30 days	15	12	0	3	**100%**	**100%**

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. It is not representative of the number of unique appeals received that have been reviewed, as there may be more than one response to an original appeal.

Special Protocol Assessments

Performance Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 45 days	234	196	8	30	**96%**	**97%**

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Total Resubmissions
47	39	8	0	55

Drug/Biological Product Proprietary Names

Submission Type	Performance Goal: Review 90 percent within	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Proprietary Names Submitted During IND Phase	180 days	180	119	0	61	**100%**	**100%**
Proprietary Names Submitted with NDA/BLA	90 days	220	182	1	37	**99%**	**100%**

First-Cycle Filing Review Notifications

First-Cycle Filing Review Notification Type	Performance Goal: Act on 90 percent within	Filed	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
NDAs and BLAs	74 days	150	121	5	24	**96%**	**97%**
Efficacy Supplements	74 days	117	91	6	20	**94%**	**95%**

Notification of Planned Review Timelines

Application Type	Applications Filed*	In 74 Day Letter	Not In 74 Day Letter	Pending†	Percent In 74 Day Letters	Highest Possible Percent In Letters
NDAs and BLAs	150	126	0	24	**100%**	**100%**
Efficacy Supplements	117	96	1	20	**99%**	**99%**

* The number of original applications filed in any given year may not match the number of first-cycle notifications due to the status of an application at the time the data are reported. Numbers are updated as appropriate in later fiscal year reports.

† Pending includes only those notification commitments that have not been issued and are within 74 days.

Appendix C: List of Approved Applications

This appendix includes the detailed review histories of the NDA and BLA submissions approved under PDUFA V in FY 2015. Approvals are grouped by priority designation and submission year and listed in order of total approval time. Approval time is presented in months and includes each review cycle's time with FDA, time with the sponsor, and the total time on that application.

Review histories of NDA and BLA submissions approved prior to FY 2015 can be found in the appendices of the earlier PDUFA Performance Reports available at: www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm

Please note: When determining total time, FDA calculates the number of months and rounds to the nearest tenth. Therefore, when cycle times are added, rounding discrepancies can occur.

Because months consist of varying numbers of days, FDA uses the average number of days in a month to calculate review time in months. Therefore, a submission may appear overdue even though it was approved on the goal date. For example, the submission *AVYCAZ (ceftazidime-avibactam)*on page C-3 was received on 06/25/2014 and had an 8-month review goal date of 2/25/2015 as it was reviewed under the PDUFA V NME review program. FDA approved the submission on the goal date, but because FDA uses the average number of days in a month to calculate months, the time taken to review the submission is reported as 8.1 months and the review appears overdue.

Terms and Coding Used in Tables

Action Codes:

AE = Approvable
AP = Approved
CR = Complete Response
NA = Not Approvable
TA = Tentative Approval
WD = Withdrawn

▲ Denotes Class 1 Resubmission (2 month review-time goal)

△ Denotes Class 2 Resubmission (6 month review-time goal)

◊ Expedited review and TA of an NDA by FDA for fixed dose combinations and co-packaged antiretroviral medications as part of the President's Emergency Plan for AIDS Relief (PEPFAR)

♦ Application reviewed under the PDUFA V NME Review Program with review goals starting from the 60-day filing date, rather than the submission date

♯ Major amendment was received, which extended the action goal date by 3 months [Note: Under PDUFA V, a major amendment can be received anytime during the review cycle and extend the goal date by 3 months. If the review cycle occurred prior to FY 2013, the major amendment must have been received within 3 months of the action due date to extend the action goal date by 3 months.

Table 1
FY 2015 Priority NDA and BLA Approvals (by FY of receipt)

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Submitted in FY 2015							
TECHNIVIE (ombitasvir, paritaprevir, and ritonavir)	Abbvie Inc	N	First	4.9	AP	4.9	Y
INVEGA TRINZA (paliperidone palmitate)	Janssen Pharmaceuticals Inc	N	First	6.0	AP	6.0	Y
PROMACTA (eltrombopag)	Novartis Pharmaceuticals Corp	N	First	6.0	AP	6.0	Y
ENTRESTO (sacubitril/valsartan)	Novartis Pharmaceuticals Corp	Y	First	6.7	AP	6.7	Y♦
ORKAMBI (lumacaftor/ivacaftor)	Vertex Pharmaceuticals Inc	Y	First	7.9	AP	7.9	Y♦
XURIDEN (uridine triacetate)	Wellstat Therapeutics Corp	Y	First	7.9	AP	7.9	Y♦
PRALUENT (alirocumab)	Sanofi-Aventis U.S. LLC	Y	First	8.0	AP	8.0	Y♦
Submitted in FY 2014							
BLINCYTO (blinatumomab)	Amgen, Inc.	Y	First	2.5	AP	2.5	Y♦
TRUMENBA (Meningococcal Group B Vaccine)	Wyeth Pharmaceuticals, Inc.	Y	First	4.4	AP	4.4	Y♦
OPDIVO (nivolumab)	Bristol-Myers Squibb Company	Y	First	4.8	AP	4.8	Y♦
OFEV (nintedanib)	Boehringer Ingelheim Pharmaceuticals Inc	Y	First	5.5	AP	5.5	Y♦
IBRANCE (palbociclib)	Pfizer Inc	Y	First	5.7	AP	5.7	Y♦
BEXSERO (Meningococcal Group B Vaccine)	Novartis Vaccines And Diagnostics, Inc.	Y	First	6.0	AP	6.0	Y♦
KALYDECO (ivacaftor)	Vertex Pharmaceuticals Inc	N	First	6.0	AP	6.0	Y
LENVIMA (lenvatinib)	Eisai Inc	Y	First	6.0	AP	6.0	Y♦
PAZEO (olopatadine hydrochloride)	Alcon Research Ltd	N	First	6.1	AP	6.1	Y
HYSINGLA ER (hydroconone bitartrate)	Purdue Pharma Lp	N	First	6.8	AP	6.8	N
XTORO (finafloxacin)	Alcon Research Ltd	Y	First	7.8	AP	7.8	Y♦
CRESEMBA (isavuconazonium sulfate)	Astellas Pharma Us Inc	Y	First	7.9	AP	7.9	Y♦

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
CRESEMBA (isavuconazonium sulfate)	Astellas Pharma Us Inc	N	First	7.9	AP	7.9	Y[7]
Anthraxsil (Anthrax Immune Globulin Intravenous (Human))	Cangene Corporation	Y	First	8.0	AP	8.0	Y♦
HARVONI (ledipasvir and sofosbuvir)	Gilead Sciences Inc	Y	First	8.0	AP	8.0	Y♦
ZERBAXA (ceftolozane/tazobactam)	Cubist Pharmaceuticals LLC	Y	First	8.0	AP	8.0	Y♦
VIEKIRA PAK (ombitasvir, paritaprevir, ritonavir, dasabuvir)	Abbvie Inc	Y	First	8.0	AP	8.0	Y♦
AVYCAZ (ceftazidime-avibactam)	Cerexa Inc	Y	First	8.1	AP	8.1	Y♦
CORLANOR (ivabradine)	Amgen Inc	Y	First	9.6	AP	9.6	Y♦♯
LYNPARZA (olaparib)	Astrazeneca Pharmaceuticals Lp	Y	First	10.5	AP	10.5	Y♦♯
OBIZUR (Antihemophilic Factor (Recombinant), Porcine Sequence	Baxter Healthcare Corporation	Y	First	10.9	AP	10.9	Y♦
UNITUXIN (dinutuximab)	United Therapeutics Corporation	Y	First	10.9	AP	10.9	Y♦♯
VIBERZI (eluxadoline)	Forest Tosara Ltd	Y	First	11.0	AP	11.0	Y♦♯
FARYDAK (panobinostat)	Novartis Pharmaceuticals Corp	Y	First	11.1	AP	11.1	Y♦♯
CHOLBAM (cholic acid)	Retrophin Inc	Y	First	15.8	AP	15.8	N♦♯
DAKLINZA (daclatasvir)	Bristol-Myers Squibb Co	Y	First	7.9	CR	7.9	Y♦
			Sponsor	2.6		10.5	
			Second	5.3	AP	15.8	Y△
ritonavir tablets, 25 mg and 50 mg	Cipla Ltd	N	First	5.8	CR	5.8	Y
			Sponsor	6.1		11.9	
			Second	6.0	TA	17.9	Y△◊

[7] Same active ingredient as preceding approval. The sponsor submitted two applications for same drug with different indications, but only one application can receive the NME designation.

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Submitted in FY 2013							
lopinavir and ritonavir oral pellets 40mg/10mg	Cipla Ltd	N	First	5.6	CR	5.6	Y
			Sponsor	11.1		16.7	
			Second	6.0	TA	22.7	Y△◊
Submitted in FY 2010							
ESBRIET (pirfenidone)	Genentech Inc	Y	First	6.0	CR	6.0	Y[8]
			Sponsor	48.7		54.7	
			Second	4.8	AP	59.5	Y△

[8] This submission is a Type I NewNME that was not reviewed under the PDUFA V Program Review timeline. The timeline went into effect 10/1/2012.

Table 2
FY 2015 Standard NDA and BLA Approvals (by FY of receipt)

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Submitted in FY 2015							
LONSURF (trifluridine and tipiracil)	Taiho Oncology Inc	Y	First	9.1	AP	9.1	Y♦
FERRIPROX (deferiprone)	Apopharma Inc	N	First	9.7	AP	9.7	Y
cefazolin injection	Celerity Pharmaceuticals LLC	N	First	9.7	AP	9.7	Y
cabazitaxel injection	Actavis LLC	N	First	9.9	TA	9.9	Y
potassium chloride	Pharma Research Software Solution LLC	N	First	9.9	AP	9.9	Y
SPRITAM (levetiracetam)	Aprecia Pharmaceuticals Co	N	First	10.0	AP	10.0	Y
Submitted in FY 2014							
phenylephrine hydrochloride	Akorn Inc	N	First	6.2	AP	6.2	Y
argatroban injection	Teva Pharmaceuticals Usa	N	First	9.5	AP	9.5	Y
potassium chloride oral solution	Pharma-Med Inc	N	First	9.8	AP	9.8	Y
IRESSA (gefitinib)	Astrazeneca UK Ltd	N	First	9.8	AP	9.8	Y
ODOMZO (sonidegib)	Novartis Pharmaceuticals Corp	Y	First	9.9	AP	9.9	Y♦
EVOTAZ (atazanavir and cobicistat)	Bristol-Myers Squibb Co	N	First	9.9	AP	9.9	Y
NAMZARIC (memantine hydrochloride extended-release/donepezil hydrochloride)	Forest Laboratories LLC	N	First	9.9	AP	9.9	Y
FINACEA (azelaic acid)	Bayer Healthcare Pharmaceuticals Inc	N	First	9.9	AP	9.9	Y
EPIDUO FORTE (adapalene and benzoyl peroxide)	Galderma Laboratories Inc	N	First	9.9	AP	9.9	Y
cabazitaxel injection	Accord Healthcare Inc	N	First	9.9	TA	9.9	Y
abacavir and lamivudine tablets for oral suspension	Mylan Laboratories Ltd	N	First	10.0	TA	10.0	Y◊
abacavir and lamivudine tablets for oral suspension	Mylan Laboratories Ltd	N	First	10.0	TA	10.0	Y◊
ALBENZA (albendazole)	Amedra Pharmaceuticals LLC	N	First	10.0	AP	10.0	Y
SOTYLIZE (sotalol hydrochloride)	Arbor Pharmaceuticals LLC	N	First	10.0	AP	10.0	Y

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
PREZCOBIX (darunavir and cobicistat)	Janssen Products Lp	N	First	10.0	AP	10.0	Y
Hydrocodone And Guaifenesin	Sovereign Pharmaceuticals LLC	N	First	10.0	AP	10.0	Y
Aptensio (Methylphenidate Hydrochloride)	Rhodes Pharmaceuticals Lp	N	First	10.0	AP	10.0	Y
Liletta (Levonorgestrel)	Medicines360	N	First	10.0	AP	10.0	Y
TRIFERIC (ferric pyrophosphate citrate)	Rockwell Medical Inc	N	First	10.0	AP	10.0	Y
codeine phosphate and chlorpheniramine maleate	Spriaso LLC	N	First	10.0	AP	10.0	Y
DUTREBIS (lamivudine and raltegravir)	Merck Sharp And Dohme Corp	N	First	10.0	AP	10.0	Y
JADENU (deferasirox)	Novartis Pharmaceuticals Corp	N	First	10.0	AP	10.0	Y
TUZISTRA XR (Codeine Polistirex and Chlorpheniramine Polistirex)	Vernalis R And D Ltd	N	First	10.0	AP	10.0	Y
PRESTALIA (perindopril arginine and amlodipine)	Symplmed Pharmaceuticals LLC	N	First	10.1	AP	10.1	Y
TOUJEO (insulin glargine)	Sanofi-Aventis Us LLC	N	First	10.1	AP	10.1	Y
PHOXILLUM (bk4/2.5 and b22k4/0)	Gambro Renal Products	N	First	10.1	AP	10.1	Y
UCERIS (budesonide)	Valeant Pharmaceuticals International	N	First	10.0	TA	10.0	Y
			Sponsor	0.6		10.6	
			Second	0.2	AP	10.8	Y▲
PROAIR RESPICLICK (albuterol sulfate)	Teva Branded Pharmaceutical Products R And D Inc	N	First	10.0	TA	10.0	Y
			Sponsor	0.0		10.0	
			Second	0.8	AP	10.8	Y▲
KYBELLA (deoxycholic acid)	Kythera Biopharmaceuticals Inc	Y	First	11.6	AP	11.6	Y♦
RAPIVAB (peramivir)	Biocryst Pharmaceuticals Inc	Y	First	11.9	AP	11.9	Y♦
VARUBI (rolapitant)	Tesaro Inc	Y	First	11.9	AP	11.9	Y♦
REXULTI (brexpiprazole)	Otsuka Pharmaceutical Co Ltd	Y	First	12.0	AP	12.0	Y♦
Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)	Merck Sharpe & Dohme Corp.	Y	First	12.0	AP	12.0	Y♦

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Quadracel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine	Sanofi Pasteur Limited	Y	First	12.0	AP	12.0	Y♦
XIGDUO XR (dapagliflozin and metformin hcl extended release)	Astrazeneca Ab	N	First	12.0	AP	12.0	Y[9]
GLYXAMBI (empagliflozin and linagliptin)	Boehringer Ingelheim	N	First	12.0	AP	12.0	Y[10]
SOOLANTRA (ivermectin)	Galderma Laboratories Lp	N	First	12.0	AP	12.0	Y♯
SAVAYSA (edoxaban tosylate)	Daiichi Sankyo Inc	Y	First	12.0	AP	12.0	Y♦
STIOLTO RESPIMAT (tiotropium bromide and olodaterol)	Boehringer Ingelheim Pharmaceuticals Inc	N	First	12.0	AP	12.0	Y♦[11]
REPATHA (evolocumab)	Amgen, Inc.	Y	First	12.0	AP	12.0	Y♦
DURLAZA (aspirin)	New Haven Pharmaceuticals Inc	N	First	12.0	AP	12.0	Y♯
SAXENDA (liraglutide [rdna origin] injection)	Novo Nordisk Inc	N	First	12.1	AP	12.1	N
SYNJARDY (empagliflozin and metformin hydrochloride)	Boehringer Ingelheim Pharmaceuticals Inc	N	First	10.0	CR	10.0	Y
			Sponsor	0.9		10.9	
			Second	1.8	AP	12.7	Y
SIGNIFOR LAR (pasireotide)	Novartis Pharmaceuticals Corp	N	First	13.0	AP	13.0	Y♯
paricalcitol injection	Hikma Pharmaceuticals Co Ltd	N	First	13.0	AP	13.0	Y♯
KITABIS PAK (tobramycin inhalation solution USP)	Pulmoflow Inc	N	First	10.0	TA	10.0	Y
			Sponsor	1.3		11.3	
			Second	2.0	AP	13.3	Y▲
COSENTYX (secukinumab)	Novartis Pharmaceuticals Corporation	Y	First	14.9	AP	14.9	Y♦♯
NATPARA (parathyroid hormone)	Nps Pharmaceuticals	Y	First	15.0	AP	15.0	Y♦♯

[9] Non NME reviewed under the PDUFA V program. At time of receipt the active ingredient Dapagliflozin had never been approved in the USA allowing for NME designation, however at time of approval Dapagliflozin had already been approved for marketing in another application, causing this application for lose its NME designation.
[10] Non NME reviewed under the program. At time of receipt the active ingredient Empagliflozin had never been approved in the USA allowing for NME designation, however at time of approval Empagliflozin had already been approved for marketing in another application, causing this application for lose its NME designation.
[11] Non NME reviewed under the program. At time of receipt the active ingredient Olodaterol had never been approved in the USA allowing for NME designation, however at time of approval Olodaterol had already been approved for marketing in another application, causing this application for lose its NME designation.

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
RAPLIXA (Fibrin Sealant (Human))	Profibrix, BV.	Y	First	15.0	AP	15.0	Y♦♯
Nuwiq (Antihemophilic Factor (Recombinant), rAHF)	Octapharma Pharmazeutika Produktionsges.M. B.H.	Y	First	15.0	AP	15.0	Y♦♯
ENVARSUS XR (tacrolimus extended-release tablets)	Veloxis Pharmaceuticals Inc	N	First	10.0	TA	10.0	Y
			Sponsor	7.4		17.4	
			Second	0.9	AP	18.3	Y▲
linezolid	Hospira Inc	N	First	10.0	TA	10.0	Y
			Sponsor	2.8		12.8	
			Second	6.0	AP	18.8	Y△
Submitted in FY 2013							
AKYNZEO (netupitant and palonosetron)	Helsinn Healthcare Sa	Y	First	12.4	AP	12.4	N♦
meropenem	B Braun Medical Inc	N	First	9.9	CR	9.9	Y
			Sponsor	3.2		13.1	
			Second	6.0	AP	19.1	Y△
DUOPA (carbidopa and levodopa)	Abbvie Inc	N	First	10.0	CR	10.0	Y
			Sponsor	3.5		13.5	
			Second	6.0	AP	19.5	Y△
moxifloxacin	Fresenius Kabi Usa LLC	N	First	9.9	CR	9.9	Y
			Sponsor	6.0		15.9	
			Second	6.0	AP	21.9	Y△
ORALTAG (iohexol)	Interpharma Praha As	N	First	10.0	CR	10.0	Y
			Sponsor	8.6		18.6	
			Second	6.0	AP	24.6	Y△
HUMALOG (insulin lispro)	Eli Lilly And Co	N	First	10.0	CR	10.0	Y
			Sponsor	8.6		18.6	
			Second	6.0	AP	24.6	Y△

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Anavip (Crotalidae Immune F(ab')2 (Equine))	Instituto Bioclon, S.A.de C.V.	Y	First	12.0	CR	12.0	Y
			Sponsor	11.6		23.6	
			Second	2.0	AP	25.6	Y♦▲
KENGREAL (cangrelor)	The Medicines Co	Y	First	12.0	CR	12.0	Y♦
			Sponsor	7.8		19.8	
			Second	6.0	AP	25.8	Y△
VRAYLAR (cariprazine)	Forest Research Institute Inc	Y	First	12.0	CR	12.0	Y♦
			Sponsor	12.9		24.9	
			Second	9.0	AP	33.9	Y♯△
Submitted in FY 2012							
daptomycin	Hospira Inc	N	First	10.0	TA	10.0	Y
			Sponsor	17.1		27.1	
			Second	6.1	TA	33.2	Y△
LUMASON (sulfur hexafluoride lipid-type a microspheres)	Bracco Diagnostics Inc	Y	First	10.0	CR	10.0	Y[12]
			Sponsor	7.4		17.4	
			Second	5.9	CR	23.3	Y△
			Sponsor	4.4		27.7	
			Third	6.0	AP	33.7	Y△
neostigmine methylsulfate	Fresenius Kabi Usa LLC	N	First	13.1	CR	13.1	Y♯
			Sponsor	17.4		30.5	
			Second	6.0	AP	36.5	Y△
RYTARY (carbidopa and levodopa extended-release capsules)	Impax Laboratories Inc	N	First	13.0	CR	13.0	Y♯
			Sponsor	14.7		27.7	
			Second	9.0	AP	36.7	Y♯△

[12] This submission is a Type I NewNME that was not reviewed under the PDUFA V Program Review timeline. The timeline went into effect 10/1/2012.

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
IXINITY (Coagulation Factor IX (Recombinant))	Cangene Corporation	Y	First	9.8	CR	9.8	Y
			Sponsor	11.8		21.6	
			Second	6.1	CR	27.7	Y△
			Sponsor	3.0		30.7	
			Third	6.0	AP	36.7	Y△
glucagon	Fresenius Kabi Usa LLC	N	First	10.0	CR	10.0	Y
			Sponsor	22.4		32.4	
			Second	9.0	AP	41.4	Y♯△
Submitted in FY 2011							
paricalcitol injection	Hospira Inc	N	First	10.0	CR	10.0	Y
			Sponsor	26.5		36.5	
			Second	6.0	AP	42.5	Y△
RYZODEG (insulin degludec and insulin aspart injection)	Novo Nordisk Inc	N	First	16.4	CR	16.4	N♯
			Sponsor	25.5		41.9	
			Second	6.0	AP	47.9	Y△
TRESIBA (insulin degludec injection)	Novo Nordisk Inc	Y	First	16.4	CR	16.4	N♯
			Sponsor	25.5		41.9	
			Second	6.0	AP	47.9	Y△
FLOWTUSS (hydrocodone bitartrate and guaifenesin)	Mikart Inc	N	First	10.0	CR	10.0	Y
			Sponsor	37.7		47.7	
			Second	5.8	AP	53.5	Y△
Submitted in FY 2010							
argatroban	Fresenius Kabi Usa LLC	N	First	9.9	CR	9.9	Y
			Sponsor	11.2		21.1	
			Second	5.7	CR	26.8	Y△
			Sponsor	2.7		29.5	
			Third	5.8	CR	35.3	Y△
			Sponsor	5.3		40.6	
			Fourth	5.5	CR	46.1	Y△
			Sponsor	10.8		56.9	

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
			Fifth	2.0	AP	58.9	Y▲
DYLOJECT (diclofenac sodium)	Javelin Pharmaceuticals Inc A Wholly Owned Sudsidiary Of Hospira Inc	N	First	9.9	CR	9.9	Y
			Sponsor	32.9		42.8	
			Second	5.9	CR	48.7	Y△
			Sponsor	10.3		59.0	
			Third	1.8	AP	60.8	Y△
ADDYI (flibanserin)	Sprout Pharmaceuticals Inc	Y	First	10.0	CR	10.0	Y[13]
			Sponsor	31.1		41.1	
			Second	6.0	CR	47.1	Y△
			Sponsor	16.7		63.8	
			Third	6.0	AP	69.8	Y△
Submitted in FY 2009							
metaxalone	Corepharma LLC	N	First	9.7	CR	9.7	Y
			Sponsor	36.3		46.0	
			Second	6.0	CR	52.0	Y△
			Sponsor	11.9		63.9	
			Third	5.5	AP	69.4	Y△
Submitted in FY 2008							
HYCOFENIX (hydrocodone/guaifenesin/pseudoephedrine)	MIKART INC	N	First	10.0	CR	10.0	Y
			Sponsor	13.1		23.1	
			Second	6.0	CR	29.1	Y△
			Sponsor	5.8		34.9	
			Third	5.8	CR	40.7	Y△
			Sponsor	34.8		75.5	
			Fourth	5.3	AP	80.8	Y△

[13] This submission is a Type I NewNME that was not reviewed under the PDUFA V Program Review timeline. The timeline went into effect 10/1/2012.

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Submitted in FY 2007							
TOLAK (fluorouracil)	Hill Dermaceuticals Inc	N	First	22.1	CR	22.1	N
			Sponsor	65.9		88.0	
			Second	9.0	AP	97.0	Y♯△

Appendix D: Filed Application Numbers by Review Division

The tables below and on the pages that follow show the number of applications filed in FY 2015 for various application types and review designations broken out by review division. This new reporting for PDUFA V is required under section 104 of FDASIA.

Original Applications Filed in FY 2015 by Review Division/Office

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CDER Review Divisions					
Division of Anesthesia, Analgesia, and Addiction Products	2	10	0	0	0
Division of Anti-Infective Products	0	7	0	1	1
Division of Antiviral Products	4	5	0	0	1
Division of Bone, Reproductive, and Urologic Products	0	4	0	0	0
Division of Cardiovascular and Renal Products	1	7	0	0	0
Division of Dermatology and Dental Products	0	6	0	1	1
Division of Gastroenterology and Inborn Errors Products	3	6	2	0	0
Division of Hematology Products	4	8	3	0	1
Division of Medical Imaging Products	0	2	0	0	1
Division of Metabolism and Endocrinology Products	0	11	1	0	0
Division of Neurology Products	2	9	0	1	0
Division of Nonprescription Regulatory Development	0	3	0	0	0
Division of Oncology Products 1 (DOP1)	1	2	0	0	0
Division of Oncology Products 2 (DOP2)	6	2	0	1	0
Division of Psychiatry Products	2	4	0	0	0
Division of Pulmonary, Allergy, and Rheumatology Products	1	5	2	0	1
Division of Transplant and Ophthalmology Products	1	3	0	0	1
CDER Totals	*27*	*94*	*8*	*4*	*7*

Original Applications Filed in FY 2015 by Review Division/Office (continued)

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CBER Review Offices					
Office of Blood Research and Review	0	0	0	8	0
Office of Cellular Tissue and Gene Therapies	0	0	1	0	0
Office of Vaccines Research and Review	0	0	0	2	0
CBER Totals	*0*	*0*	*1*	*10*	*0*
FDA Totals	**27**	**94**	**9**	**14**	**7**

Efficacy Supplements Filed in FY 2015 by Review Division/Office

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Review Divisions			
Division of Anesthesia, Analgesia, and Addiction Products	1	8	0
Division of Anti-Infective Products	4	3	0
Division of Antiviral Products	14	11	0
Division of Bone, Reproductive, and Urologic Products	0	2	0
Division of Cardiovascular and Renal Products	1	6	0
Division of Dermatology and Dental Products	0	3	0
Division of Gastroenterology and Inborn Errors Products	0	5	2
Division of Hematology Products	9	7	0
Division of Medical Imaging Products	1	2	0
Division of Metabolism and Endocrinology Products	0	22	0
Division of Neurology Products	2	5	3
Division of Nonprescription Regulatory Development	0	1	0
Division of Oncology Products 1 (DOP1)	0	1	1
Division of Oncology Products 2 (DOP2)	15	11	0
Division of Psychiatry Products	0	3	0
Division of Pulmonary, Allergy, and Rheumatology Products	4	10	0
Division of Transplant and Ophthalmology Products	0	2	1
CDER Totals	*51*	*102*	*7*
CBER Review Offices			
Office of Blood Research and Review	0	5	0
Office of Cellular Tissue and Gene Therapies	0	0	0
Office of Vaccines Research and Review	0	9	0
CBER Totals	*0*	*14*	*0*
FDA Totals	**51**	**116**	**7**

Submissions with Special Designations Filed in FY 2015 by Review Division

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
CDER Review Divisions				
Division of Anesthesia, Analgesia, and Addiction Products	1	1	0	1
Division of Anti-Infective Products	0	0	1	0
Division of Antiviral Products	0	3	1	5
Division of Bone, Reproductive and Urologic Products	0	0	0	0
Division of Cardiovascular and Renal Products	0	1	2	0
Division of Dermatology and Dental Products	0	0	0	1
Division of Gastroenterology and Inborn Errors Products	1	6	8	3
Division of Hematology Products	2	2	10	3
Division of Medical Imaging Products	0	0	0	0
Division of Metabolism and Endocrinology Products	0	0	1	0
Division of Neurology Products	2	2	4	0
Division of Nonprescription Clinical Evaluation	0	0	0	0
Division of Oncology Products 1 (DOP1)	0	1	1	4
Division of Oncology Products 2 (DOP2)	2	5	6	8
Division of Psychiatry Products	0	1	0	2
Division of Pulmonary, Allergy, and Rheumatology Products	1	1	2	3
Division of Transplant and Ophthalmology Products	0	0	0	1
CDER Totals	9	23	36	31
CBER Review Offices				
Office of Blood Research and Review	0	0	2	0
Office of Cellular Tissue and Gene Therapies	0	0	0	5
Office of Vaccines Research and Review	0	0	0	2
CBER Totals	0	0	2	7
FDA Totals	**9**	**23**	**38**	**38**

* This column does not represent filed figures; rather it shows the number of breakthrough designations granted on INDs, NDAs, and BLAs during FY 2015. Breakthrough designation is granted based on indication, and therefore one submission may have more than one breakthrough designation granted.

Appendix E: Definitions of Key Terms

A. The term "review and act on" means 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.

B. Goal Date Extensions for Major Amendments

1. A major amendment to an original application, efficacy supplement, or Class 2 resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by 3 months. [Note: If the review cycle occurred prior to FY 2013, the major amendment must have been received within 3 months of the action due date to extend the action goal date by 3 months.]
2. A major amendment may include, for example, a major new clinical safety/efficacy study report; major re-analysis of previously submitted study (studies); submission of a REMS with Elements to Assure Safe Use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.
3. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by 2 months. [Note: If the review cycle occurred prior to FY 2013, the major amendment must have been received within 2 months of the action due date to extend the action goal date by 2 months.]
4. Only one extension can be given per review cycle.
5. Consistent with the underlying principles articulated in the Good Review Management Principles and Practices for PDUFA Products guidance, FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling
2. Draft labeling
3. 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)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform Phase 4 postmarketing studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the agency as fitting the Class 1 category)

10. Other specific items may be added later as the agency gains experience with the scheme and will be communicated via guidance documents to industry

E. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. Meeting Requests commit FDA to notify the requestor of a formal meeting in writing within 14 days of request for Type A meetings or within 21 days of request for Type B and Type C meetings.

G. Scheduled meetings should be made within 30 days of receipt of request for Type A meetings, 60 days for Type B meetings, and 75 days for Type C meetings. If the requested date for any of these types of meetings is greater than 30, 60, or 75 days, as appropriate, from the date the request is received by FDA, the meeting date should be within 14 days of the requested date.

H. Meeting minutes are to be prepared by FDA clearly outlining agreements, disagreements, issues for further discussion, and action items. They will be available to the sponsor within 30 days of the meeting.

I. A Type A Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (a "critical path" meeting) or to address an important safety issue.

J. A Type B Meeting is a 1) pre-IND, 2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or 3) a pre-NDA/BLA meeting. Each requestor should usually only request 1 each of these Type B Meetings for each potential application (NDA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

K. A Type C Meeting is any other type of meeting.

L. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

M. Information Technology-specific definitions:

1. "Program" refers to the organizational resources, procedures, and activities assigned to conduct "the process for the review of human drug applications," as defined in the Prescription Drug User Fee Act.
2. "Standards-based" means compliant with published specifications that address terminology or information exchange between FDA and regulated parties or external stakeholders, as adopted by FDA or other agencies of the federal government, and often based on the publications of national or international Standards Development Organizations.
3. "FDA Standards" means technical specifications that have been adopted and published by FDA through the appropriate governance process. FDA standards may apply to terminology, information exchange, engineering or technology specifications, or other technical matters related to information systems. FDA standards often are based on the publications of other federal agencies, or the publications of national or international Standards Development Organizations.
4. "Product life cycle" means the sequential stages of human drug development, regulatory review and approval, post-market surveillance and risk management, and where applicable, withdrawal of an approved drug from the market. In the context of the process for the review of human drug applications, the product life cycle begins with the earliest regulatory submissions in the IND phase, continues through the NDA or BLA review phase, and includes post-market surveillance and risk management activities as covered under the process for the review of human drug applications.

N. Special Protocol Assessments: Upon specific request by a sponsor, FDA will evaluate certain protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

O. First Cycle Filing Review Notifications: Under PDUFA V, FDA committed to report 90 percent of substantive review issues (or lack thereof) identified during the initial filing review to the applicant by letter, telephone conference, facsimile, secure e-mail, or other expedient means within 74 days of receipt of the original submission.

P. Planned Review Timeline Notifications: FDA is to inform the applicant of the planned timeline for feedback related to labeling and PMRs and PMCs. Beginning in FY 2013, applications being reviewed under the Program are to include additional information about the planned date for the internal mid-cycle meeting and preliminary plans on whether to hold an Advisory Committee meeting to discuss the application.

Q. The Application Integrity Policy focuses on the integrity of data and information in applications submitted to FDA for review and approval. It describes FDA's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. More information on the policy is available at www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/UCM072631.pdf.

Department of Health and Human Services
Food and Drug Administration

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