U.S. FOOD & DRUG ADMINISTRATION

FY 2017

PERFORMANCE REPORT TO CONGRESS

for the

Prescription Drug User Fee Act

Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA or the Agency) Fiscal Year (FY) 2017 Prescription Drug User Fee Act (PDUFA) Performance Report. This report marks the 25th year of PDUFA and the 5th year of PDUFA V (FY 2013 through FY 2017).

This report presents updated data on FDA's progress in meeting FY 2016 performance goals, preliminary data on meeting FY 2017 review performance goals, and other commitments under PDUFA V as of September 30, 2017.

One of the key programs under PDUFA V has been the Enhanced Review Transparency and Communication for New Molecular Entity (NME) NDAs and Original BLAs (the Program). As of September 30, 2017, FDA has received 276 applications through this Program since its inception, which involves more communication and transparency between the applicant and the FDA review team during review of the marketing application. The FY 2016 Program cohort is closed, with 100 percent of applications acted on within the goal date. The FY 2017 Program cohort has received 54 applications to date. While most of these applications are still under review and within their PDUFA goal date, all applications that received a first cycle action by September 30, 2017, were acted on within the goal date.

We are committed to meeting all PDUFA performance goals related to human drug review. In FY 2017, the Agency engaged in sustained efforts to recruit and hire new talent for the human drug review program to better enable FDA to meet increasing demands on the program, particularly in the area of meeting management goals. Moving forward into FY 2018, FDA will continue to enhance the program's staffing in addition to strengthening our efforts to improve program performance 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.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Acronyms

BLA – Biologics License Application

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

ECT – Enhanced Communication Team

ETASU – Elements to Assure Safe Use

FAERS – FDA Adverse Event Reporting System

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

NDA – New Drug Application

NIH – National Institutes of Health

NME – New Molecular Entity

OND – Office of New Drugs

OPQ – Office of Pharmaceutical Quality

OSE – Office of Safety and Epidemiology

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

REMS – Risk Evaluation and Mitigation Strategy

VAERS – Vaccine Adverse Event Reporting System

Executive Summary

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992, and it authorizes 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, 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 fourth re-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 Food and Drug Administration Amendments Act of 2007 (FDAAA), 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 2016 and FY 2017, the fourth and fifth years under PDUFA V. Specifically, it updates performance data for submissions received in FY 2016 (initially reported in the FY 2016 PDUFA Performance Report)[2] and presents preliminary data on FDA's progress in meeting FY 2017 goals. Updates on FDA's accomplishments related to additional PDUFA V commitments for FY 2017 and historical review trend data are also included. Details of FY 2016 and FY 2017 performance, review cycle data on all original new drug applications (NDAs) and biologics license applications (BLAs) approved during FY 2017, 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 2017

Among the changes made under PDUFA V, FDA established a modified review program (the Program) for new molecular entity (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 2016, 47 applications were received through the Program. As of September 30, 2017, 100 percent of these applications were acted on within goal. During FY 2017, 54 applications were received and will be reviewed under the Program. As of September 30, 2017, 19 of these applications had been reviewed and acted on, with all reviews

[1] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf
[2] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm548126.htm

completed on time. The remaining 35 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.

The estimated[3] median approval times for priority NDA and BLA applications received in FY 2016 decreased slightly, while standard approval times remained the same compared to estimated median approval times in FY 2015. The preliminary data show that the percentage of priority and standard applications filed in FY 2016 and approved during the first review cycle were 71 percent and 61 percent, respectively.

Review Performance

The FY 2016 cohort had a workload of 2,697 actions. FDA met or exceeded the 90 percent performance level for all 12 review performance goals.

As of September 30, 2017, FDA had completed 1,583 actions for the FY 2017 cohort. FDA is currently meeting or exceeding all 12 review performance goals for FY 2017. With 1,380 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 2017.

Procedural and Processing Performance

FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2016 cohort totaled 9,089. FDA met or exceeded the 90 percent performance level for 12 of 18 procedural and processing goals, while the remaining 6 goals were met with 69 percent or higher on-time performance.

FDA is currently meeting or exceeding 12 of 18 procedural and processing goals for the FY 2017 cohort. With 1,238 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 2017, with 2 goals that could exceed 86 percent on-time performance.

Additional PDUFA V Commitments

During FY 2017, 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 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.

[3] 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. Some applications may be approved several years after their original receipt.

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Introduction

On July 9, 2012, the President signed the 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 new drug application (NDA) and biologics license application (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 the 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.[4]

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. Significant 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 the FY 2016 cohort of submissions based on actions completed in FY 2016 and FY 2017. In addition, it includes preliminary performance for the FY 2017 cohort of submissions that had actions completed or due for completion in FY 2017. Final performance for the FY 2017 cohort will be presented in the FY 2018 PDUFA Performance Report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2017.

Among other changes made under PDUFA V, FDA established a modified review program (the Program) for the New Molecular Entity (NME) NDAs and original BLAs received from October 1, 2012, through September 30, 2017. The goals of the Program are to increase the efficiency

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

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 later in 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 submitted for approval under NDAs (not BLAs).
  - *Submission* applies to all of the above.
  - *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 reflect final determination of NME status. FDA often receives multiple submissions for the same NME (e.g., different dosage forms). All such submissions 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 data presented in this report do not include biosimilar INDs or BLAs. These data are presented in the annual Biosimilars User Fee Act (BsUFA) Performance Reports located on the FDA website.[5]

- 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 Program (see the PDUFA V Commitment Letter[6] 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.

[5] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm384244.htm
[6] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

- FDA reports PDUFA performance data annually for each fiscal year receipt cohort (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 2016 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 2017 submissions is shown as the percentage of submissions reviewed on time as of September 30, 2017, 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 2017 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, 2017.

- 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 an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States.
- **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 biological 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. The Center for Drug Evaluation and Research (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 2012 to FY 2017

In the table below, preliminary workload numbers from FY 2017 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements. FDA noted a large increase in the number of Original Priority non-NME NDAs in FY 2017. Other Submission types, notably Original Priority NMEs and BLAs, as well as Original Standard non-NME NDAs, Class 1 and Class 2 Resubmitted NDAs and BLAs, and both Priority and Standard NDA and BLA Efficacy Supplements, all showed increased workloads in FY 2017.

Workload for original applications (priority and standard) will appear to be 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. The data presented in this section represent receipts by FDA of the submission types listed in the table.

Workload for Applications and Submissions

Submission Type	FY 12	FY 13	FY 14	FY 15	FY 16*	FY 17	FY 12 to FY 16 5-Year Average	FY 17 Compared to 5-Year Average
Original Priority NMEs and BLAs	18	19	28	25	23	34[†]	23	+48%
Original Standard NMEs and BLAs	32	35	21	32	24	23	29	-21%
Original Priority non-NME NDAs	8	8	10	9	12	29[†]	9	+222%
Original Standard non-NME NDAs	72	76	72	84	72	77	75	+3%
Class 1 Resubmitted NDAs and BLAs	6	11	7	7	5	8	7	+14%
Class 2 Resubmitted NDAs and BLAs	36	38	35	37	31	49	35	+40%
Priority NDA and BLA Efficacy Supplements	39	29	40	52	54	78[‡]	43	+81%
Standard NDA and BLA Efficacy Supplements	108	123	165	136	145	165	135	+22%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	4	2	7	0	3	3	3	0%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	19	10	10	11	11	11	12	-8%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	872	873	776	765	842	991	826	+20%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,566	1,542	1,392	1,614	1,475	1,495	1,518	-2%

* FY 2016 numbers were changed to reflect updates to data presented in the FY 2016 PDUFA Performance Report.
† FY 2017 numbers are preliminary. Six non-NME NDAs and two BLAs included in the "priority" rows above have an undesignated review priority as of September 30, 2017, and will be updated in the FY 2018 PDUFA Performance Report.
‡ FY 2017 numbers are preliminary. Caution should be exercised in interpreting these data, since 17 efficacy supplements included in the "priority" row above have an undesignated review priority as of September 30, 2017. Some of these submissions may ultimately be assigned a review priority of "standard," which will be updated in the FY 2018 PDUFA Performance Report.

Final FY 2016 Review Performance

Final FY 2016 review goal performance is presented in the table below. Final performance for submission types that met the goal (90 percent or more actions 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 all 12 review performance goals in FY 2016. More detailed information on performance is available in Appendix A.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2016 Performance
Original Priority NMEs and BLAs	6 months from filing date	23 of 23 on time	**100%**
Original Standard NMEs and BLAs	10 months from filing date	24 of 24 on time	**100%**
Original Priority non-NME NDAs	6 months	11 of 12 on time	**92%**
Original Standard non-NME NDAs	10 months	69 of 72 on time	**96%**
Class 1 Resubmitted NDAs and BLAs	2 months	5 of 5 on time	**100%**
Class 2 Resubmitted NDAs and BLAs	6 months	31 of 31 on time	**100%**
Priority NDA and BLA Efficacy Supplements	6 months	54 of 54 on time	**100%**
Standard NDA and BLA Efficacy Supplements	10 months	137 of 145 on time	**94%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	3 of 3 on time	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	10 of 11 on time	**91%**
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	810 of 842 on time	**96%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1463 of 1475 on time	**99%**

Preliminary FY 2017 Review Performance

Preliminary FY 2017 review goal performance is presented in the table below.

- The 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. 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). 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, 2017, is shown in bold text. FDA is currently meeting or exceeding the 90 percent performance level for 12 of 12 review performance goals.
- 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	Progress*	Goal: Act on 90 Percent Within	FY 2017 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	16 of 32 complete	6 months	**100%**	100%
Original Standard NMEs and BLAs	3 of 23 complete	10 months	**100%**	100%
Original Priority non-NME NDAs	10 of 23 complete	6 months	**100%**	100%
Original Standard non-NME NDAs	20 of 77 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	6 of 8 complete	2 months	**100%**	100%
Class 2 Resubmitted NDAs and BLAs	18 of 49 complete	6 months	**100%**	100%
Priority NDA and BLA Efficacy Supplements	30 of 61 complete	6 months	**100%**	100%
Standard NDA and BLA Efficacy Supplements	40 of 165 complete	10 months	**98%**	99%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3 of 3 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	4 of 11 complete	6 months	**100%**	100%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	613 of 991 complete	4 months	**97%**	98%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	820 of 1495 complete	6 months	**99%**	99%

*Does not include undesignated applications in total. Undesignated applications have only pending status.

PDUFA Procedural and Processing Goals and Commitments

Procedural and Processing Workload: FY 2012 to FY 2017

FY 2017 procedural and processing workload, which includes activities related to meeting management, procedural responses, and procedural notifications, is compared to the previous 5-year averages in the table below. The marked upward trend of meeting management workload during PDUFA V continued into FY 2017. From FY 2013 to 2017, meeting workload increased by over 38 percent as measured by either meeting requests received or meetings scheduled and written responses sent. Meeting type definitions and other terms can be found in Appendix E.

Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request Type	FY 12	FY 13	FY 14	FY 15	FY 16*	FY 17	FY 12 to FY 16 5-Year Average	FY 17 Compared to 5-Year Average
Type A Meeting Requests	184	140	160	121	135	269[†]	148	+82%
Type B Meeting Requests	1,322	1,394	1,467	1,664	1,738	1,799	1,517	+19%
Type C Meeting Requests	785	932	995	1,237	1,372	1,345	1,064	+26%
Type A Meetings Scheduled	168	118	145	107	123	255[†]	132	+93%
Type B Meetings Scheduled	1,261	1,189	1,154	1,204	1,183	1,261	1,198	+5%
Type C Meetings Scheduled	725	611	543	603	596	653	616	+6%
Type B Written Response	--	153	249	382	469	469	--[‡]	--[‡]
Type C Written Response	--	281	393	546	658	622	--[‡]	--[‡]
Meeting Minutes	1,585	1,486	1,503	1,517	1,500	1,702	1,518	+12%
Responses to Clinical Holds	178	161	148	161	232	194	176	+10%
Major Dispute Resolutions	32	25	33	15	17	20	24	-17%
Special Protocol Assessments	288	222	201	231	215	170	231	-26%
Review of Proprietary Names Submitted During IND Phase	164	161	170	178	158	175	166	+5%
Review of Proprietary Names Submitted with NDA/BLA	216	224	209	213	202	253	213	+19%
First-Cycle Filing Review Notifications: NDAs and BLAs	126	138	131	149	130	160	135	+19%
First-Cycle Filing Review Notifications: Efficacy Supplements	96	99	136	127	117	146	115	+27%
Notification of Planned Review Timelines: NDAs and BLAs	126	138	131	149	130	160	135	+19%
Notification of Planned Review Timelines: Efficacy Supplements	96	99	136	127	114	144	114	+26%

* FY 2016 numbers were changed to reflect updates to data presented in the FY 2016 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 2016 Procedural and Processing Performance

The table below presents final performance for FY 2016 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 procedural and processing goals in FY 2016. More detailed information on performance is available in Appendix A.

Submission/Request Type	Goal: 90 Percent Within	Total	FY 2016 Performance
Type A Meeting Requests	14 days	124 of 135 on time	**92%**
Type B Meeting Requests	21 days	1605 of 1738 on time	**92%**
Type C Meeting Requests	21 days	1203 of 1372 on time	88%
Type A Meetings Scheduled	30 days	85 of 123 on time	69%
Type B Meetings Scheduled	60 days	841 of 1183 on time	71%
Type C Meetings Scheduled	75 days	460 of 596 on time	77%
Type B Written Response	60 days	373 of 469 on time	80%
Type C Written Response	75 days	546 of 658 on time	83%
Meeting Minutes	30 days	1361 of 1500 on time	**91%**
Responses to Clinical Holds	30 days	219 of 232 on time	**94%**
Major Dispute Resolutions	30 days	16 of 17 on time	**94%**
Special Protocol Assessments	45 days	208 of 215 on time	**97%**
Review of Proprietary Names Submitted During IND Phase	180 days	158 of 158 on time	**100%**
Review of Proprietary Names Submitted with NDA/BLA	90 days	201 of 202 on time	**100%**
First-Cycle Filing Review Notifications: NDAs and BLAs	74 days	124 of 130 on time	**95%**
First-Cycle Filing Review Notifications: Efficacy Supplements	74 days	113 of 117 on time	**97%**
Notification of Planned Review Timelines: NDAs and BLAs	74 days	126 of 130 on time	**97%**
Notification of Planned Review Timelines: Efficacy Supplements	74 days	111 of 114 on time	**97%**

Preliminary FY 2017 Procedural and Processing Performance

The table below presents preliminary performance for FY 2017 submissions in achieving goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA V.

- The progress (the number of review activities completed or pending overdue) and the total number of submissions received for each submission type are shown in the second column. 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). More detailed information on the completed review activities is available in Appendix B.
- FDA is currently meeting or exceeding 12 of 18 procedural and processing goals. 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	Goal: 90 Percent Within	Goal: 90 Percent Within	FY 2017 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	189 of 269 complete	14 days	81%	87%
Type B Meeting Requests	1,763 of 1,799 complete	21 days	**92%**	92%
Type C Meeting Requests	1,327 of 1,345 complete	21 days	**92%**	92%
Type A Meetings Scheduled	163 of 255 complete	21 days	72%	82%
Type B Meetings Scheduled	1,201 of 1,261 complete	30 days	67%	69%
Type C Meetings Scheduled	620 of 653 complete	75 days	76%	77%
Type B Written Response	400 of 469 complete	60 days	76%	80%
Type C Written Response	523 of 622 complete	75 days	85%	87%
Meeting Minutes	1,219 of 1,702 complete	30 days	**92%**	94%
Responses to Clinical Holds	187 of 194 complete	30 days	**91%**	92%
Major Dispute Resolutions	19 of 20 complete	30 days	**95%**	95%
Special Protocol Assessments	150 of 170 complete	45 days	**96%**	96%
Review of Proprietary Names Submitted During IND Phase	98 of 175 complete	180 days	**99%**	99%
Review of Proprietary Names Submitted with NDA/BLA	198 of 253 complete	90 days	**98%**	99%
First-Cycle Filing Review Notifications: NDAs and BLAs	121 of 160 complete	74 days	**95%**	96%
First-Cycle Filing Review Notifications: Efficacy Supplements	130 of 146 complete	74 days	**97%**	97%
Notification of Planned Review Timelines: NDAs and BLAs	123 of 160 complete	74 days	**99%**	99%
Notification of Planned Review Timelines: Efficacy Supplements	128 of 144 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 specific performance 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. For FY 2016, the percentage of NDAs and BLAs for FY 2016 that met their target date was 64 percent (77 percent for Efficacy Supplements). Preliminary data for FY 2017 shows the percentage of NDAs and BLAs for FY 2017 that met their target date is 78 percent (75 percent for Efficacy Supplements).

Final FY 2016 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	126	9	74	42	1	**64%**[†]
Efficacy Supplements	111	4	82	24	1	**77%**

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

[†] FY 2016 numbers were changed to reflect updates to data presented in the FY 2016 PDUFA Performance Report.

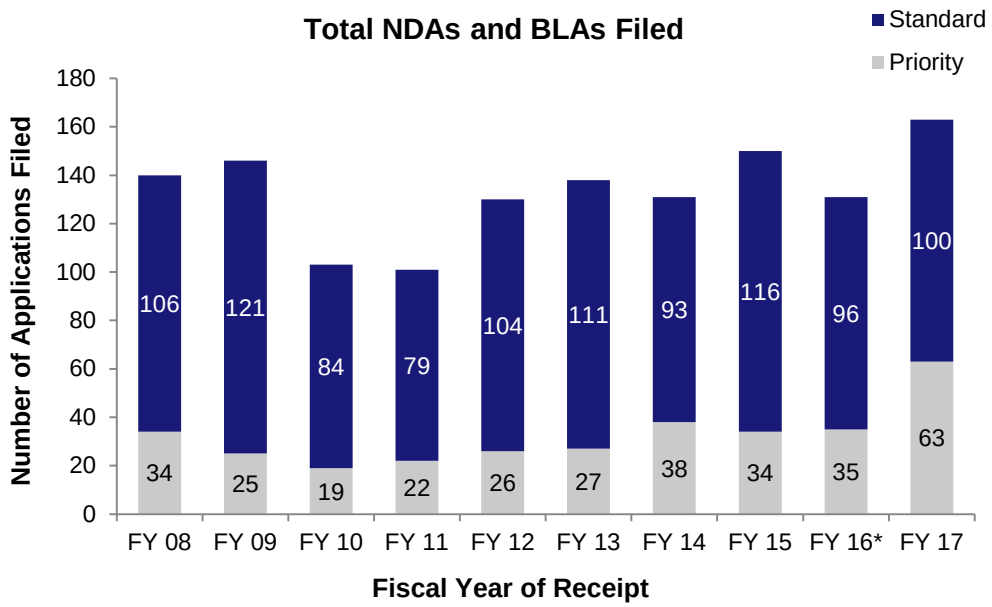
Preliminary FY 2017 Cohort Performance

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	122	2	58	16	46	0	**78%**
Efficacy Supplements	127	0	43	14	70	0	**75%**

* Target dates for seven NDAs/BLAs were met by communicating deficiencies.

PDUFA Trend Graphs

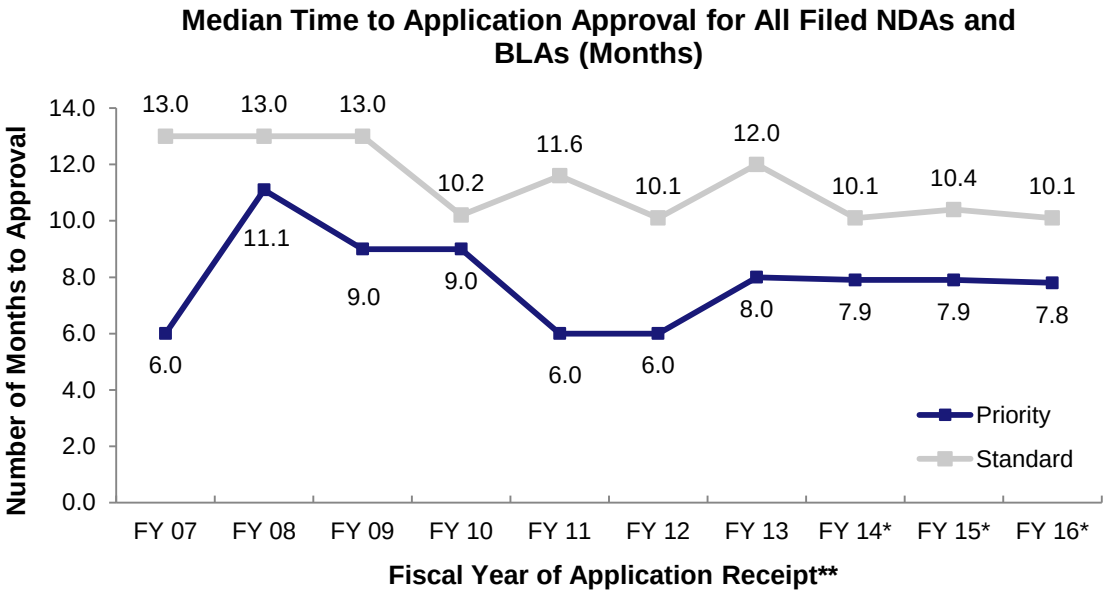
The number of NDAs and BLAs filed from FY 2008 to FY 2017 is presented in the graph below. The total number of standard applications of NDAs and BLAs filed in FY 2017 increased compared to the number filed in FY 2016, and the total number of priority applications filed reached a new high in FY 2017.



* FY 2016 numbers were changed to reflect updates to data presented in the FY 2016 PDUFA Performance Report.

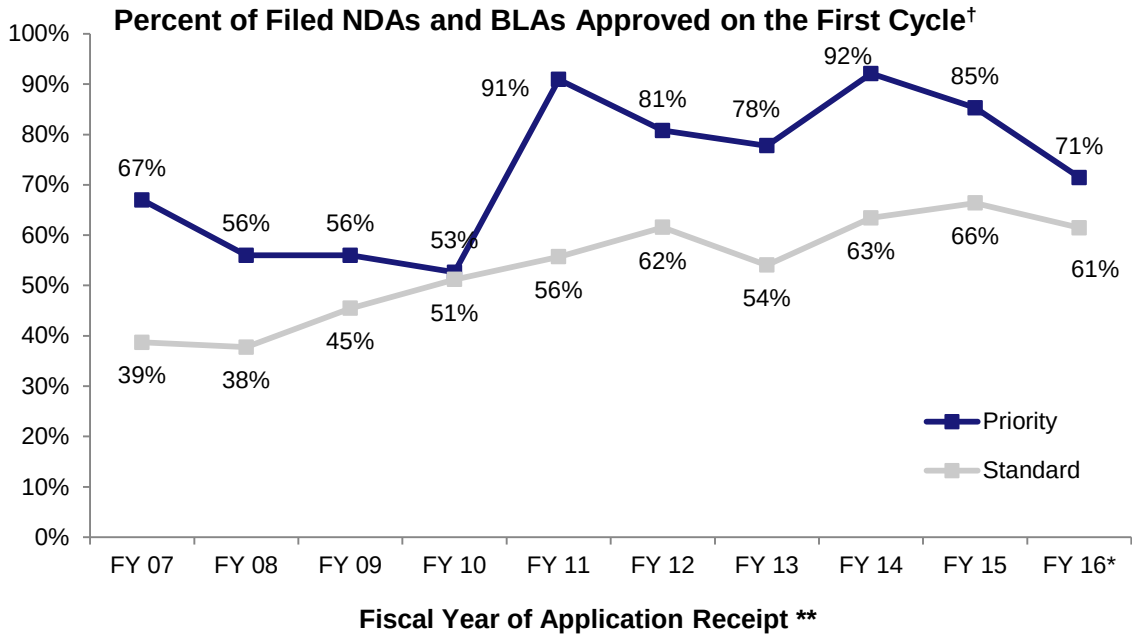
Median total time to approval for priority and standard applications received from FY 2007 through FY 2016 are presented in the graph below.[7] Data represented in the graph is updated based on the approvals reported in Appendix C. FY 2017 data are too preliminary to estimate the median approval time.

[7] The total time for applications that are approved on the first cycle includes only FDA response time. Applications that are approved after multiple review cycles include both FDA and sponsor time. Median total approval time is the median of all application times for a given cohort, including applications that have gone through multiple review cycles.



† Data represents all NDAs and BLAs.
* Data represented in this graph are based on the approvals reported in Appendix C.

The graph below depicts the percentages of priority and standard NDAs and BLAs approved in the first review cycle for the receipt cohorts from FY 2007 to FY 2016. These data are based on the approvals reported in Appendix C. Standard applications saw a steady increase in first-cycle approvals from FY 2009 to FY 2012, decreased slightly in FY 2013, increased again in FY 2014 and FY 2015, before a slight decrease in FY 2016. For the FY 2016 cohort, which is still preliminary, 61 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications decreased slightly in FY 2016, with 71 percent of approved priority applications being approved on the first cycle. The FY 2017 data are too preliminary to estimate the percent of first-cycle approvals.



† Data were changed to reflect updates to data presented in the FY 2016 PDUFA Performance Report
* First cycle approvals are still possible for FY 2016 standard applications, so the data are preliminary.
** Data represented in this graph are based on the approvals reported in Appendix C.

Additional PDUFA V Commitments

Under section XIII of the PDUFA Commitment Letter, FDA committed to report its progress on the additional program enhancements identified in the following sections of the Commitment Letter:[8]

- 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. The progress reports in this section discuss the work FDA performed in FY 2017 on commitments in sections IX-XII of the Commitment Letter. Commitments that were met and reported in the FY 2016 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.

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

Section IX: Enhancing Regulatory Science and Expediting Drug Development

Commitment Title	FY 2017 Accomplishments
IX.A Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• CDER's enhanced communication functions are located in CDER's Office of New Drugs and the Center for Biologics Evaluation and Research's (CBER) Manufacturing Assistance and Technical Training Branch. During FY 2017, CDER's Enhanced Communication Team (ECT) responded to 151 contacts regarding the drug development process, referred 75 contacts regarding other issues to the appropriate resources, and received 0 requests for facilitation of issues with review divisions. CDER's ECT provided external training on best communication practices to the sponsor community at professional conferences. (IX.A.1-.6) • During FY2017, CBER's Office of Communications Outreach and Development responded to over 260 contacts regarding the drug development process, and provided assistance as appropriate. • CBER and CDER offered internal communication skills training in areas such as interpersonal communication, negotiation, collaboration, constructive conflict management, and how to approach difficult conversations. (IX.A.7)
IX.B. Advancing the Science of Meta-Analysis Methodologies	• FDA maintained efforts in FY 2017 to recruit and hire additional statistical, epidemiological, and medical reviewers to evaluate and conduct meta-analyses to explore safety signals. (IX.B.1). • FDA continued work on a draft guidance on meta-analyses of randomized controlled clinical trials to evaluate safety, and FDA's intended approach for the use of meta-analyses in regulatory decision-making began in FY 2017. FDA expects to publish this draft guidance in early FY 2018 for comment. Through the publication of this draft guidance, FDA's intended approach for the use of meta-analyses in regulatory decision-making will be clarified. (IX.B.2-3) • CBER created a database of influenza vaccine clinical trials, particularly those assessing quadrivalent influenza vaccines. The database will be used to evaluate novel statistical methods to examine subgroup differences in safety and/or efficacy. (IX.B.1) • CBER developed a database and analytical platform for evaluating safety issues with chimeric antigen receptor T-cell products across multiple products. (IX.B.1) • CBER developed a novel empirical Bayesian meta-analysis methodology for synthesizing historical data to evaluate product safety and identify heterogeneous subgroups. This work led to a publication and numerous presentations and posters at scientific conferences: Li, J. X., Chen, Wei-Chen., & Scott, J.A. (2016). Addressing Prior-data Conflict with Empirical Meta-analytic Predictive Priors in Clinical Studies with Historical Information. *Journal of Biopharmaceutical Statistics, 2*(6), 1056-1066. [9] (IX.B.1)

[9] www.tandfonline.com/doi/full/10.1080/10543406.2016.1226324

IX.C. Advancing the Use of Biomarkers and Pharmacogenomics	• All positions under this enhancement remain filled and are being applied in IND/NDA/BLA review, regulatory science efforts, outreach and training, and guidance and policy development. (IX.C.1) • FDA continued to host 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) • FDA working groups continue to meet regularly, including: 1. the FDA-wide Genomics Working Group (all Centers): focuses on high-throughput sequencing issues, 2. the Intercenter Drug-Test Collaborative (CBER, CDER, and the Center for Devices and Radiological Health (CDRH)) focuses on policy, process, and product-specific issues, 3. the FDA-wide Biomarkers Working Group, and 4. the Omics Working Group (Oncology Center of Excellence) (IX.C.1) • FDA continues to participate biannually in trilateral exchanges with the European Medicines Agency (EMA) and the Pharmaceuticals and Medical Devices Agency pharmacogenomics cluster to discuss emerging topics in the area of genomics/biomarkers in drug development/approval. (IX.C) • In cooperation with the National Institutes of Health (NIH), FDA published the BEST (Biomarkers, EndpointS, and other Tools) glossary[10] to improve communication and to align expectations between stakeholders; public stakeholders can provide comments and future content suggestions. (IX.C) • FDA co-sponsored a public workshop[11] on high-throughput sequencing computational standards for regulatory sciences (with The George Washington University). (IX.C.2) • CDER Biomarker Qualification program activities: o Implementation of the 21st Century Cures Act legislative requirements to support Biomarker Qualification, including transition of existing legacy projects into the new process. o Monthly meetings with FDA's EMA counterparts to discuss policy, process, and shared projects towards the goal of harmonization of approaches when feasible and appropriate. o Completion of the White Paper "Framework for Defining the Evidentiary Criteria for Biomarker Qualification."[12] o Co-sponsorship of a public workshop entitled "Scientific and Regulatory Considerations for the Analytical Validation of Assays Used in the Qualification of Biomarkers in Biological Matrices."[13] o Participation in more than 35 external conferences/workshops. o Web content updates to include educational resources in the form of case studies, videos, and supporting documents.[14] o Issuance of three Letters of Support. • FDA held 23 Critical Path Innovation Meetings (CPIM) with stakeholders from private industry, academia, and public-private consortia. (IX.C) • FDA completed Step 4 on the International Council for Harmonisation (ICH) E18 guideline related to "Genomic Sampling and Management of Genomic Data."[15] (IX.C) • FDA established the Memoranda of Understanding and Research Collaborative Agreements with external stakeholders to carry out research activities related to the use of genomic biomarkers to characterize safety and efficacy. (IX.C)

Commitment Title	FY 2017 Accomplishments

IX.D. Advancing Development of Patient Reported Outcomes (PROs) and Other Endpoint Assessment Tools	• FDA and the Duke-Margolis Center for Health Policy convened three meetings/expert workshops in order to: (1) Advance the conceptual and methodological considerations for using PerfOS in the regulatory setting; and (2) Explore and discuss methodologies and best practices surrounding meaningful within-patient change, and identify specific recommendations on methodologies used to derive and interpret meaningful within-patient change with use of clinical outcome assessment (COA) endpoints in medical product development:
	  • Duke-Margolis Think Tank Meeting: Performance Outcome Measures, December 7-8, 2017
	  • Duke-Margolis Experts Workshop: Meaningful Change, April 4, 2017
	  • Duke-Margolis Expert Workshop: Personalized COAs, April 5, 2017(IX.D.1)

IX.E Advancing Development of Drugs for Rare Diseases	• The Rare Disease Program (RDP) at FDA continued to conduct yearly internal 1-day training for FDA review staff including various topics related to rare disease drug development, review, and approval. The RDP developed, tested, and implemented a "Rare Diseases 101" half-day course for new reviewers. (IX.E.3) • The RDP developed and inaugurated a monthly EMA/FDA Rare Disease Cluster to help make rare disease drug development more efficient and effective through education, information sharing, and improved harmonization of review processes at FDA and at EMA. (IX.E.3) • The RDP continued to support the Data Analysis Search Host (DASH) database, which provides rapid 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, NME drug and therapeutic biologic actions, and major efficacy supplements (new indications and/or new populations). The database has improved FDA's understanding of the impact of expedited development programs, informed the expedited programs and the common issues in rare diseases drug development guidances, and supported 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) • The RDP developed a catalog of sponsor meetings to which RDP contributed to help track rare disease applications through the regulatory process. (IX.E.6) • The RDP helped support and spoke at the first externally-led Patient Focused Drug Development (EL PFDD) meeting conducted by the Myotonic Dystrophy Foundation. The RDP also helped organize, and presented at, other EL PFDD meetings for Acute Intermittent Porphyria, Amyloidosis, C3 Glomerulopathy, Friedreich's Ataxia, Spinal Muscular Atrophy, Thalassemia, and Tuberous Sclerosis Complex. (IX.E.4) • CBER participated in, and gave presentations about, CBER's role in facilitating the development of products for rare diseases at the following annually-held rare

[10] www.ncbi.nlm.nih.gov/books/NBK326791/pdf/Bookshelf_NBK326791.pdf
[11] hive.biochemistry.gwu.edu/htscsrs/workshop_2017
[12] fnih.org/sites/default/files/final/pdf/Evidentiary%20Criteria%20Framework%20Final%20Version%20Oct%2020%202016.pdf
[13] healthpolicy.duke.edu/events/public-workshop-scientific-and-regulatory-considerations-analytical-validation-assays-used
[14] www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/default.htm
[15] www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E18/E18EWG_Step4_Guideline_2017_0803.pdf

Commitment Title	FY 2017 Accomplishments
	disease events: the annual National Organization for Rare Diseases (NORD) Summit in October 2016, NIH Rare Disease Day in February 2017, and the EveryLife Foundation's Scientific Symposium in September 2017. In addition, CBER also gave rare disease-focused presentations at other external events. (IX.E.4) • CBER met with patient organizations for rare diseases including the Friedreich's Ataxia Research Alliance (FARA), the Alpha-1 Foundation, and the National Hemophilia Foundation, to learn more about these organizations and to enhance mutual understanding of respective roles in advancing the development of products for rare diseases. CBER has also engaged with patient organizations in the context of specific product development programs. (IX.E) • CBER rare disease experts contributed to external initiatives aimed at improving clinical trial methodologies and designs for rare disease populations, such as: The International Rare Diseases Research Consortium's (IRDiRC) ongoing development of international recommendations for rare disease clinical trials and the Duke-Margolis meeting on statistical methods for rare disease trials in May, 2017. (IX.E)

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

Commitment Title	FY 2017 Accomplishments
Implementation of a Structured Framework for Benefit-Risk Assessment in the New Drug and Biologic Review Process	• In September 2017, FDA conducted a public meeting[16] entitled "Benefit-Risk Assessment in Drug Regulatory Decision Making." This meeting included presentations and panel discussions focused on regulatory and industry experiences with approaches to structured benefit-risk assessment, approaches to incorporating patient perspectives into structured benefit-risk assessment, and exploration of methods to advance structured benefit-risk assessment. (X.A.2) • In FY 2017, FDA received completed data collection and an analysis from a contractor in accordance with the FY 2015 contract explained below. The contractor presented a summary of the evaluation and key findings at the 2017 public meeting. In FY 2015, FDA awarded a contract to a qualified third party to evaluate the Benefit-Risk Framework implementation into CDER's and CBER's new drug review. The evaluation, with oversight by an FDA Technical Advisory Group, included an independent review by the contractor of review processes and documentation, as well as interviews with FDA staff, applicants, and external stakeholders such as patients, healthcare providers, and patient organizations. (X.A.3). • CDER continued implementation of FDA's Benefit-Risk Framework in the new drug review process for NME NDAs and original BLAs received by the Agency on or after March 1, 2015. In FY 2017, 38 NME NDA and original BLA approvals contained one or more completed Benefit-Risk Frameworks within the publicly available drug review documentation. In September 2017, CDER further integrated the Benefit-Risk Framework into the review templates for premarket reviews of all NDAs and BLAs (including in supplemental NDAs and BLAs) where benefit-risk assessment is applicable. (X.A.1) • CBER continued incorporating the benefit-risk evaluation into the clinical review of BLAs and BLA supplements. This included completing the addition of FDA's Benefit-Risk Framework to the clinical review template. (X.A.1) • In FY 2017, FDA continued the Benefit-Risk Implementation Committee (BRIC), which serves the advisory, oversight, and support functions of the "Change Control Board" and the "Benefit-Risk Advisory Group" outlined in the FDA's 2013 Draft Implementation Plan.[17] (X.A.1) • CDER's rollout of the revised templates for NME NDAs and original BLAs has been accompanied by: (a) an internal website with guidelines and samples; (b) multi-module training on the Benefit-Risk Framework and templates, offered bi-monthly; and (c) individual coaching and support to reviewers. (X.D) • CBER's Office of Biostatistics and Epidemiology offered internal courses on risk assessment, risk management, and risk communication. Benefit-Risk assessment approaches, such as multi-criteria decision analysis, the CIRS-BRAT framework, the Unified Methods for Benefit-Risk Assessment, and number needed to treat/harm, were covered in these courses. (X.D) • FDA provided leadership on the ICH M4E (R2) working group that finalized the guideline entitled *Revision of M4E Guideline on Enhancing the Format and Structure of Benefit-Risk Information in ICH*[18] in June 16, 2016. In FY 2017, FDA published guidance entitled *M4E(R2): The CTD – Efficacy Guidance for Industry*,[19] which integrates the ICH guidelines on presenting benefit-risk information. (X.A)

[16] www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm378861.htm
[17] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf
[18] www.ich.org/fileadmin/Public_Web_Site/ICH_Products/CTD/M4E_R2_Efficacy/M4E_R2__Step_4.pdf

Commitment Title	FY 2017 Accomplishments

Patient-Focused Drug Development (PFDD)	• FDA held four PFDD meetings on the following disease areas in FY 2017 (X.C):
	  • Sarcopenia
	  • Autism
	  • Alopecia areata
	  • Hereditary angioedema
	• FDA published the following PFDD summary reports[20] in FY 2017 (X.C):
	  • In November 2016, FDA published the summary report of the March 2016 meeting on psoriasis.
	  • In February 2017, FDA published the summary report of the June 2016 meeting on neuropathic pain associated with peripheral neuropathy.
	  • In April 2017, FDA published the summary report of the September 2016 meeting on organ transplant.
	• Patient stakeholders conducted nine externally led patient-focused drug development meetings in FY 2017. (X.C). Disease areas included:
	  • Mytonic dystrophy
	  • Acute porphyrias
	  • Osteoarthritis
	  • Spinal muscular atrophy
	  • Friedreich ataxia
	  • Tuberous sclerosis complex
	  • C-3 Glomerulopathy
	  • Thallasemia
	  • Lupus

[19] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM465221.pdf
[20] www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm368342.htm

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

Commitment Title	FY 2017 Accomplishments
XI.A Measure the Effectiveness of Risk Evaluation and Mitigation Strategy (REMS) and Standardize and Better Integrate REMS into the Healthcare System	• FDA standardized REMS by developing a new REMS document template, including standardized text and section headers. This template was designed based on stakeholder feedback about how they use REMS information. It promotes the efficient development, review, and integration of REMS documents into the healthcare delivery system by standardizing REMS information according to the '"4 W's"[21] of REMS. (XI.A) • FDA promoted the integration of REMS information into the healthcare delivery system by issuing the draft guidance *Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.*[22] This draft guidance describes how to submit REMS in electronic format using SPL. (XI.A.2) • In 2017, FDA redesigned the REMS@FDA website to prominently display the goals of the REMS and a summary of what stakeholders need to know. The website is also more easily searchable. The website redesign was based on stakeholder feedback to improve the original website launched in 2015. (XI.A.2) • In September 2017, FDA issued a paper entitled, *A Framework for Benefit-Risk Counseling to Patients About Drugs with a REMS,*[23] which highlights some best practices to support healthcare providers who are considering prescribing medications that have a REMS, or are already treating patients with such medications. (XI.A.2) • FDA published the *REMS Platform Standards Initiative: Needs Assessment*[24] with the purpose of providing REMS stakeholders, standards developers, and health information technology systems developers with specific, detailed information on the areas in which standards development is needed and the information that the data standards would need to communicate. The goal of the REMS Platform Standards Initiative is to leverage electronic health data standards to standardize certain activities in REMS with Elements to Assure Safe Use (ETASU) and integrate them into health IT systems. Under the initiative, FDA seeks to encourage the development of electronic data standards that may be used to facilitate communication between REMS systems and their participants. (XI.A)

[21] www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM563796.pdf
[22] www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM574460.pdf
[23] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM577883.pdf
[24] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM565594.pdf

Commitment Title	FY 2017 Accomplishments
XI.B Sentinel as a Tool for Evaluating Drug Safety Issues That May Require Regulatory Action	• FDA held its annual public workshop[25] on February 2, 2017, 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 advanced multiple Sentinel projects in FY 2017 through the development and revision of protocols or surveillance plans for vaccines, blood products, and drugs. These were all posted to the Sentinel website.[26] They include the following: o The revised study protocol for the evaluation of influenza vaccines and birth outcomes; o The rapid surveillance capability protocol for 2017-18 seasonal influenza vaccine surveillance; o The study protocol and report for the evaluation of thromboembolic events after immunoglobulin administration; o Modular program reports assessing TDAP vaccination during pregnancy and blood transfusions during pregnancy; o Modular program reports assessing trends in influenza antiviral drug use; o An analysis of antipsychotic use and stroke risk; o An analysis of continuous or extended-cycle oral contraceptive use and venous thromboembolism; o An analysis of ranolazine and seizures; o An analysis of contrast and non-contrast magnetic resonance imaging (MRI) and seizures; and o An analysis of indications of use among oral antifungal drug users. (XI.B.2) • FDA has completed the final assessment of Sentinel in PDUFA V to evaluate the strengths, limitations, and the appropriate use of Sentinel for informing regulatory actions to manage safety issues. The final assessment was posted on the PDUFA V public website[27] on September 27, 2017. (XI.B.4) • FDA completed several projects in Sentinel and posted results to the Sentinel website, including: missing laboratory results data in electronic health databases and implications for monitoring diabetes risk;[28] application of propensity-score matched cohort analyses to glyburide, glipizide, and hypoglycemia;[29] anti-emetic use among pregnant women in the United States;[30] the impact of FDA regulatory activities on incident dispensing of long-acting beta agonist-containing medication;[31] and comparing enrollment and retention in United States pregnancy registries to manufacturers' capture of spontaneous reports for product-exposed pregnancies.[32] (XI.B)

[25] healthpolicy.duke.edu/events/ninth-annual-sentinel-initiative-public-workshop
[26] www.sentinelinitiative.org/
[27] www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm464042.htm
[28] www.sentinelinitiative.org/communications/publications/missing-laboratory-results-data-electronic-health-databases
[29] www.sentinelinitiative.org/communications/publications/sentinel-modular-program-propensity-score-matched-cohort-analyses
[30] www.sentinelinitiative.org/communications/publications/antiemetic-use-among-pregnant-women-united-states-escalating-use
[31] www.sentinelinitiative.org/communications/publications/impact-fda-regulatory-activities-incident-dispensing-laba-containing
[32] www.sentinelinitiative.org/communications/publications/enrollment-and-retention-34-united-states-pregnancy-registries

Commitment Title	FY 2017 Accomplishments
XI.C Conduct and Support Activities Designed to Modernize the Process of Pharmacovigilance	• FDA announced the availability of its FDA Adverse Event Reporting System (FAERS) Regional Implementation Specifications for the International Conference on Harmonisation (ICH) E2B (R3) Specification.[33] FDA issued this technical specifications document to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and ICSR attachments) to CDER and CBER. (XI.C) • In September 2017, FDA launched the FAERS Public Dashboard, a new user-friendly search tool that improves access to data on adverse events associated with drug and biologic products through FAERS. The tool is designed to make it easier for consumers, providers, and researchers to access this information.[34] (XI.C) • FDA implemented a subcomponent of the Sentinel System known as the system of Active Risk Identification and Analysis (ARIA), consisting of automated tools and the Sentinel Common Data Model. Aria was implemented to integrate the Sentinel System into FDA's regulatory pre/post-market review process. (XI.C.1) • FDA convened a broad range of training events to strengthen FDA staff understanding of the Sentinel System and FDA regulatory processes. The trainings focused on: o New analytical tools for assessing use of medical products in pregnant women o Overview of capabilities through new Sentinel Data Partners o Regulatory training in assessing sufficiency of the Sentinel System o Technical training in propensity score matching in Sentinel analyses (XI.C.1) • FDA continued supporting research into text mining, natural language processing, analytical methods, and machine learning to accurately classify unstructured data within MedWatch and FAERS reports. o FDA evaluated the use of advanced technologies such as text mining and machine learning methods to aid FDA drug safety evaluators in identifying reports most likely to demonstrate a causal relationship to the suspect medication. These models would enable FDA safety evaluators to focus on the most informative, highest-quality reports. OSE collaborated with the University of California, San Francisco (UCSF), to conduct research under the FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) program.[35] o OSE conducted a research study to explore text mining of social media data in support of a contract awarded by the FDA Office of the Chief Scientist. The objective was to determine whether specific product-related adverse events were reported in social media before they were reported to FAERS. The research was completed and published during FY2017.[36,37] (XI.D)

[33] www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm
[34] www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm
[35] Han L, Ball R, Pamer C, Altman R, Proestel S. *Development of an Automated Assessment Tool for MedWatch Reports in the FDA Adverse Event Reporting System.* J Am Med Inform Assoc 2017 Mar 21. doi: 10.1093/jamia/ocx022. E pub ahead of print.
[36] Dasgupta N, Pierce CE, Bouri K, Pamer **C**, Proestel S, Rodriguez HW, Van Le H, Freifeld CC, Brownstein JS, Walderhaug M, Edwards IR. *Poster: Can Facebook and Twitter Monitoring Yield Earlier Detection of Safety Signals for Medical Products?* 32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management. Dublin, Ireland August 25 – 28, 2016. Pharmacoepidemiol Drug Safety 2016;25 (Supplement 3):408. Abstract number 699.

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

Commitment Title	FY 2017 Accomplishments
Electronic Submissions Requirement	• FDA set up new systems for application submissions. As of May 5, 2017, NDAs, applicable BLAs, and Abbreviated New Drug Applications (ANDA) must be submitted in the eCTD format. For additional information on the guidance, including any exemptions, please refer to the final guidance for industry: "Providing Regulatory Submissions in Electronic Format – eCTD Specifications."[38] (XII.C-D,G)
Standardization of Drug Application Data	• FDA posted version 3.3 of the Study Data Standards Technical Conformance Guide[39] in March 2017. (XII.D) • FDA published annual updates to the FDA Data Standards Catalog and quarterly updates to the FDA Data Standards Strategy Action Plan. (XII.D) • FDA published a *Federal Register* notice for public comment in July 2017 announcing the availability of standardized Pharmaceutical Quality/Chemistry, Manufacturing, and Controls data elements and terminologies. (XII.D-F)
Clinical Terminology Standards	• FDA published the Therapeutic Area (TA) Standards Initiative Summary Report, FY2013 - FY 2017, on the external FDA webpage in September 2017.[40] The ongoing internal FDA project involves developing recommendations for efficacy endpoints in regulated clinical trials. (XII.E) • The FDA's Therapeutic Area (TA) (Disease/Domain) Data Standards Prioritization List[41] lists 54 areas that were identified as key areas in need of standardization and worked continued to develop TA standards. FDA added support for 4 additional TAs in FY2017: Ebola, Kidney transplant, malaria and rheumatoid arthritis. (XII.E)

[37] Pierce CE, Bouri K, Pamer **C**, Proestel S, Rodriguez HW, Van Le H, Freifeld CC, Brownstein JS, Walderhaug M, Edwards IR, Dasgupta N. *Evaluation of Facebook and Twitter Monitoring to Detect Safety Signals for Medical Products: An Analysis of Recent FDA Safety Alerts.* Drug Saf 2017;40(4):317-331.
[38] www.fda.gov/downloads/drugs/guidances/ucm384686.pdf
[39] www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf
[40] www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM575224.pdf
[41] www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm297093.pdf

Section XIV. Information Technology Goals

Performance Goal	FY 2017 Accomplishments
Supporting Regulatory Operations	• In June 2017, FDA posted the results of the assessment entitled "Assessment of Impact of Electronic Submissions and Data Standards on the Efficiency and Other Performance Attributes of the Human Drug Review Process." The assessment indicated that primary clinical reviewers "strongly agree" or "agree" that standardized data makes a difference in different aspects of their review activities.[42] (XIV.B.1) • The 2nd Generation Electronic Submissions Gateway (ESG) Modernization Phase II was completed in September 2017. Phase II is providing a number of benefits to FDA and industry users to include increased system availability so users can always submit files and access historical submissions; the elimination of system downtime for planned outages; and an enhanced ESG User Interface for web-based users that eases navigation, eliminates Java dependency, and supports multi-file upload. (XIV.A)
Communications and Technical Interactions	• Conducted quarterly meetings with industry on the following dates: December 13, 2016, and March 7, June 6, and September 12, 2017. Quarterly meeting participants discussed prospective implementation of the IT plan, progress toward long term goals, 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 reported the FY 2017 IT metrics and measures in the PDUFA IT Annual Assessment and post to the FDA webpage by the end of December 2017. (XIV.C.1)

[42] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM564913.pdf

FY 2017 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 2017 status of FDA's hiring and placement for the 129 full-time equivalents (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,[43] 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 2017, 127 of 129 (98 percent) of the FTEs have been hired.

Office	Allocated FTEs	Hired
Enhanced Communication		
CDER/Office of New Drugs	6	6
CBER	1	1
Methods for Meta-analysis		
CDER/Office of New Drugs	4	4
CDER/Office of Translational Sciences	4	4
CBER	2	2
Biomarkers and Pharmacogenomics		
CDER/Office of New Drugs	3	3
CDER/Office of Translational Sciences	10	10
CBER	2	2
Use of Patient-Reported Outcomes		
CDER/Office of New Drugs	10	10
CDER/Office of Translational Sciences	5	5
CBER	2	2
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	7
OC/Office of Health and Constituent Affairs	0	0
CBER	2	2
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	2
CDER/Office of the Center Director	1	1
Electronic Submissions and Data Standards		
CDER/Office of Translational Sciences	4	4
CDER/Office of Strategic Programs	6	6

[43] An office comprised of smaller subordinate offices.

Office	Allocated FTEs	Hired
Review Program Data and Systems Upgrades		
CDER/Office of Strategic Programs	3	2
PDUFA V Total Direct FTEs	**92**	**90**
PDUFA V Indirect FTEs Allocations		
CDER	33	33
CBER	4	4
OC	0	0
TOTAL PDUFA V FTEs	**129**	**127**

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 was 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 took action on a Program application, ERG also conducted interviews with the applicant and the FDA review team to identify best practices and opportunities for improvement of the Program. Two Program assessments were published during PDUFA V: an interim assessment[44] was published March 31, 2015, and a final assessment[45] was published on December 9, 2016. All tasks related to the Independent Assessment were concluded on April 30, 2017. 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. The table below provides information on the total number of applications filed for review under the first 4 years of the Program and the review actions completed for each fiscal year.

Fiscal Year of Application Receipt	Filed	Approved	Withdrawn	Complete Response
FY 2013	56	40	3	13
FY 2014	57	49	2	6
FY 2015	62	47	1	14
FY 2016	47	34	1	12
Total	**222**	**170**	**7**	**45**

FDA filed 56 applications (36 NME NDAs and 20 BLAs) for review in the Program in FY 2013, and 57 applications (38 NME NDAs and 19 BLAs) during FY 2014. FDA filed 62 applications (39 NME NDAs and 23 BLAs) for review in the Program during FY 2015, and 47 applications (27 NME NDAs and 20 BLAs) during FY 2016.

In the first 4 years of the Program, ERG evaluated numerous interactions between FDA and applicants, including 182 pre-submission meetings, 188 mid-cycle communications, and 163

[44] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM436448.pdf
[45] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM552923.pdf

late-cycle meetings. For the 194 applications that received a first-cycle FDA action by December 31, 2016, ERG also conducted 170 post-action interviews with applicants and 179 with FDA review teams.

Program Quality Metrics

The tables below provide information on FY 2016 and FY 2017 applications that had a completed first action reviewed under the Program as of September 30, 2017. These counts capture the Program milestones completed for applications received in the listed fiscal year. Metrics for applications received in FY 2017 will be updated in the FY 2018 PDUFA Performance Report.

Quality System Metric	FY 2016	FY 2017*
Applications Filed with a First Action	47	19
Pre-NDA/BLA Meetings Held	41	17
Applications with Agreement on Complete Application	33	17
Applications with Agreement on Late Component Submission	17	9
74-Day Letters Issued	47	24
Mid-Cycle Communications	47	23
Primary Reviews Completed	279	98
Secondary Reviews Completed	97	29
Late Cycle Meeting Packages	44	22
Late Cycle Meetings Held	43	22
Discipline Review Letters Issued	4	0

*****FY 2017 data are preliminary.

Disciplines Referenced in Discipline Review Letters*

	FY 2016	FY 2017**
Clinical	2	0
Clinical Pharmacology	2	0
Nonclinical	1	0
Quality	0	0
Statistical	2	0

* More than one discipline may be referenced in a single discipline review letter.

** FY 2017 data are preliminary.

Appendices

Appendix A: Final FY 2016 Cohort Performance Detail

The following tables detail the final performance for the FY 2016 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 2016 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 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, 2017, 100 percent of FY 2016 cohort applications in the Program were reviewed within their PDUFA goal timelines.

Products Reviewed Under PDUFA V Program

Application Type (Final Designation)	Filed	On Time	Overdue	Pending Within Goal
Priority NDAs and BLAs†	24	24	0	0
Standard NDAs and BLAs	21	21	0	0
Priority Efficacy Supplements*	2	2	0	0
Standard Efficacy Supplements*	0	0	0	0
Total Program Performance	47	47	0	0

* Some applications that are submitted as NME NDAs may be considered efficacy supplements at the time of approval.

Original Applications

Original Application Type	Performance Goal	Filed	On Time	Overdue	Percent on Time
Priority NMEs & BLAs	Act on 90 percent within 6 months	23	23	0	**100%**
Standard NMEs & BLAs	Act on 90 percent within 10 months	24	24	0	**100%**
Priority Non-NME NDAs	Act on 90 percent within 6 months	12	11	1	**92%**
Standard Non-NME NDAs	Act on 90 percent within 10 months	72	69	3	**96%**

Resubmitted Original Applications

Resubmitted Application Type	Performance Goal	Filed	On Time	Overdue	Percent on Time
Class 1	Act on 90 percent within 2 months	5	5	0	**100%**
Class 2	Act on 90 percent within 6 months	31	31	0	**100%**

Efficacy Supplements

Efficacy Supplement Type	Performance Goal	Filed	On Time	Overdue	Percent on Time
Priority	Act on 90 percent within 6 months	54	54	0	**100%**
Standard	Act on 90 percent within 10 months	145	137	8	**94%**

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	3	3	0	**100%**
Class 2	Act on 90 percent within 6 months	11	10	1	**91%**

Manufacturing Supplements

Manufacturing Supplement Type	Performance Goal	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	Act on 90 percent within 4 months	842	810	32	**96%**
Prior Approval Not Required	Act on 90 percent within 6 months	1,475	1,463	12	**99%**

Procedural and Processing Goal Performance

Meeting Management

Type	Performance Goal	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests	Respond to 90 percent within 14 days	135	124	11	**92%**
Type B Meeting Requests	Respond to 90 percent within 21 days	1,738	1,605	133	**92%**
Type C Meeting Requests	Respond to 90 percent within 21 days	1,372	1,203	169	88%
Type A Meetings Scheduled	Schedule 90 percent within 30 days	123	85	38	69%
Type B Meetings Scheduled	Schedule 90 percent within 60 days	1,183	841	342	71%
Type C Meetings Scheduled	Schedule 90 percent within 75 days	596	460	136	77%
Type B Written Response	Respond to 90 percent within 60 days	469	373	96	80%
Type C Written Response	Respond to 90 percent within 75 days	658	546	112	83%
Meeting Minutes	Issue 90 percent within 30 days	1,500	1,361	139	**91%**

* 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.

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Responses to Clinical Holds

Performance Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	232	219	13	**94%**

Major Dispute Resolutions

Performance Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	17	16	1	**94%**

* 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

Performance Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	215	208	7	**97%**

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Total Resubmissions
35	32	2	1	39

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	158	158	0	**100%**
Submitted with NDA/BLA	Review 90 percent within 90 days	202	201	1	**100%**

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	130	124	6	**95%**
Efficacy Supplements	Act on 90 percent within 74 days	117	113	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	130	126	4	**97%**
Efficacy Supplements	114**	111	3	**97%**

* 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.

** Three efficacy supplements were never issued 74-day letters and were not included in calculations of final performance.

Appendix B: Preliminary FY 2017 Cohort Performance Detail

The following detailed performance information for FY 2017 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 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, if it is the same applicant and 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, 2017, all FY 2017 cohort applications in the Program are being reviewed within their PDUFA goal timelines.

Products Reviewed Under the PDUFA V Program

Application Type (Final Designation)	Filed	On Time	Overdue	Pending Within Goal
Priority NDAs and BLAs	32	16	0	16
Standard NDAs and BLAs	20	1	0	19
NDAs and BLAs Review Priority Undesignated*	0	--	--	--
Priority Efficacy Supplements†	2	2	0	0
Standard Efficacy Supplements†	0	0	0	0
Efficacy Supplements Review Priority Undesignated*	0	--	--	--
Total Program Performance	54	19	0	35

* 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	32	16	0	16	**100%**	100%
Standard NMEs & BLAs	10 months of filing date	23	3	0	20	**100%**	100%
Priority Non-NME NDAs	6 months	23	10	0	13	**100%**	100%
Standard Non-NME NDAs	10 months	77	20	0	57	**100%**	100%
Review Priority Undesignated*	To Be Determined	8	--	--	**--**	**--**	--

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

Resubmitted Original 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	8	6	0	2	**100%**	100%
Class 2	6 months	49	18	0	31	**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	61	30	0	31	**100%**	100%
Standard	10 months	165	39	1	125	**98%**	99%
Review Priority Undesignated*	To Be Determined	17	--	--	--	**--**	--

* 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	3	3	0	0	**100%**	100%
Class 2	6 months	11	4	0	7	**100%**	100%

Manufacturing Supplements

Manufacturing 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
Prior Approval Required	4 months	991	595	18	378	**97%**	98%
Prior Approval Not Required	6 months	1,495	811	9	675	**99%**	99%
Review Priority Undesignated	To Be Determined	0	--	--	--	**--**	**--**

Procedural and Processing Goal Performance

Meeting Management

Type	Performance Goal: 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	269	154	35	80	81**%**	87%
Type B Meeting Requests	21 Days	1,799	1,615	148	36	**92%**	92%
Type C Meeting Requests	21 Days	1,345	1,217	110	18	**92%**	92%
Type A Meetings Scheduled†	30 Days	255	117	46	92	72%	82%
Type B Meetings Scheduled	60 Days	1,261	806	395	60	67%	69%
Type C Meetings Scheduled	75 Days	653	471	149	33	76%	77%
Type B Written Response	60 Days	469	304	96	69	76%	80%
Type C Written Response	75 Days	622	443	80	99	85%	87%
Meeting Minutes	30 Days	1,702	1,121	98	483	**92%**	94%

* 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 200 meetings (100 requests and 100 scheduling) coded as undesignated in the database as of September 30, 2017. 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 2018 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	194	171	16	7	**91%**	92%

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	20	18	1	1	**95%**	95%

* 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	170	144	6	20	**96%**	96%

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Total Resubmissions
31	26	4	1	37

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	175	97	1	77	**99%**	99%
Proprietary Names Submitted with NDA/BLA	90 days	253	195	3	55	**98%**	99%

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	160	115	6	39	**95%**	96%
Efficacy Supplements	74 days	146	126	4	16	**97%**	97%

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	160	122	1	37	**99%**	99%
Efficacy Supplements	144**	127	1	16	**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.

** Two efficacy supplements were never issued 74-day letters and were not included in the performance calculations.

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 2017. 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 2017 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 *EMFLAZA (Deflazacort)* on page C-3 was received on 06/09/2016 and had an 8-month review goal date of 02/09/2017, as it was reviewed under the PDUFA V Program and had priority review. 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 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 2017 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 2017							
Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate	Aurobindo Pharma Ltd.	N	First	1.1	TA	1.1	Y◊
Vyxeos (Daunorubicin and Cytarabine)	Celator Pharmaceuticals, Inc.	N	First	4.1	AP	4.1	Y
Verzenio (abemaciclib)	Eli Lilly and Co.	Y	First	4.8	AP	4.8	Y♦
Zejula (Niraparib)	Tesaro, Inc.	Y	First	4.9	AP	4.9	Y♦
Lynparza (Olaparib)	Astrazeneca Pharmaceuticals LP	N	First	5.8	AP	5.8	Y
Norvir (Ritonavir)	Abbvie, Inc.	N	First	6.0	AP	6.0	Y
Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate	Mylan Laboratories Ltd.	N	First	6.0	TA	6.0	Y◊
Roxybond (Oxycodone Hydrochloride)	Daiichi Sankyo, Inc.	N	First	6.0	AP	6.0	Y
Gleolan (Aminolevulinic Acid Hydrochloride)	NX Development Corp.	N	First	6.0	AP	6.0	Y
Aliqopa (Copanlisib)	Bayer Healthcare Pharmaceuticals, Inc.	Y	First	6.0	AP	6.0	Y♦
Imfinzi (Durvalumab)	Astrazeneca UK Ltd,	Y	First	6.6	AP	6.6	Y
Tisagenlecleucel	Novartis Pharmaceuticals Corp.	Y	First	6.9	AP	6.9	Y♦
Idhifa (Enasidenib)	Celgene Corp.	Y	First	7.0	AP	7.0	Y♦
Vosevi (Sofosbuvir, Velpatasvir, and Voxilaprevir)	Gilead Sciences, Inc.	Y	First	7.3	AP	7.3	Y♦
Mavyret (Glecaprevir and Pibrentasvir)	Abbvie, Inc.	Y	First	7.6	AP	7.6	Y♦
Solosec (Secnidazole)	Symbiomix Therapeutics LLC	Y	First	7.9	AP	7.9	Y♦
Besponsa (Inotuzumab Ozogamicin)	Wyeth Pharmaceuticals, Inc.	Y	First	7.9	AP	7.9	Y♦
Tremfya (Guselkumab)	Janssen Biotech, Inc.	Y	First	7.9	AP	7.9	Y♦
Benznidazole	Chemo Research Sl	Y	First	8.0	AP	8.0	Y♦

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Vabomere (Meropenem and Vaborbactam)	Rempex Pharmaceuticals	Y	First	8.0	AP	8.0	Y♦
Bevyxxa (Betrixaban)	Portola Pharmaceuticals, Inc.	Y	First	8.0	AP	8.0	Y♦
Baxdela (Delafloxacin)	Melinta Therapeutics, Inc.	Y	First	8.0	AP	8.0	Y♦
Baxdela (Delafloxacin)	Melinta Therapeutics, Inc.	N[46]	First	8.0	AP	8.0	Y♦
Submitted in FY 2016							
Spinraza (Nusinersen)	Biogen, Inc.	Y	First	3.0	AP	3.0	Y♦
Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate	Mylan Pharmaceuticals, Inc.	N	First	5.9	TA	5.9	Y◊
Rubraca (Rucaparib)	Clovis Oncology, Inc.	Y	First	5.9	AP	5.9	Y♦
Vermox (Mebendazole Chewable Tablets)	Janssen Pharmaceuticals, Inc.	N	First	6.0	AP	6.0	Y
Evzio (Naloxone Hydrochloride Injection)	Kaleo, Inc.	N	First	6.0	AP	6.0	Y
Selzentry (Maraviroc)	Viiv Healthcare Co.	N	First	6.0	AP	6.0	Y
Bavencio (Avelumab)	Emd Serono, Inc.	Y	First	6.0	AP	6.0	Y♦
Kisqali (Ribociclib)	Novartis Pharmaceuticals Corp.	Y	First	6.5	AP	6.5	Y♦
Lartruvo (Olaratumab)	Eli Lilly and Co.	Y	First	7.8	AP	7.8	Y♦
Rydapt (Midostaurin)	Novartis Pharmaceuticals Corp,	Y	First	8.0	AP	8.0	Y♦
Alunbrig (Brigatinib)	Ariad Pharmaceuticals, Inc.	Y	First	8.0	AP	8.0	Y♦
Ingrezza (Valbenazine)	Neurocrine Biosciences, Inc.	Y	First	8.0	AP	8.0	Y♦
Dupixent (Dupilumab)	Regeneron Pharmaceuticals, Inc.	Y	First	8.0	AP	8.0	Y♦
Emflaza (Deflazacort)	PTC Therapeutics, Inc.	Y	First	8.1	AP	8.1	Y♦

[46] These two NDAs (Baxdela) are for the same moiety but different dosage forms (tablet vs. injection). Only one NDA retains the NME designation upon approval; in this case, the NDA for the tablet form retained the NME designation.

Proprietary Name (established name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Emflaza (Deflazacort)	Ptc Therapeutics, Inc.	N[47]	First	8.1	AP	8.1	Y♦
Zinplava (Bezlotoxumab)	Merck Sharp & Dohme Corp	Y	First	10.9	AP	10.9	Y♦♯
Xermelo (Telotristat Ethyl)	Lexicon Pharmaceuticals, Inc	Y	First	11.0	AP	11.0	Y♦♯
Brineura (Cerliponase Alfa)	Biomarin Pharmaceutical, Inc.	Y	First	11.0	AP	11.0	Y♦♯
Ocrevus (Ocrelizumab)	Genentech, Inc.	Y	First	11.0	AP	11.0	Y♦♯
Soliqua (Insulin Glargine and Lixisenatide Injection)	Sanofi-Aventis U.S. LLC	N[48]	First	11.1	AP	11.1	Y♦♯
Zerviate (Cetirizine Ophthalmic Solution)	Nicox Ophthalmics, Inc.	N	First	5.7	CR	5.7	Y
			Sponsor	5.0		10.7	
			Second	2.7	AP	13.4	Y△
Submitted in FY 2012							
Efavirenz, Lamivudine, and Tenofovir Disoproxil Fumarate	Hetero Labs Ltd. Unit III	N	First	6.0	TA	6.0	Y◊
			Sponsor	42.1		48.1	
			Second	0.5	CR	48.6	Y◊△
			Sponsor	7.3		55.9	
			Third	5.9	TA	61.8	Y◊△

[47] These two NDAs (Emflaza) are for the same moiety but different dosage forms (tablet vs. solution), and only one retains the NME designation upon approval; in this case, the NDA for the tablet form retained the NME designation.
[48] Non-NME NDA reviewed under the PDUFA V program. At time of receipt, the active ingredient Lixisenatide had never been approved in the United States, allowing for NME designation; however, at time of approval, Lixisenatide had already been approved for marketing in another application, causing this application to lose its 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 2006							
Lamivudine/Zidovudine	Pharmacare Ltd.	N	First	5.9	TA	5.9	Y◊
			Sponsor	121.0		126.9	
			Second	5.9	AP	132.8	Y◊△

Table 2
FY 2017 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 2017							
Nikita (Pitavastatin)	Lupin Ltd.	N	First	9.5	AP	9.5	Y
Gemcitabine	Accord Healthcare, Inc.	N	First	9.7	AP	9.7	Y
Duzallo (Lesinurad/Allopurinol)	Ardea Biosciences, Inc.	N	First	9.9	AP	9.9	Y
Gocovri (Amantadine Extended-Release)	Adamas Pharma LLC	N	First	10.0	AP	10.0	Y
Carospir (Spironolactone)	CMP Pharma, Inc.	N	First	10.0	AP	10.0	Y
Adzenys ER (Amphetamine)	Neos Therapeutics, Inc.	N	First	10.0	AP	10.0	Y
Admelog (Insulin Lispro Injection)	Sanofi-Aventis U.S. LLC	N	First	10.0	TA	10.0	Y
Mylotarg (Gemtuzumab Ozogamicin)	Wyeth Pharmaceuticals, Inc.	N	First	10.0	AP	10.0	Y
Trelegy Ellipta (Fluticasone Furoate 100 Mcg, Umeclidinium 62.5 Mcg, and Vilanterol 25 Mcg)	Glaxosmithkline Intellectual Property Development Ltd England	N	First	10.0	AP	10.0	Y
Xhance (Fluticasone Propionate)	Optnose U.S., Inc.	N	First	10.0	AP	10.0	Y
Qvar Redihaler (Beclomethasone Dipropionate)	Norton Waterford Ltd	N	First	10.0	AP	10.0	Y
Submitted in FY 2016							
Esbriet (Pirfenidone)	Genentech, Inc,	N	First	9.5	AP	9.5	Y
Isopto Atropine (Atropine Sulfate Ophthalmic Solution)	Novartis Pharmaceuticals Corp.	N	First	9.6	AP	9.6	Y
Tirosint-Sol (Levothyroxine Sodium Oral Solution)	Institut Biochimique Sa (Ibsa)	N	First	9.7	AP	9.7	Y
Clindamycin	Baxter Healthcare Corp.	N	First	9.7	AP	9.7	Y
Jadenu (Deferasirox)	Novartis Pharmaceuticals Corp.	N	First	9.9	AP	9.9	Y
Tepadina (Thiotepa)	Adienne Sa	N	First	9.9	AP	9.9	Y
Rhofade (Oxymetazoline Hydrochloride)	Allergan, Inc.	N	First	9.9	AP	9.9	Y
Bortezomib	Hospira, Inc.	N	First	9.9	TA	9.9	Y
Benlysta (Belimumab)	Human Genome Sciences, Inc.	N	First	9.9	AP	9.9	Y
Rituxan Hycela (Rituximab and Hyaluronidase Human)	Genentech, Inc.	N	First	9.9	AP	9.9	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Vemlidy (Tenofovir Alafenamide)	Gilead Sciences Inc	N	First	10.0	AP	10.0	Y
Vyvanse (Lisdexamfetamine Dimesylate)	Shire Development LLC	N	First	10.0	AP	10.0	Y
Bortezomib	Actavis LLC	N	First	10.0	TA	10.0	Y
Synjardy (Empagliflozin and Metformin Hydrochloride)	Boehringer Ingelheim Pharm, Inc.	N	First	10.0	AP	10.0	Y
Cabazitaxel	Sandoz, Inc.	N	First	10.0	TA	10.0	Y
Fluticasone Propionate	Teva Pharmaceutical Industries Ltd	N	First	10.0	AP	10.0	Y
Fluticasone Propionate/Salmeterol	Teva Pharmaceutical Industries Ltd	N	First	10.0	AP	10.0	Y
Varibar (Barium Sulfate Paste, 40% (W/V))	Bracco Diagnostics, Inc.	N	First	10.0	AP	10.0	Y
Triptodur (Triptorelin)	Arbor Pharmaceuticals LLC	N	First	10.0	AP	10.0	Y
Xyrosa (Doxycycline)	Sun Pharmaceutical Industries Ltd	N	First	10.0	TA	10.0	Y
Minolira (Minocycline Hydrochloride)	Dr Reddys Laboratories Ltd	N	First	10.0	AP	10.0	Y
Ganciclovir	Exela Pharma Sciences LLC	N	First	10.0	AP	10.0	Y
Nipride Rtu (Sodium Nitroprusside)	Exela Pharma Sciences LLC	N	First	10.0	AP	10.0	Y
Omeprazole	Dexcel Pharma Technologies Ltd	N	First	10.0	AP	10.0	Y
Nityr (Nitisinone)	Cycle Pharmaceuticals Ltd	N	First	10.0	AP	10.0	Y
Endari (L-Glutamine)	Emmaus Medical Inc	N	First	10.0	AP	10.0	Y
Xyzal Allergy 24hr (Levocetirizine Dihydrochloride)	Sanofi-Aventis U.S. LLC	N	First	10.1	AP	10.1	Y
Xyzal Allergy 24hr (Levocetirizine Dihydrochloride)	Sanofi-Aventis U.S. LLC	N	First	10.1	AP	10.1	Y
Qtern (Dapagliflozin and Saxagliptin)	Astrazeneca Ab	N	First	10.1	AP	10.1	Y
Corphedra (Ephedrine Sulfate)	Par Sterile Products LLC	N	First	10.4	AP	10.4	Y♯
Lamivudine and Tenofovir Disoproxil Fumarate	Hetero Labs Ltd Unit Iii	N	First	10.6	TA	10.6	N◊
Radicava (Edaravone)	Mitsubishi Tanabe Pharma Corp	Y	First	10.6	AP	10.6	Y♦
Autologous Cultured Chondrocytes N Porcine Collagen Membrane	Vericel Corporation	Y	First	11.3	AP	11.3	Y♦
Eucrisa (Crisaborole)	Anacor Pharmaceuticals Inc	Y	First	11.3	AP	11.3	Y♦
Trulance (Plecanatide)	Synergy Pharmaceuticals Inc	Y	First	11.7	AP	11.7	Y♦
C1 Esterase Inhibitor Subcutaneous (Human)	CSL Behring GMBH	Y	First	11.7	AP	11.7	Y♦
Rabies Immune Globulin (Human)	Kamada Ltd	Y	First	11.8	AP	11.8	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Nerlynx (Neratinib Maleate)	Puma Biotechnology, Inc.	Y	First	11.9	AP	11.9	Y♦
Coagulation Factor IX (Recombinant), Glycopegylated	Novo Nordisk, Inc.	Y	First	11.9	AP	11.9	Y♦
Fibrinogen (Human)	Octapharma Pharmazeutika Productionsges M.B.H	Y	First	11.9	AP	11.9	Y♦
Symproic (Naldemedine)	Shionogi, Inc.	Y	First	12.0	AP	12.0	Y♦
Steritalc (Talc)	Novatech Sa	N	First	12.5	AP	12.5	Y♯
Pantoprazole Sodium	Exela Pharma Sciences LLC	N	First	12.8	AP	12.8	Y♯
Drax Exametazime	Jubilant Draximage, Inc.	N	First	12.9	AP	12.9	Y♯
Noctiva (Desmopressin)	Serenity Pharmaceuticals LLC	N	First	12.9	AP	12.9	Y♯
Arymo Er (Morphine Sulfate)	Egalet Corp	N	First	12.9	AP	12.9	N
Calcium Gluconate	Fresenius Kabi USA LLC	N	First	13.0	AP	13.0	Y♯
Tymlos (Abaloparatide)	Radius Health, Inc.	Y	First	13.0	AP	13.0	Y♦♯
Clorotekal (Chloroprocaine Hcl)	Sintetica Sa	N	First	13.0	AP	13.0	Y♯
Tracleer (Bosentan)	Actelion Pharmaceuticals Ltd	N	First	13.0	AP	13.0	Y♯
Intrarosa (Prasterone)	Amag Pharmaceuticals, Inc.	N	First	13.1	AP	13.1	Y♯
Bonjesta (Doxylamine Succinate and Pyridoxine Hydrochloride)	Duchesnay, Inc.	N	First	13.1	AP	13.1	Y♯
Abacavir And Lamivudine	Cipla Ltd	N	First	13.3	TA	13.3	N◊
Lusduna (Insulin Glargine Injection)	Merck Sharp and Dohme Corp A, Sub of Merck and Co., Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	1.7		11.7	
			Second	1.9	TA	13.6	Y▲
Siliq (Brodalumab)	Valeant Pharmaceuticals Luxembourg S.A.R.L. (VPL)	Y	First	15.0	AP	15.0	Y♦♯
Kevzara (Sarilumab)	Sanofi-Aventis U.S. LLC	Y	First	12.0	CR	12.0	Y♦
			Sponsor	4.8		16.8	
			Second	2.0	AP	18.8	Y▲
Fiasp (Insulin Aspart Injection)	Novo Nordisk, Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	5.7		15.7	
			Second	6.1	AP	21.8	Y△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
Submitted in FY 2015							
Xultophy (100/3.6 (Insulin Degludec and Liraglutide Injection)	Novo Nordisk, Inc.	N[49]	First	14.3	AP	14.3	Y♦♯
Ephedrine Sulfate	Akorn, Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	5.0		15.0	
			Second	2.5	AP	17.5	Y△
Parsabiv (Etelcalcetide)	Kai Pharmaceuticals, Inc.	Y	First	12.1	CR	12.1	Y♦
			Sponsor	3.5		15.6	
			Second	2.0	AP	17.6	Y▲
Voriconazole	Xellia Pharmaceuticals APS	N	First	10.1	TA	10.1	Y
			Sponsor	7.6		17.7	
			Second	2.0	AP	19.7	Y▲
Xatmep (Methotrexate)	Silvergate Pharmaceuticals, Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	3.9		13.9	
			Second	6.0	AP	19.9	Y△
Austedo (Deutetrabenazine)	Teva Branded Pharmaceutical Products R and D, Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	4.2		16.2	
			Second	6.0	AP	22.2	Y△
Daptomycin	Sagent Pharmaceuticals, Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	9.0		19.0	
			Second	5.7	AP	24.7	Y△
Vantrela Er (Hydrocodone Bitartrate)	Teva Branded Pharmaceutical Products R&D, Inc.	N	First	24.9	AP	24.9	N
Xadago (Safinamide)	US WorldMeds LLC	Y	First	15.0	CR	15.0	Y♦♯
			Sponsor	5.8		20.8	
			Second	6.0	AP	26.8	Y△
Zypitamag (Pitavastatin)	Zydus	N	First	9.9	CR	9.9	Y

[49] Non-NME NDA reviewed under the PDUFA V program. At time of receipt, the active ingredient Insulin Degludec had never been approved in the United States, allowing for NME designation; however, at time of approval, Insulin Degludec had already been approved for marketing in another application, causing this application to lose its NME designation.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
	Pharmaceuticals USA, Inc.		Sponsor	11.7		21.6	
			Second	5.9	AP	27.5	Y△
Cotempla Xr-Odt (Methylphenidate)	Neos Therapeutics, Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	13.4		23.3	
			Second	6.0	AP	29.3	Y△
Submitted in FY 2014							
Carnexiv (Carbamazepine)	Lundbeck Pharmaceuticals LLC	N	First	10.0	CR	10.0	Y
			Sponsor	17.5		27.5	
			Second	6.0	AP	33.5	Y△
Caspofungin Acetate	Fresenius Kabi USA LLC	N	First	9.8	CR	9.8	Y
			Sponsor	7.2		17.0	
			Second	5.8	TA	22.8	Y△
			Sponsor	11.4		34.1	
			Third	2.0	AP	36.1	Y▲
Symjepi (Epinephrine Injection)	Adamis Pharmaceuticals Corp	N	First	10.0	CR	10.0	Y
			Sponsor	8.3		18.3	
			Second	6.0	CR	24.3	Y△
			Sponsor	6.4		30.7	
			Third	6.0	AP	36.7	Y△
Submitted in FY 2013							
Tigecycline	Fresenius Kabi USA LLC	N	First	10.0	CR	10.0	Y
			Sponsor	12.0		22.0	
			Second	5.9	TA	27.9	Y△
			Sponsor	6.2		34.1	
			Third	6.0	AP	40.1	Y△
Colprep Kit (Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate)	Gator Pharmaceuticals, Inc.	N	First	10.0	TA	10.0	Y
			Sponsor	36.8		46.8	
			Second	2.0	AP	48.8	Y▲
Submitted in FY 2006							
Mydayis	Shire Development	N	First	9.9	AE	9.9	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (mos.)	Cycle Result	Total Time (mos.)	Goal Met
	LLC		Sponsor	115.2		125.1	
			Second	6.0	AP	131.1	Y△

Appendix D: Filed Application Numbers by Review Division

The tables below and the pages that follow show the number of applications filed in FY 2017 for various application types and review designations broken out by review division. This reporting for PDUFA V is required under section 104 of FDASIA.

Original Applications Filed in FY 2017 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	4	12	0	0	0
Division of Anti-Infective Products	9	4	0	0	0
Division of Antiviral Products	11	1	1	0	0
Division of Bone, Reproductive, and Urologic Products	2	5	1	0	1
Division of Cardiovascular and Renal Products	2	9	0	0	0
Division of Dermatology and Dental Products	0	6	1	2	0
Division of Gastroenterology and Inborn Errors Products	0	6	2	0	1
Division of Hematology Products	7	3	2	2	2
Division of Medical Imaging Products	1	1	0	0	0
Division of Metabolism and Endocrinology Products	1	13	0	0	0
Division of Neurology Products	0	3	0	1	1
Division of Nonprescription Drug Products	0	1	0	0	0
Division of Oncology Products 1 (DOP1)	4	4	1	0	0
Division of Oncology Products 2 (DOP2)	0	6	0	0	1
Division of Psychiatry Products	0	4	0	0	2
Division of Pulmonary, Allergy, and Rheumatology Products	2	7	0	1	0
Division of Transplant and Ophthalmology Products	0	4	0	0	0
CDER Totals	*43*	*89*	*8*	*6*	*8*

Original Applications Filed in FY 2017 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	1	0
Office of Cellular Tissue and Gene Therapies	0	0	4	3	0
Office of Vaccines Research and Review	0	0	0	1	0
CBER Totals	*0*	*0*	*4*	*5*	*0*
FDA Totals	**43**	**89**	**12**	**11**	**8**

Efficacy Supplements Filed in FY 2017 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	0	8	0
Division of Anti-Infective Products	6	1	0
Division of Antiviral Products	10	10	0
Division of Bone, Reproductive, and Urologic Products	0	10	1
Division of Cardiovascular and Renal Products	0	3	0
Division of Dermatology and Dental Products	0	8	0
Division of Gastroenterology and Inborn Errors Products	1	7	1
Division of Hematology Products	16	13	3
Division of Medical Imaging Products	2	7	1
Division of Metabolism and Endocrinology Products	1	15	0
Division of Neurology Products	2	14	0
Division of Nonprescription Drug Products	0	1	0
Division of Oncology Products 1 (DOP1)	7	8	5
Division of Oncology Products 2 (DOP2)	10	25	3
Division of Psychiatry Products	1	3	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Pulmonary, Allergy, and Rheumatology Products	3	19	3
Division of Transplant and Ophthalmology Products	2	1	0
CDER Totals	*61*	*153*	*17*
CBER Review Offices			
Office of Blood Research and Review	0	0	0
Office of Cellular Tissue and Gene Therapies	0	6	0
Office of Vaccines Research and Review	0	6	0
CBER Totals	*0*	*12*	*0*
FDA Totals	**61**	**165**	**17**

Submissions with Special Designations Filed in FY 2017 by Review Division/Office

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
CDER Review Divisions				
Division of Anesthesia, Analgesia, and Addiction Products	0	2	1	1
Division of Anti-Infective Products	0	6	3	2
Division of Antiviral Products	0	8	4	2
Division of Bone, Reproductive, and Urologic Products	0	1	1	1
Division of Cardiovascular and Renal Products	0	0	1	2
Division of Dermatology and Dental Products	0	0	0	3
Division of Gastroenterology and Inborn Errors Products	0	2	2	0
Division of Hematology Products	2	4	11	12
Division of Medical Imaging Products	0	1	1	0
Division of Metabolism and Endocrinology Products	0	0	2	2
Division of Neurology Products	0	1	2	0
Division of Nonprescription Drug Products	0	0	0	0
Division of Oncology Products 1 (DOP1)	0	4	1	5
Division of Oncology Products 2 (DOP2)	0	0	2	10
Division of Psychiatry Products	0	0	0	2
Division of Pulmonary, Allergy, and Rheumatology Products	0	2	2	1

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
Division of Transplant and Ophthalmology Products	0	0	2	0
CDER Totals	*2*	*31*	*35*	*43*
CBER Review Offices				
Office of Blood Research and Review	0	0	0	0
Office of Cellular Tissue and Gene Therapies	0	0	3	8
Office of Vaccines Research and Review	0	0	0	0
CBER Totals	*0*	*0*	*3*	*8*
FDA Totals	**2**	**31**	**38**	**51**

* This column does not represent filed figures; rather it shows the number of breakthrough designations granted on INDs, NDAs, and BLAs during FY 2017. 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 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,[50] 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

[50] www.fda.gov/downloads/Drugs/.../Guidances/ucm079748.pdf

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, such as for 21 CFR Part 312 Subpart E or 21 CFR Part 314 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 within 74 days.

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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Office of Planning
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Phone: 301-796-4850

This report is available on the FDA Home Page at www.fda.gov.