U.S. FOOD & DRUG ADMINISTRATION

FY 2019

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) 2019 Prescription Drug User Fee Act (PDUFA) Performance Report. This report marks the 27th year of PDUFA and the second year of PDUFA VI (FY 2018 through FY 2022).

This report presents updated data on FDA's progress in meeting FY 2018 performance goals, preliminary data on meeting FY 2019 review performance goals, and data on other commitments under PDUFA VI as of September 30, 2019.

We are committed to meeting all PDUFA performance goals related to human drug review. In FY 2019, 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 2020, FDA will continue to enhance the program's staffing in addition to strengthening 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.

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Acronyms

BLA – Biologics License Application

BT – Breakthrough Therapy

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

CID – Complex Innovative Design

DDT – Drug Development Tool

EMA – European Medicines Agency

EOP – End of Phase

ESG – Electronic Submissions Gateway

ETASU – Elements to Assure Safe Use

FDA – Food and Drug Administration

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

ICRR – Inter-Center Consult Request

IND – Investigational New Drug

IT – Information Technology

MAPP – Manual of Policies and Procedures

MIDD – Model-Informed Drug Development

NDA – New Drug Application

NME – New Molecular Entity

OCP – Office of Combination Products

OND – Office of New Drugs

PDUFA – Prescription Drug User Fee Act

POC – Point of Contact

RDP – Rare Diseases Program

REMS – Risk Evaluation and Mitigation Strategy

RMAT – Regenerative Medicine Advanced Therapies

RWE – Real-World Evidence

SDO – Standards Developing Organization

SMG – Staff Manual Guide

Executive Summary

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

PDUFA must be reauthorized by Congress every 5 years. The fifth reauthorization (known as PDUFA VI) occurred on August 18, 2017, when the President signed into law the FDA Reauthorization Act of 2017. As directed by Congress, FDA developed proposed enhancements for PDUFA VI 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 FYs 2018 to 2022 period, detailed in a document commonly known as the PDUFA VI Commitment Letter.[1]

This report summarizes FDA's performance in meeting PDUFA goals and commitments for FY 2018 and FY 2019, the second year under PDUFA VI. Specifically, this report updates performance data for submissions received in FY 2018 (initially reported in the FY 2018 PDUFA Performance Report)[2] and presents preliminary data on FDA's progress in meeting FY 2019 goals. Updates on FDA's accomplishments related to additional PDUFA VI commitments for FY 2019 and historical review trend data are also included. Appendices include details of review cycle data on all original new drug applications (NDAs) and biologics license applications (BLAs) approved during FY 2019, the number and characteristics of applications filed by review division, and definitions of key terms used in this report. In addition, descriptions of the various submission types are included on page 4 of this report.

The estimated[3] median approval times for priority NDAs and BLAs received in FY 2018 increased slightly, while approval times for standard NDAs and BLAs remained the same compared to the estimated median approval times in FY 2017. The preliminary data show that the percentage of priority and standard applications filed in FY 2018 and approved during the first review cycle were 89 percent and 61 percent, respectively.

Achievements in FY 2019

Review Performance

The FY 2018 cohort had a workload of 3,102 goal closing actions. FDA met or exceeded the 90 percent performance level for 11 of 12 review performance goals for FY 2018.

[1] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.
[2] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm.
[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.

For the FY 2019 cohort, FDA completed 1,654 actions as of September 30, 2019. FDA is currently meeting or exceeding 11 of 12 review performance goals for FY 2019. With 1,267 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 11 of 12 review performance goals for FY 2019.

Procedural and Processing Performance

For the FY 2018 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 9,434. FDA met or exceeded the 90 percent performance level for 9 of 19 procedural and processing goals.

For the FY 2019 cohort, FDA is currently meeting or exceeding 8 of 20 procedural and processing goals. With 1,280 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 8 of 20 procedural and processing goal commitments for FY 2019.

Additional PDUFA VI Commitments

During FY 2019, FDA made significant progress implementing other important PDUFA VI commitments, including enhancing patient input and integrating it into regulatory decision-making, enhancing regulatory science and use of real-world evidence, expediting drug development, enhancing benefit-risk assessment in regulatory decision-making, enhancing regulatory decision tools to support drug development and review, 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 are included in this report.

To highlight just a few of these achievements, there were a number of important PDUFA commitments completed in FY 2019, including the following:

- Published guidances addressing patient oriented labeling, patient-focused drug development, and model-informed drug development,
- Developed procedures and timelines to review and provide comment on the protocols for Human Factors studies,
- Held public meetings to discuss enhancing patient engagement in clinical trials, benefit-risk assessments, analysis data standards, and FDA's Sentinel.

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Introduction

On August 18, 2017, the President signed the Food and Drug Administration (FDA or the Agency) Reauthorization Act of 2017 (FDARA) into law, which included the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA) for Fiscal Year (FY) 2018 through FY 2022, known as PDUFA VI. PDUFA VI continues to provide FDA 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 enactment 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 a demonstration of safety, efficacy, and quality of new drugs and biologics before approval. The efficiency gains under PDUFA have revolutionized the drug review process in the United States and enabled FDA to ensure more timely access to innovative and important new therapies for patients.

More information on the history of PDUFA is available on the FDA website.[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 the PDUFA workload (such as reviews of investigational new drug (IND) applications, labeling supplements, and annual reports, as well as the ongoing monitoring of drug safety in the postmarket setting) are not captured by PDUFA goals and are therefore not presented in this report.

PDUFA performance information related to achieving these 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 2018 cohort of submissions based on actions completed in FY 2018 and FY 2019. In addition, this report includes preliminary performance for the FY 2019 cohort of submissions that had actions completed or due for completion in FY 2019. Final performance for the FY 2019 cohort will be presented in the FY 2020 PDUFA Performance Report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2019.

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

- The following terminology is used throughout this document:

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

- *Application* means a new, original application.
- *Supplement* means a request to approve a change in an application that has been approved.
- *Resubmission* means a resubmitted application or supplement in response to a complete response, approvable, not approvable, or tentative approval letter.
- *New molecular entities (NMEs)* refer 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 VI, the preliminary counts of NMEs in workload tables for the current fiscal year may not reflect the 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 other submissions 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 biosimilar BLAs. These data are presented in the annual Biosimilars User Fee Act (BsUFA) Performance Reports located on the FDA website.[5]

- FDA files applications only 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 VI 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.

- FDA annually reports PDUFA performance data 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 NME NDA/BLA) with longer

[5] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm384244.htm.
[6] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.

(e.g., within 10 months of the 60-day filing date) 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 2018 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 2019 submissions is shown as the percentage of submissions reviewed on time as of September 30, 2019, excluding actions pending within the PDUFA goal date. Submission types with a current performance of 90 percent or more reviewed by the goal date are shown as currently meeting the goal. The highest possible percent of reviews that may be completed on time (i.e., the highest possible performance) if all non-overdue pending reviews are completed within the goal is also shown.

- Filed applications and supplements include submissions that have been filed or are in pending filing status. Data do not include submissions that are unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

- FY 2019 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, 2019.

- 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 an 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** – An 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 (FD&C Act) or has been previously marketed as a drug in the United States.
- **BLA** – A 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 2014 to FY 2019

In the table below, preliminary workload numbers from FY 2019 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 standard NMEs and BLAs and priority non-NME NDA submissions in FY 2019.

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 14	FY 15	FY 16	FY 17	FY 18*	FY 19	FY 14 to FY 18 5-Year Average	FY 19 Compared to 5-Year Average
Original Priority NMEs and BLAs	28	25	23	31	48	47	31	+52%
Original Standard NMEs and BLAs	21	32	24	22	22	31	24	+29%
Original Priority non-NME NDAs	10	9	12	24	16	25	14	+79%
Original Standard non-NME NDAs	72	84	72	81	69	63	76	-17%
Class 1 Resubmitted NDAs and BLAs	7	7	5	8	9	7	7	0%
Class 2 Resubmitted NDAs and BLAs	35	37	31	49	50	41	40	+3%
Priority NDA and BLA Efficacy Supplements	40	52	54	78	97	91	64	+42%
Standard NDA and BLA Efficacy Supplements	165	136	145	173	177	177	159	+11%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	7	0	3	3	3	4	3	+33%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	10	11	11	11	11	2	11	-82%
NDA and BLA Manufacturing Supplements requiring prior approval	776	765	842	968	992	993	869	+14%
NDA and BLA Manufacturing Supplements not requiring prior approval	1,392	1,614	1,475	1,540	1,610	1,440	1,526	-6%

* FY 2018 numbers were changed to reflect updates to data presented in the FY 2018 PDUFA Performance Report.

Final FY 2018 Review Performance

Final FY 2018 review goal performance is presented in the table below. Final performance for submission types that met the goal (i.e., 90 percent or more actions were completed by the goal date) is shown in bold text. FDA met or exceeded the 90 percent performance level for 11 out of 12 review performance goals in FY 2018.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2018 Performance
Original Priority NMEs and BLAs	6 months of filing date	48 of 48 on time	**100%**
Original Standard NMEs and BLAs	10 months of filing date	19 of 21 on time	**90%**
Original Priority non-NME NDAs	6 months	15 of 16 on time	**94%**
Original Standard non-NME NDAs	10 months	67 of 69 on time	**97%**
Class 1 Resubmitted NDAs and BLAs	2 months	8 of 9 on time	89%
Class 2 Resubmitted NDAs and BLAs	6 months	48 of 50 on time	**96%**
Priority NDA and BLA Efficacy Supplements	6 months	96 of 97 on time	**99%**
Standard NDA and BLA Efficacy Supplements	10 months	171 of 177 on time	**97%**
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	965 of 992 on time	**97%**
NDA and BLA Manufacturing Supplements not requiring prior approval	6 months	1,590 of 1,610 on time	**99%**

Final FY 2018 Review Goal Performance Detail

The following tables detail the final performance for the FY 2018 cohort of submissions. These data include the number of submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past goal or pending past the goal date) and the final *percent on time* (i.e., 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 2018 PDUFA Performance Report.

Original Applications

Original Application Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent On Time
Priority NMEs & BLAs	6 months of filing date	48	48	0	100%
Standard NMEs & BLAs	10 months of filing date	22	19	2	90%*
Priority Non-NME NDAs	6 months	16	15	1	94%
Standard Non-NME NDAs	10 months	69	67	2	97%

* One NME is still pending within goal. This table represents data as of October 4, 2019.

Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent On Time
Class 1	2 months	9	8	1	89%
Class 2	6 months	50	48	2	96%

Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent On Time
Priority	6 months	97	96	1	99%
Standard	10 months	177	171	6	97%

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent On Time
Class 1	2 months	3	3	0	100%
Class 2	6 months	11	10	1	91%

Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent On Time
Prior Approval Required	4 months	992	965	27	97%
Prior Approval Not Required	6 months	1610	1590	20	99%

Preliminary FY 2019 Review Performance

Preliminary FY 2019 review goal performance is presented in the table below.

- The *progress* (i.e., the number of reviews completed) and the total number of submissions received for each submission type are shown in the second column. *Current performance* includes submissions reviewed on time (i.e., acted on by the PDUFA goal date) or overdue (i.e., acted on past goal or pending past the goal date). Current performance for submission types with a greater proportion of reviews completed will be more representative of final performance. *Highest possible final performance* is the best potential final performance taking into account actions pending within the PDUFA goal date.
- Current performance for submission types that are meeting the performance goal (i.e., 90 percent or more reviews were completed by the goal date) as of September 30, 2019, is shown in bold text. FDA is currently meeting or exceeding the 90 percent performance level for 11 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 11 out of 12 review performance goals.

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2019 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	16 of 43 complete	6 months of filing date	**100%**	100%
Original Standard NMEs and BLAs	0 of 31 complete	10 months of filing date	--	100%
Original Priority non-NME NDAs	10 of 16 complete	6 months	**100%**	100%
Original Standard non-NME NDAs	11 of 63 complete	10 months	**91%**	98%
Class 1 Resubmitted NDAs and BLAs	5 of 7 complete	2 months	80%	86%
Class 2 Resubmitted NDAs and BLAs	19 of 41 complete	6 months	**95%**	98%
Priority NDA and BLA Efficacy Supplements	54 of 74 complete	6 months	**98%**	99%
Standard NDA and BLA Efficacy Supplements	42 of 177 complete	10 months	**95%**	99%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	4 of 4 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	1 of 2 complete	6 months	**100%**	100%
NDA and BLA Manufacturing Supplements requiring prior approval	671 of 993 complete	4 months	**98%**	99%
NDA and BLA Manufacturing Supplements not requiring prior approval	821 of 1,440 complete	6 months	**99%**	99%

* This column does not include undesignated applications in the total. Undesignated applications have only pending status.

Preliminary FY 2019 Review Goal Performance Detail

The following detailed performance information for FY 2019 cohort submissions includes the number of submissions filed, reviewed *on time* (i.e., acted on by the PDUFA goal date), and *overdue* (i.e., 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 (*highest possible percent on time*).

Original Applications

Application Type	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	43	16	0	27	100%	100%
Standard NMEs & BLAs	10 months of filing date	31	0	0	31	--	100%
Priority Non-NME NDAs	6 months	16	10	0	6	100%	100%
Standard Non-NME NDAs	10 months	63	10	1	52	91%	98%
Review Priority Undesignated*	N/A	13	--	--	13	--	--
Total		166	36	1	129	--	--

* These applications have not yet received a review priority designation.

Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Class 1	2 months	7	4	1	2	80%	86%
Class 2	6 months	41	18	1	22	95%	98%

Efficacy Supplements

Efficacy Supplement Type	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	74	53	1	20	98%	99%
Standard	10 months	177	40	2	135	95%	99%
Review Priority Undesignated*	N/A	17	--	--	17	--	--

* These applications have not yet received a review priority designation.

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	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	4	4	0	0	100%	100%
Class 2	6 months	2	1	0	1	100%	100%

Manufacturing Supplements

Manufacturing Supplement Type	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	993	658	13	322	98%	99%
Prior Approval Not Required	6 months	1,440	809	12	619	99%	99%
Review Priority Undesignated*	N/A	0	--	--	--	--	--

* These applications have not yet received a review priority designation.

PDUFA Procedural and Processing Goals and Commitments

Procedural and Processing Workload: FY 2014 to FY 2019

The FY 2019 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 upward trend of meeting management workload continued into FY 2019.

A new category of Type B meeting, Type B End of Phase (EOP), was created under PDUFA VI, therefore when comparing PDUFA VI (i.e., FY 2018 and FY 2019) data to previous years' data, it is important to combine both Type B meeting categories. This new category also included a new meeting metric, Type B(EOP) Preliminary Response. Meeting type definitions and other terms can be found in Appendix E. The table shows updated final FY 2018 performance as well as presents new reporting required under PDUFA VI.

Beginning in FY 2019, FDA committed to establish timelines for the review and comment on protocols for Human Factor studies of combination drug-device and biologic-device products. This additional goal is reflected in the number of procedural and processing goals reported in FY 2019.

Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request Type	FY 14	FY 15	FY 16	FY 17	FY 18*	FY 19	FY 14 to FY 18 5-Year Average	FY 19 Compared to 5-Year Average
Type A Meeting Requests	160	121	135	175	146	263**	147	+79%
Type B Meeting Requests	1,467	1,664	1,738	1,850	1,609	1,685	1,666	+1%
Type B(EOP) Meeting Requests	--	--	--	--	343	335	--†	--†
Type C Meeting Requests	995	1,237	1,372	1,391	1,403	1,488	1,280	+16%
Type A Meetings Scheduled	145	107	123	159	127	242	132	+83%
Type B Meetings Scheduled	1,154	1,204	1,183	1,293	945	937	1,156	-19%
Type B(EOP) Meetings Scheduled	--	--	--	--	324	319	--†	--†
Type C Meetings Scheduled	543	603	596	660	640	711	608	+17%
Type A Written Response	--	--	--	--	6	5	--†	--†
Type B Written Response	249	382	469	482	578	678	432	+57%
Type B(EOP) Written Response	--	--	--	--	14	12	--†	--†
Type C Written Response	393	546	658	652	686	675	587	+15%
Type B(EOP) Preliminary Response	--	--	--	--	303	298	--†	--†
Meeting Minutes	1,503	1,517	1,500	1,679	1,541	1,610	1,548	+4%
Responses to Clinical Holds	148	161	232	193	199	195	187	+4%

Submission/Request Type	FY 14	FY 15	FY 16	FY 17	FY 18*	FY 19	FY 14 to FY 18 5-Year Average	FY 19 Compared to 5-Year Average
Major Dispute Resolutions	33	15	17	20	23	28	22	+27%
Special Protocol Assessments	201	231	215	173	160	158	196	-19%
Review of Proprietary Names Submitted During IND Phase	170	178	158	176	159	211	168	+26%
Review of Proprietary Names Submitted with NDA/BLA	209	213	202	255	228	227	221	+3%
Human Factors Protocol Submissions	--	--	--	--	--	71	--[†]	--[†]

* FY 2018 numbers were changed to reflect updates to data presented in the FY 2018 PDUFA Performance Report.
** Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 129 undesignated meetings counted as Type A meeting "requests" and "scheduled" 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 2020 PDUFA Performance Report.
[†] Because of changing reporting requirements, no past average is presented for this area.

Final FY 2018 Procedural and Processing Performance

The table below presents final performance for FY 2018 submissions in meeting goals related to meeting management, procedural responses, and procedural notifications. Final performance for submission types that met the goal (i.e., 90 percent or more reviews were completed by the goal date) is shown in bold text. FDA exceeded the 90 percent performance level for 9 of 19 procedural and processing goals in FY 2018.

Submission/Request Type	Goal: 90 Percent	Total	FY 2018 Performance
Type A Meeting Requests	Respond within 14 days	136 of 146 on time	**93%**
Type B Meeting Requests	Respond within 21 days	1,446 of 1,609 on time	**90%**
Type B(EOP) Meeting Requests	Respond within 14 days	274 of 343 on time	80%
Type C Meeting Requests	Respond within 21 days	1,284 of 1,403 on time	**92%**
Type A Meetings Scheduled	Schedule within 30 days	95 of 127 on time	75%
Type B Meetings Scheduled	Schedule within 60 days	597 of 945 on time	63%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	239 of 324 on time	74%
Type C Meetings Scheduled	Schedule within 75 days	482 of 640 on time	75%
Type A Written Response	Respond within 30 days	4 of 6 on time	67%
Type B Written Response	Respond within 60 days	446 of 578 on time	77%
Type B(EOP) Written Response	Respond within 70 days	8 of 14 on time	57%
Type C Written Response	Respond within 75 days	578 of 686 on time	84%

Submission/Request Type	Goal: 90 Percent	Total	FY 2018 Performance
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	259 of 303 on time	85%
Meeting Minutes	Issue within 30 days after meeting date	1,401 of 1,541 on time	**91%**
Responses to Clinical Holds	Respond within 30 days	188 of 199 on time	**94%**
Major Dispute Resolutions	Respond within 30 days	23 of 23 on time	**100%**
Special Protocol Assessments	Respond within 45 days	153 of 160 on time	**96%**
Review of Proprietary Names Submitted During IND Phase	Review within 180 days	159 of 159 on time	**100%**
Review of Proprietary Names Submitted with NDA/BLA	Review within 90 days	225 of 228 on time	**99%**

Final FY 2018 Procedural and Processing Goal Performance Detail

The following tables detail the final performance for the FY 2018 cohort of submissions. These data include the number of submissions reviewed *on time* (i.e., acted on by the PDUFA goal date) or *overdue* (i.e., acted on past goal or pending past the goal date) and the final *percent on time* (i.e. 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 2018 PDUFA Performance Report.

Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent On Time
Type A Meeting Requests	Respond within 14 days	146	136	10	93%
Type B Meeting Requests	Respond within 21 days	1,609	1,446	163	90%
Type B(EOP) Meeting Requests	Respond within 14 days	343	274	69	80%
Type C Meeting Requests	Respond within 21 days	1,403	1,284	119	92%
Type A Meetings Scheduled	Schedule within 30 days	127	95	32	75%
Type B Meetings Scheduled	Schedule within 60 days	945	597	348	63%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	324	239	85	74%
Type C Meetings Scheduled	Schedule within 75 days	640	482	158	75%
Type A Written Response	Respond within 60 days	6	4	2	67%
Type B Written Response	Respond within 70 days	578	446	132	77%
Type B(EOP) Written Response	Respond within 75 days	14	8	6	57%
Type C Written Response	Respond within 30 days	686	578	108	84%
Preliminary response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	303	259	44	85%
Meeting Minutes	Issue within 30 days after meeting date	1,541	1,401	140	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.

Responses to Clinical Holds

Goal	Received	On Time	Overdue	Percent On Time
Respond to 90 percent within 30 days	199	188	11	94%

Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Percent On Time
Respond to 90 percent within 30 days	23	23	0	100%

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. This figure 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

Goal	Received	On Time	Overdue	Percent On Time
Respond to 90 percent within 45 days	160	153	7	96%

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
28	23	4	0	1	35

Drug/Biological Product Proprietary Names

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent On Time
Submitted During IND Phase	Review within 180 days	159	159	0	100%
Submitted with NDA/BLA	Review within 90 days	228	225	3	99%

Preliminary FY 2019 Procedural and Processing Performance

The table below presents preliminary performance for FY 2019 submissions in achieving goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA VI.

- The *progress* (i.e., 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. *Current performance* includes the number of submissions reviewed on time (i.e., acted on by the PDUFA goal date) or overdue (i.e., acted on past goal or pending past the goal date). *Highest possible final performance* is the best potential final performance taking into account actions pending within the PDUFA goal date.
- Current performance for submission types that are meeting the performance goal as of September 30, 2019, is shown in bold text. FDA is currently meeting or exceeding the performance level for 8 of 20 procedural and processing goals. If all pending submissions are reviewed on time, FDA has the potential to meet 8 of 20 goals, as seen in the Highest Possible Final Performance column.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2019 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	168 of 263 complete	Respond within 14 days	76%	84%
Type B Meeting Requests	1,656 of 1,685 complete	Respond within 21 days	**91%**	91%
Type B(EOP) Meeting Requests	330 of 335 complete	Respond within 14 days	82%	83%
Type C Meeting Requests	1,455 of 1,488 complete	Respond within 21 days	89%	89%
Type A Meetings Scheduled	130 of 242 complete	Schedule within 30 days	70%	84%
Type B Meetings Scheduled	892 of 937 complete	Schedule within 60 days	63%	65%
Type B(EOP) Meetings Scheduled	308 of 319 complete	Schedule within 70 days	76%	77%
Type C Meetings Scheduled	677 of 711 complete	Schedule within 75 days	74%	75%
Type A Written Response	5 of 5 Complete	Respond within 30 days	80%	80%
Type B Written Response	573 of 678 complete	Respond within 60 days	82%	84%
Type B(EOP) Written Response	10 of 12 complete	Respond within 70 days	70%	75%
Type C Written Response	542 of 675 complete	Respond within 75 days	80%	84%
Preliminary response for Type B(EOP) Meetings	235 of 298 complete	Issue no later than 5 days prior to meeting date	86%	89%
Meeting Minutes	1,150 of 1,610 complete	Issue within 30 days after meeting date	**92%**	95%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2019 Current Performance	Highest Possible Final Performance
Responses to Clinical Holds	187 of 195 complete	Respond within 30 days	**96%**	96%
Major Dispute Resolutions	25 of 28 complete	Respond within 30 days	**96%**	96%
Special Protocol Assessments	143 of 158 complete	Respond within 45 days	**94%**	94%
Review of Proprietary Names Submitted During IND Phase	127 of 211 complete	Review within 180 days	**98%**	99%
Review of Proprietary Names Submitted with NDA/BLA	194 of 227 complete	Review within 90 days	**98%**	98%

Submission/Request Type	Progress	Goal: 50 Percent	FY 2019 Current Performance	Highest Possible Final Performance
Human Factors Protocol Submissions	61 of 71 complete	Respond within 60 days	**90%**	92%

Preliminary FY 2019 Procedural and Processing Goal Performance Detail

The following detailed performance information for FY 2019 cohort submissions includes the number of submissions *received*, reviewed *on time* (i.e., acted on by the PDUFA goal date), and *overdue* (i.e., 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 (*highest possible percent on time*).

Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Type A Meeting Requests†	Respond within 14 days	263	127	41	95	76%	84%
Type B Meeting Requests	Respond within 21 days	1,685	1,509	147	29	91%	91%
Type B(EOP) Meeting Requests	Respond within 14 days	335	272	58	5	82%	83%
Type C Meeting Requests	Respond within 21 days	1,488	1,295	160	33	89%	89%
Type A Meetings Scheduled†	Schedule within 30 days	242	91	39	112	70%	84%
Type B Meetings Scheduled	Schedule within 60 days	937	565	327	45	63%	65%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	319	234	74	11	76%	77%
Type C Meetings Scheduled	Schedule within 75 days	711	500	177	34	74%	75%
Type A Written Response†	Respond within 30 days	5	4	1	0	80%	80%
Type B Written Response	Respond within 60 days	678	467	106	105	82%	84%
Type B(EOP) Written Response	Respond within 70 days	12	7	3	2	70%	75%
Type C Written Response	Respond within 75 days	675	433	109	133	80%	84%
Preliminary response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	298	203	32	63	86%	89%
Meeting Minutes	Issue within 30 days after meeting date	1,610	1,062	88	460	92%	95%

* 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 129 undesignated meetings counted as Type A meeting "requests" and "scheduled" 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 2020 PDUFA Performance Report.

Responses to Clinical Holds

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 30 days	195	179	8	8	96%	96%

Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 30 days	28	24	1	3	96%	96%

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. This figure 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

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Respond to 90 percent within 45 days	158	134	9	15	94%	94%

Special Protocol Assessment Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
28	23	5	0	0	33

Drug/Biological Product Proprietary Names

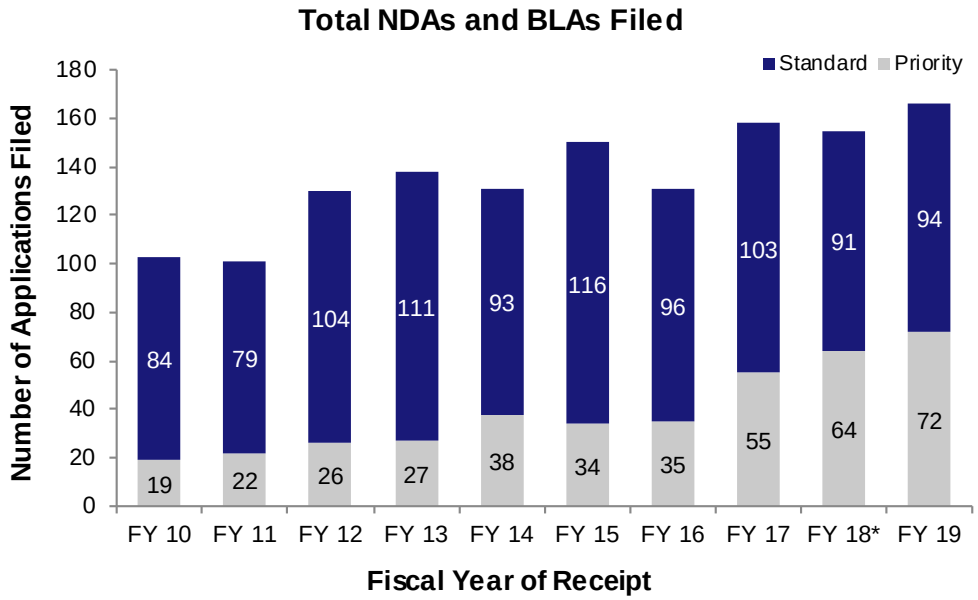
Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Proprietary Names Submitted During IND Phase	Review within 180 days	211	124	3	84	98%	99%
Proprietary Names Submitted with NDA/BLA	Review within 90 days	227	190	4	33	98%	98%

Human Factors Protocol Submissions

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent On Time	Highest Possible Percent On Time
Human Factors Protocol Submissions	Respond within 60 days	71	55	6	10	90%	92%

PDUFA Trend Graphs

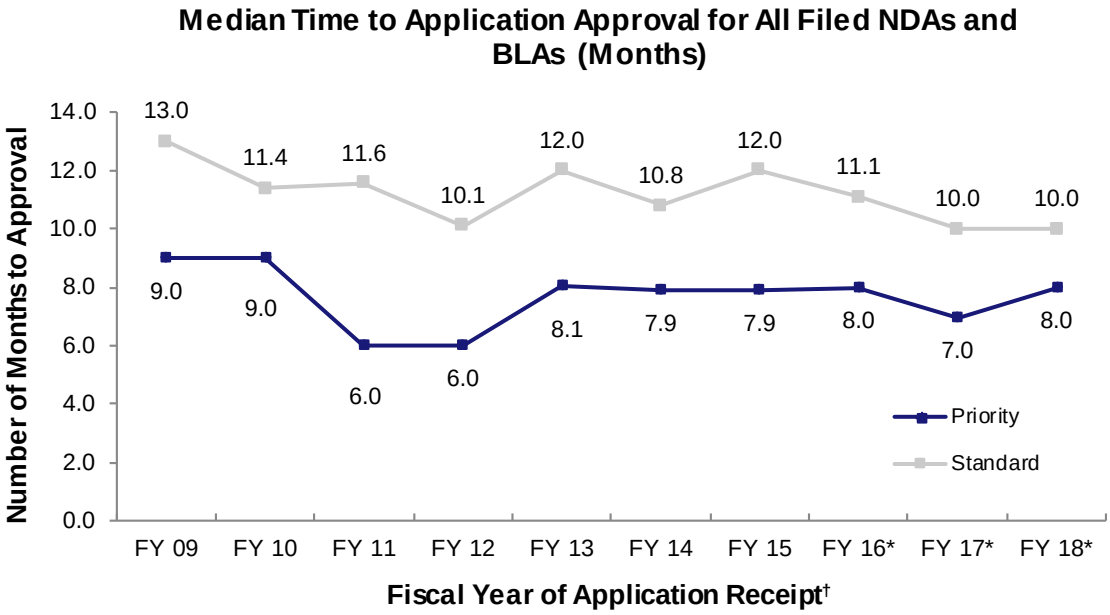
The number of NDAs and BLAs filed from FY 2010 to FY 2019 is presented in the graph below. The total number of all original applications (NDAs and BLAs) filed in FY 2019 increased from the number filed in FY 2018, and the total number of priority applications filed reached a new high in FY 2019.



* FY 2018 numbers were changed to reflect updates to data presented in the FY 2018 PDUFA Performance Report.

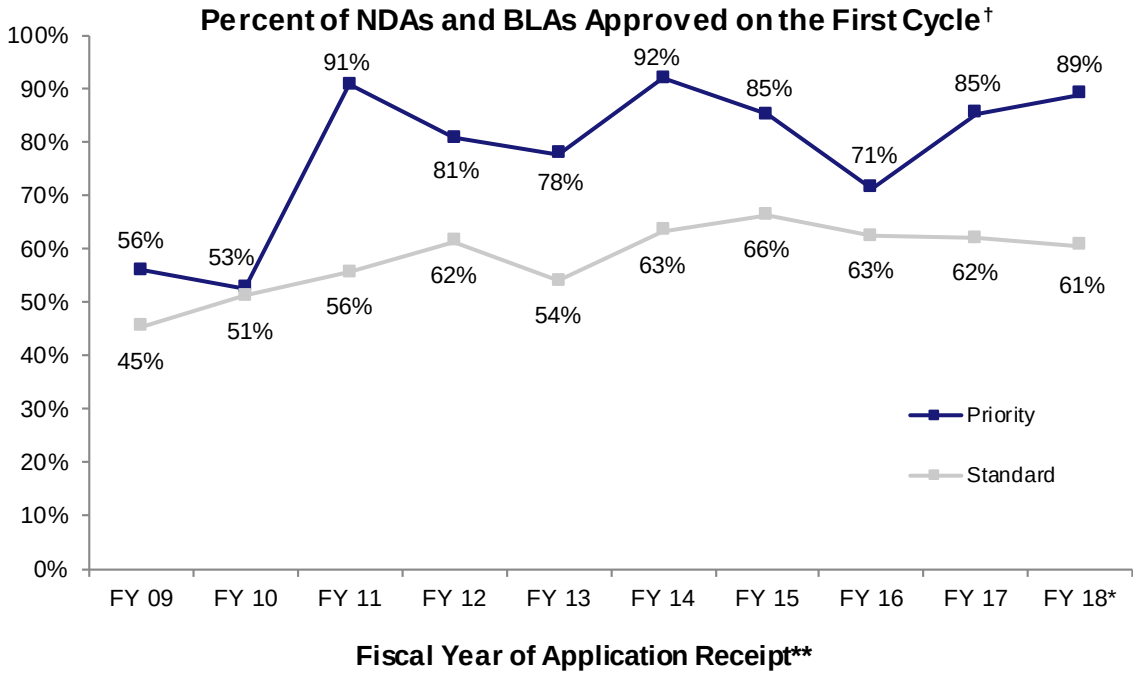
Median total time to approval for priority and standard applications received from FY 2009 through FY 2018 are presented in the graph below.[7] Data represented in the graph are updated based on the approvals reported in Appendix A. FY 2019 data are too preliminary to estimate the median approval time.

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



* The median approval times for the 3 most recent years are estimated.
† Data represented in this graph are based on the approvals reported in Appendix A.

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 2009 to FY 2018. These data are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals slightly decreased in FY 2017 and FY 2018. For the FY 2018 cohort, which is still preliminary, 61 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications increased in FY 2018, with 89 percent of approved priority applications being approved on the first cycle. The FY 2019 data are too preliminary to estimate the percent of first-cycle approvals.



* First cycle approvals are still possible for FY 2018 standard applications, so the data are preliminary.
† Data were changed to reflect updates to the data presented in the FY 2018 PDUFA Performance Report.
** Data represented in this graph are based on the approvals reported in Appendix A.

Additional PDUFA VI Commitments

Under Section VI of the PDUFA VI Commitment Letter, FDA committed to report its progress on the specific commitments identified in the following sections of the Commitment Letter:[8]

- Section I.I: Enhancing Regulatory Science and Expediting Drug Development,
- Section I.J: Enhancing Regulatory Decision Tools to Support Drug Development and Review,
- Section I.K: Enhancement and Modernization of the FDA Drug Safety System,
- Section II: Enhancing Management of User Fee Resources,
- Section III: Improving FDA Hiring and Retention of Review Staff, and
- Section IV: Information Technology Goals

Further, section 736B(a) of the FD&C Act, as amended by section 103 of FDARA, requires FDA to report on the Agency's performance under PDUFA VI.

FDA and industry designed these enhancements to improve the efficiency of drug development and the human drug review process. The progress reports in this section detail the work FDA performed in FY 2019 on commitments in Sections I.I-K of PDUFA VI. In addition, this report includes updates on FDA's accomplishments under Section II: Enhancing Management of User Fee Resources, Section III: Improving FDA Hiring and Retention of Review Staff, and Section IV: Information Technology Goals. The Section II progress reports are duplicated in the FY 2019 PDUFA VI Financial Report. Each accomplishment includes a reference to a specific section of the Commitment Letter. External references are also provided to published guidances, meeting summaries, and other pertinent public information.

FDA is dedicated to the goals outlined in these sections of the Commitment Letter. When 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/UCM511438.pdf.

Section I.I: Enhancing Regulatory Science and Expediting Drug Development

Commitment Title	FY 2019 Accomplishments
I.I.1 Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• The contractor that FDA hired to perform a third-party assessment of communication between FDA and sponsors during drug development continued data collection efforts in 2019, including attending and assessing FDA-sponsor meetings and conducting post-meeting surveys and interviews with FDA review teams and sponsors (I.I.1.a).
I.I.2 Ensuring Sustained Success of Breakthrough Therapy Program	• Under the Breakthrough Therapy (BT) Program (see www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-breakthrough-therapies), FDA: o Received 177 BT Designation requests, o Granted 62 BT Designation requests, o Approved 14 original and 13 supplemental marketing applications for BT-Designated products. (Note: BT Approvals are tracked and posted on the FDA.gov website by calendar year. However, the BT approval numbers included in this PDUFA report are reflective of the 2019 fiscal year.) • In FY 2019, the Center for Biologics Evaluation and Research (CBER) received 20 BT Designation requests (based on receipt date). CBER granted 8 BT Designation requests regardless of when they were received (based on communication date). CBER approved one original BLA for a BT-designated product. No supplements were approved by CBER for BT Designated products. • In FY2019, CDER received 157 BT Designation requests (based on receipt date). CDER granted 54 BT Designation requests regardless of when they were received (based on communication date). CDER approved 13 original NDAs/BLAs for BT-designated products. Thirteen supplements were approved by CDER for BT Designated products. • In FY 2019, under the Regenerative Medicine Advanced Therapies (RMAT) Program, CBER: o Processed 37 Designation requests o Granted 15 RMAT Designation requests (Note: The RMAT Program expedites development and review for designated regenerative medicine PDUFA products and is often used in lieu of requesting BT Designation.)
I.I.3 Early Consultation on the Use of New Surrogate Endpoints	• The internal process for the new Type C novel surrogate endpoint meeting was developed and fully implemented. To date, FDA has had approximately seven requests for this new meeting type including products by both Centers.
I.I.4 Advancing Drug Development of Drugs for Rare Diseases	• The CDER Rare Diseases Program (RDP) held meetings with CBER to coordinate efforts in documenting FDA's progress in advancing development of drugs for rare diseases through review, training, and stakeholder engagement activities. • In FY 2019, CDER RDP staff attended approximately 218 product-specific meetings within the Office of New Drugs (OND). • CDER held an annual training in September 2019 with 250 FDA staff that focused on regulatory approaches to innovative therapeutic technology as well as regulatory flexibility for cell and gene therapy. CDER also implemented a new rare disease training program for new clinical reviewers.

	• In FY 2019, CDER RDP staff participated in approximately 52 engagements, conferences, and/or trainings with patient stakeholders. • As part of furthering consistency (specifically with other regulatory agencies), CDER continues to hold Rare Disease cluster meetings. • The CDER RPD-led draft guidance *Natural History Studies for Drug Development* was published in FY 2019 (see www.fda.gov/media/122425/download). • RDP staff participated in the development process of draft guidance *Rare Pediatric Disease Priority Review Vouchers-Draft #2*, which published in 2019. • The CBER RDP assessed CBER review offices and determined that they consistently considered flexible and feasible approaches in the review of biologics for rare diseases and initiated a series of case study presentations of flexibility in the review of biologics for rare diseases during CBER Rare Disease Coordinating Committee meetings. • CBER continues to track rare disease-related outreach activities. In FY 2019, CBER staff participated in a minimum of 131 outreach activities intended to support development of biologics for rare diseases. These activities included presentations (62%), publications (17%), and poster/abstracts (21%). • On September 16, 2019, CBER held a public workshop on developing therapeutics for alpha-1 antitrypsin deficiency, a rare genetic disorder.
I.I.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• FDA continues to expand hiring and enhance training of staff to develop the capacity and capability to review combination products effectively across the Centers (I.I.5.a). • Building on progress from prior years' streamlining and implementation efforts for the Inter-Center Consult Request (ICCR) process across the medical product Centers, in FY19, Office of Combination Products (OCP) facilitated the implementation of a new tool (Salesforce) to support the streamlined process across CDER, CBER, and the Center for Devices and Radiological Health (CDRH). As part of that implementation, several supporting documents were created and/or updated (I.I.5.b.iii). • Staff Manual Guide (SMG) 4101 on the combination ppoducts ICCR Process was effective June 11, 2018. FDA continues the ICCRs process for CDER-led combination products (I.I.5.c.i). • CDER published two Manuals of Policies and Procedures (MAPPs) with an effective date of September 27, 2019: o Internal MAPP 5017.6 *Conducting Quality Assessments of CDER-Led Combination Products, Including Coordinating Application-Related Facility Inspections*, and o Internal MAPP 5017.7 *Facilities and Quality System Regulation* (I.I.5.c.ii). • The MAPP, entitled *Procedures for DMEPA Intra-Center Consult to DMPP on Patient-Oriented Labeling Submitted with Human Factors Validation Study Protocols*, was completed and in effect as of September 18, 2019 (I.I.5.c.iii). • As of January 2018, FDA posted key points of contact (POCs) for combination product review on FDA's website (I.I.5.d) (see www.fda.gov/combination-products/classification-and-jurisdictional-information/combination-product-contacts). • CBER revised (SOPP) 8001.5 *Inter-Center Consultative Review Process* on April 8, 2019, to reflect the new ICCR process and SMG 4101.

	• Procedures for the review of human factors protocols for combination products were implemented in FY18. FDA issued draft guidance in September 2018 entitled *Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications* (I.I.5.e.i.1). • CBER revised Job Aid 900.17 *Human Factors Consult Requests* on July 23, 2019, to include the review of human factor protocols to postmarketing application and patient-oriented labeling reviews with CDER. • In FY 2019, OCP and the Centers developed and supported the rollout of additional combination product training materials and training sessions across CBER, CDER, and CDRH. The scope of the training efforts included sessions on inter-center consult best practices, use of the new Salesforce tool, and a refresher/reminder training on combination products and associated regulatory requirements (I.I.5.f). • The third-party assessment of the current practices for combination product review is on track to publish no later than the end of FY 2020 (I.I.5.g). • The draft bridging guidance is under development, and FDA hopes to publish it in the near future (I.I.5.h.i). • In July 2019, FDA published a draft guidance for industry *Instructions for Use - Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products - Content and Format* (see www.fda.gov/regulatory-information/search-fda-guidance-documents/instructions-use-patient-labeling-human-prescription-drug-and-biological-products-and-drug-device) (I.I.5.h.ii).
I.I.6 Enhancing Use of Real World Evidence for Use in Regulatory Decision-Making	• FDA satisfied the commitment to complete a public workshop, A Framework for Regulatory Use of Real-World Evidence, in September 2017 (see healthpolicy.duke.edu/events/public-workshop-framework-regulatory-use-real-world-evidence). • FDA continues to host public meetings, including Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes (July 2019) and Developing Real-World Data and Evidence to Support Regulatory Decision-Making (Oct 2019) (PI.I.6.a) (see www.fda.gov/news-events/fda-meetings-conferences-and-workshops/leveraging-randomized-clinical-trials-generate-real-world-evidence-regulatory-purposes and www.fda.gov/drugs/regulatory-science-research-and-education/developing-real-world-data-and-evidence-support-regulatory-decision-making-10032019-10032019, respectively). • FDA satisfied the commitment to initiate Real-World Evidence (RWE) activities in FY 2017 and continues to oversee additional demonstration projects and activities aimed at addressing dynamic concerns and considerations in the use of RWE for regulatory decision-making. Topics for FY 2019-funded projects include data standards and considerations and understanding statistical analyses approaches in observational studies (PI.I.6.b).

Section I.J: Enhancing Regulatory Decision Tools to Support Drug Development and Review

Commitment Title	FY 2019 Accomplishments
I.J.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	FDA held a public meeting and then published a draft guidance for industry, FDA staff, and other stakeholders titled *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients* (see www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients-guidance-industry-food-and). This guidance addresses topics including methods for sponsors, patient organizations, academic researchers, and expert practitioners to develop and identify what are most important to patients in terms of burden of disease, burden of treatment, and other critical aspects. The guidance addresses how patient input can inform drug development and review processes and, as appropriate, regulatory decision-making (I.J.1.b.ii). • FDA continues to pilot a website, External Resources and Other Information related to Patient Experiences, that provides links to certain publicly available external reports and resources relating to patient experience data. This webpage is intended to facilitate public discussion of patient-focused drug development and evaluation (I.J.1.c). • FDA convened a public workshop through a qualified third party, titled Enhancing the Incorporation of Patient Perspectives in Clinical Trials (see www.ctti-clinicaltrials.org/briefing-room/meetings/enhancing-incorporation-patient-perspectives-clinical-trials) with the primary purpose of gathering ideas and experiences of the patient and caregiver community and their recommendations on approaches and best practices that would enhance patient engagement in clinical trials (I.J.1.e). • FDA developed and published a draft guidance titled *Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data*.
I.J.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• FDA continues to include the Benefit-Risk Framework in CDER's and CBER's reviews of drugs and biologics. As part of the New Drugs Regulatory Program Modernization, FDA has developed a new integrated review process and template. This template contains an executive summary of FDA's decision and assessment of the application, including FDA's benefit-risk determination (utilizing the Benefit-Risk Framework as currently employed in marketing application reviews). CDER continues to offer training on the Benefit-Risk Framework along with individual reviewer support (I.J.2.e). CBER continues to offer benefit and risk training to inform regulatory decision-making. • On May 16, 2019, FDA held a public meeting and opened a public docket to gather industry, patient, researcher, and other stakeholder input on applying FDA's Benefit-Risk Framework throughout the human drug life cycle and best approaches to communicating FDA's benefit-risk assessment. In advance of this meeting, FDA posted a discussion document titled Benefit-Risk Assessment Throughout the Drug Lifecycle. Input from this meeting will support development of a draft guidance on the benefit-risk assessment for new drugs and biologics (I.J.2.b).
I.J.3 Advancing Model-Informed Drug Development	• FDA formed a training committee to identify staff needs (I.J.3.a).

	• An internal scientific seminar—Model Informed Drug Development (MIDD): An update; A Year in Review—was held on September 9, 2019, to give an update about the MIDD program (I.J.3.a). • FDA held the Precision Dosing: Defining the Need and Approaches to Deliver Individualized Drug Dosing in the Real-World Setting Public Workshop on August 12, 2019. The workshop was designed to explore the need for more precision dosing, investigate opportunities in the drug development and real-world setting to generate the information needed to support precision drug dosing, and discuss the translation of the dosing information to electronic drug dosing delivery tools (I.J.3.b). • The proceedings of a workshop co-sponsored by FDA and the International Society of Pharmakometrics entitled Model Informed Drug Development (MIDD) in Oncology held on February 1, 2018, was published in April 2019 (I.J.3.b) (see www.fda.gov/drugs/news-events-human-drugs/fda-isop-public-workshop-model-informed-drug-development-midd-oncology-products). • The Office of Clinical Pharmacology held three selection committee meetings to choose qualified MIDD applications to participate in the Pilot Meeting Program (I.J.3.c). • The Office of Clinical Pharmacology conducted 19 industry meetings from October 2018 to September 2019 (I.J.3.c). • The *Population Pharmacokinetics* draft guidance was published on July 12, 2019 (I.J.3.d).
I.J.4 Enhancing Capacity to Review Complex Innovative Designs	• FDA established an internal Continuing Education-accredited program on Bayesian Methodology (I.J.4.a). • CDER/CBER Biostatistics conducted ten Complex Innovative Design (CID) pilot program presentations with internal, multi-disciplinary stakeholders (I.J.4.a). • FDA reviewed six paired meeting requests in FY 2019 and granted three; three were denied as they were deemed not appropriate for the CID Pilot Meeting Program. One paired CID meeting series has been completed thus far; the other two are in progress (I.J.4.b.i). • FDA has developed an outward presence for the CID Pilot Program through development of an external webpage on the FDA website (I.J.4.b.i). • FDA established a Selection Committee to review and vote on the CID meeting requests (I.J.4.b.ii).
I.J.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• CDER's Office of Biostatistics developed a training plan and an Analysis Data Standards (ADS) training website/material for CDER/CBER biostatisticians (I.J.5.a). • A public workshop entitled Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities was held on June 12, 2019 (I.J.5.c). • CDER/CBER Statisticians routinely participate in Standards Developing Organizations (SDOs) for strategic planning meetings. CDER's Office of Biostatistics, OND, Office of Strategic Programs, and Office of Medical Policy personnel have presented at SDO-sponsored workshops/conferences on Current Experiences with Analysis Data Standards (I.J.5.d). • FDA's training website includes a Technical Conformance guidance and Sponsor Communication Checklist to facilitate communications between reviewers and sponsors (I.J.5.e).
I.J.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• The three Drug Development Tool (DDT) qualification programs continue to hire staff (I.J.6.a). • On December 11, 2018, FDA hosted the public meeting titled Drug Development Tool Process Under the 21st Century Cures Act and Prescription Drug User Fee Act VI (I.J.6.b) (see

	www.federalregister.gov/documents/2018/11/13/2018-24656/drug-development-tool-process-under-the-21st-century-cures-act-and-prescription-drug-user-fee-act-vi). • The Biomarkers, EndpointS, and other Tools taxonomy is a living resource published at the following link: www.ncbi.nlm.nih.gov/books/NBK338448/. The resource was first published on January 28, 2016. This resource was discussed in the December 2018 DDT public meeting. In 2019, a *Federal Register* notice was published to seek additional public feedback that will be considered as part of ongoing efforts to update the taxonomy (see www.federalregister.gov/documents/2019/07/25/2019-15827/21st-century-cures-announcing-the-establishment-of-the-best-resource-taxonomy-establishment-of-a) (I.J.6.c). • To comply with the 21st Century Cures Act DDT transparency provisions, DDT programs continue to post information about DDT submissions as well as FDA's determinations and recommendations (I.J.6.f).

Section I.K: Enhancement and Modernization of the FDA Drug Safety System

Commitment Title	FY 2019 Accomplishments
I.K.1 Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System and Integration into FDA Pharmacovigilance Activities	• FDA added additional capabilities to its publicly available routine querying tools, including modules for signal identification and interrupted time series analyses (I.K.1.a). • FDA routinely notifies sponsors of planned Sentinel analyses on their products via the NDA/BLA approval letter and publicly posts the analytic packages for these analyses to promote replication and transparency (I.K.1.b, I.K.1.f). • FDA held a public workshop entitled Implementation of Signal Detection Capabilities in the Sentinel System in December 2018 and a three-day Sentinel Annual Meeting in April 2019 (I.K.1.d). • FDA published a revised guidance for industry, *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the FD&C Act*, that includes FDA's thinking on how it determines whether Sentinel's Active Postmarket Risk Identification and Analysis system is sufficient to assess or identify a serious risk (I.K.1.f). • FDA has created and revised internal forms and templates that facilitate the Active Risk Identification and Analysis process to improve consistency of implementation (I.K.1.f).
I.K.2 Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs	• FDA piloted a new process to identify, evaluate, and resolve postmarket safety signals, held a one-day workshop for CDER staff to address pilot feedback, and analyzed output from pilot participants and workshop attendees to inform changes to the process and collect user requirements for an information technology (IT) system (I.K.2.a). • FDA completed a process modernization effort to align IT system user requirements for both premarket and postmarket safety signal tracking (I.K.2.a). • CDER selected a new IT system to support workflow management and began developing the Lifecycle Signal Tracker tool to manage safety signals (I.K.2.a). • FDA updated and published MAPP 6700.9 *FDA Posting of Potential Signals of Serious Risks Identified by the Adverse Event Reporting System* and SOPP 8420 *FDAAA Section 921*

	:Posting of Potential Signals of Series Risk to notify application holders, to the extent practicable, not less than 72 hours before public posting of a safety notice under section 921 of the Food and Drug Administration Amendments Act of 2007 (I.K.2.b.2).

Section II: Enhancing the Management of User Fee Resources

Commitment Title	FY 2019 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• FDA implemented its Insight Time Reporting system throughout CDER in FY 2019. The establishment of the Insight program infrastructure and technology will enable modernized time reporting implementations in other relevant parts of FDA in subsequent years. FDA has made significant progress establishing approaches to forecasting workload. • FDA expanded its resource capacity planning staff (II.A.2). • FDA is on track to award a contract to an independent consulting firm to conduct an evaluation of options and recommendations for a new methodology to assess changes in resource and capacity needs (II.A.3).
II.B Financial Transparency and Efficiency	• The contracted evaluation of resource management was published on FDA's website (see www.fda.gov/drugs/development-resources/fiscal-year-2018-financial-management-evaluation-human-drug-user-fees-assessment-report) (II.B.1). • FDA published the FY 2019 PDUFA Five-Year Financial Plan Update in May 2019 because of the federal government shutdown (II.B.2). • FDA convened a public meeting on June 7, 2019, to discuss the PDUFA Five-Year Financial Plan, progress towards implementing modernized time reporting and resource capacity planning, and the modernized user fee structure (see www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and) (II.B.3).

Section III: Improving FDA's Hiring and Retention of Review Staff

Commitment Title	FY 2019 Accomplishments
III.A Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity	• In spring 2020, HHS is expected to deploy a Position-Based Management function to its Enterprise Human Capital Management system. In the interim, FDA is using its financial system (Integrated Budget, Acquisition and Planning System) as the position management system (III.A.1). • FDA deployed a new system (e-Class) for position classification. Approximately 5,000 position descriptions have been loaded into the system. FDA is continuing to migrate all data from the current system to e-Class (III.A.2). • FDA has completed the transition to expanded use of common vacancy announcements and applicant certificates (III.A.3).

III.B Augmentation of Hiring Staff Capacity and Capability	• FDA has awarded contracts to three vendors to provide continuous support for FDA's human resources capacity and capabilities.
III.C Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Program	• FDA has fully staffed a unit in the Office of Medical Products and Tobacco to assist with recruiting, staffing, and employee retention. • The unit has formed 110 partnerships with professional and academia that align with FDA's critical/hard-to-fill positions. • The unit has also increased presence on social media to promote positions at FDA in the form of 100 positions on LinkedIn and approximately 65,000 job views with 7,800 leads. • The unit continues to collaborate with the Centers to execute detailed strategic hiring plans to ensure specific needs are met.
III.D Set Clear Goals for Human Drug Review Program Hiring	• FDA's FY 2019 hiring goal was for 74 FTEs, and 51 FTEs were onboarded (which was 69% percent of the FY 2019 hiring goal). • FDA's hiring progress against this goal was posted on FDA's website.
III.E Comprehensive and Continuous Assessment of Hiring and Retention	• The contract for the interim assessment was awarded in June 2019, is currently underway, and is expected to be completed by March 31, 2020.

Section IV: Information Technology Goals

Goal	FY 2019 Accomplishments
IV.B Improve the Predictability and Consistency of PDUFA Electronic Submission Processes	• FDA published targets for, and to measure, Electronic Submissions Gateway (ESG) availability overall (including scheduled downtime) and during business hours (i.e., from 8 a.m. to 8 p.m. Eastern Standard Time). *ESG availability* is defined for the purposes of the Commitment Letter as the ability for an external user to complete a submission from each entry point to its delivery to the appropriate FDA Center (IV.B.2.a). • FDA continues to post the current ESG operational status on its public website (IV.B.2.b). • The Final Submission upload status to the sender-designated contact (e.g., successfully processed or rejected) continues to provide metrics (IV.B.4). • As of December 2018, FDA has invited industry to participate in user acceptance testing (IV.B.6).
IV.C Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities	• FDA held quarterly meetings with industry on both electronic submissions and data standards (IV.C.1). These meetings included discussions of PDUFA milestones and metrics (IV.C.4). • FDA held a public meeting entitled Electronic Submissions and Data Standards on April 10, 2019. FDA posted a summary of the public meeting on its PDUFA VI website (IV.C.2). • FDA posted ESG performance updates and submission statistics (IV.C.3). • FDA posted updates to the Data Standards Action Plan quarterly (IV.C.5.b). • FDA posted updates to the FDA Data Standards Catalog (IV.C.5.c).

Additional PDUFA VI Review Program Reporting

Hiring and Placement of New PDUFA VI Staff at FDA

FY 2019's hiring and placement of new staff at FDA under PDUFA VI are reported on a quarterly basis and posted on the FDARA hiring performance webpage.[9] Starting in FY 2020, FDA will report its progress in hiring new staff to support new initiatives in the annual PDUFA Financial Report, as per the PDUFA VI Commitment Letter.

[9] www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm604305.htm.

Appendices

Appendix A: List of Approved Applications

This appendix includes the detailed review histories of the NDA and BLA submissions approved under PDUFA VI in FY 2019. 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 2019 can be found in the appendices of the earlier PDUFA Performance Reports.[10]

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 *FIRDAPSE (amifampridine)* on page A-3 was received on March 28, 2018, and had an 8-month review goal date of 11/28/2018 as it was reviewed under the 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

♦ Application reviewed under the 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[11]

[10] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm.
[11] Under PDUFA VI, 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 2019 Priority NDA and BLA Approvals (by Fiscal Year 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 2019							
NUBEQA (darolutamide)	Bayer Healthcare Pharmaceuticals Inc.	Y	First	5.1	AP	5.1	Y♦
PIQRAY (alpelisib)	Novartis Pharmaceuticals Corp.	Y	First	5.2	AP	5.2	Y♦
DOVATO (dolutegravir and lamivudine)	Viiv Healthcare Co.	N	First	5.7	AP	5.7	Y
selenious acid	American Regent Inc.	N	First	6.0	AP	6.0	Y
VYNDAQUEL (tafamidis meglumine)	Foldrx Pharmaceuticals Inc. Sub Pfizer Inc.	Y	First	6.0	AP	6.0	Y♦
HARVONI (edipasvir and sofosbuvir)	Gilead Sciences Inc.	N	First	6.0	AP	6.0	Y
SOVALDI (sofosbuvir)	Gilead Sciences Inc.	N	First	6.0	AP	6.0	Y
potassium phosphates injection, USP, phosphorus 3 mmol/mL and potassium 4.7 mEq/mL	CMP Development LLC	N	First	6.1	AP	6.1	Y
RYBELSUS (semaglutide)	Novo Nordisk Inc.	N	First	6.1	AP	6.1	Y
INREBIC (fedratinib)	Impact Biomedicines Inc. A Wholly Owned Sub Of Celgene Corp.	Y	First	7.4	AP	7.4	Y♦
ZOLGENSMA (onasemnogene abeparvovec)	Avexis Inc.	Y	First	7.7	AP	7.7	Y♦
RINVOQ (upadacitinib)	Abbvie Inc.	Y	First	7.9	AP	7.9	Y♦
ROZLYTREK (entrectinib)	Genentech Inc.	Y	First	7.9	AP	7.9	Y♦
WAKIX (pitolisant)	Bioprojet Pharma.	Y	First	8.0	AP	8.0	Y♦
XENLETA (lefamulin)	Nabriva Therapeutics Ireland Dac.	Y	First	8.0	AP	8.0	Y♦
XENLETA (lefamulin)	Nabriva Therapeutics Ireland Dac.	N[12]	First	8.0	AP	8.0	Y♦
TURALIO (pexidartinib)	Daiichi Sankyo Inc.	Y	First	8.0	AP	8.0	Y♦
RECARBRIO (imipenem, cilastatin,and relebactam)	Merck Sharp. And Dohme Corp. A Sub Of Merck And Co. Inc.	Y	First	8.0	AP	8.0	Y♦
Pretomanid	The Global Alliance For Tb Drug Development	Y	First	8.0	AP	8.0	Y♦
JYNNEOS (modified vaccinia ankara - bavarian nordic (mva-bn))	Bavarian Nordic A/S	Y	First	11.0	AP	11.0	Y♯♦
Submitted in FY 2018							
POLIVY (polatuzumab vedotin-piiq)	Genentech, Inc.	Y	First	5.7	AP	5.7	Y♦

[12] These two NDAs are for the same moiety but different dosage forms (i.e., Tablet versus Injection), and only one retains the NME designation upon approval; in this case, the NDA for the Capsule 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
CORLANOR (ivabradine)	Amgen Inc.	N	First	5.9	AP	5.9	Y
ELZONRIS (tagraxofusp-erzs)	Stemline Therapeutics Inc.	Y	First	6.0	AP	6.0	Y♦
XOFLUZA (baloxavir marboxil)	Genentech Inc.	Y	First	6.0	AP	6.0	Y♦
SPRAVATO (esketamine)	Janssen Pharmaceuticals Inc.	N	First	6.0	AP	6.0	N
ULTOMIRIS (ravulizumab-cwvz)	Alexion Pharmaceuticals Inc.	Y	First	6.1	AP	6.1	Y♦
TALZENNA (talazoparib)	Pfizer Inc.	Y	First	6.4	AP	6.4	Y♦
BALVERSA (erdafitinib)	Janssen Biotech Inc.	Y	First	6.8	AP	6.8	Y♦
DAURISMO (glasdegib)	Pfizer Inc.	Y	First	6.9	AP	6.9	Y♦
EGATEN (triclabendazole)	Novartis Pharmaceuticals Corp.	Y	First	8.0	AP	8.0	Y♦
NUZYRA (omadacycline)	Paratek Pharmaceuticals Inc.	Y	First	8.0	AP	8.0	Y♦
NUZYRA (omadacycline)	Paratek Pharmaceuticals Inc.	N[13]	First	8.0	AP	8.0	Y♦
MAYZENT (siponimod)	Novartis Pharmaceuticals Corp.	Y	First	8.0	AP	8.0	Y♦
XOSPATA (gilteritinib)	Astellas Pharma Us. Inc.	Y	First	8.0	AP	8.0	Y♦
DENGVAXIA (dengue tetravalent vaccine, live)	Sanofi Pasteur Inc.	Y	First	8.0	AP	8.0	Y♦
FIRDAPSE (amifampridine)	Catalyst Pharmaceuticals Inc.	Y	First	8.1	AP	8.1	Y♦
VITRAKVI (larotrectinib)	Bayer Healthcare Pharmaceuticals Inc.	Y	First	8.1	AP	8.1	Y♦
VITRAKVI (larotrectinib)	Bayer Healthcare Pharmaceuticals Inc.	N[14]	First	8.1	AP	8.1	Y♦
AEMCOLO (rifamycin)	Cosmo Technologies Ltd.	Y	First	8.1	AP	8.1	Y♦
GAMIFANT (emapalumab-lzsg)	Swedish Orphan Biovitrum AB (PUBL)	Y	First	8.1	AP	8.1	Y♦
CABLIVI (caplacizumab-yhdp)	Ablynx NV	Y	First	8.1	AP	8.1	Y♦
ELCYS (cysteine hydrochloride)	Exela Pharma Sciences LLC	N	First	8.7	AP	8.7	Y♯
Vancomycin	Xellia Pharmaceuticals Aps.	N	First	8.8	AP	8.8	Y♯
RUZURGI (amifampridine)	Jacobus Pharmaceutical Co. Inc.	N[15]	First	10.7	AP	10.7	Y♦♯
LORBRENA (lorlatinib)	Pfizer Inc.	Y	First	10.9	AP	10.9	Y♦♯
XPOVIO (selinexor)	Karyopharm Therapeutics Inc.	Y	First	10.9	AP	10.9	Y♦♯

[13] These two NDAs are for the same moiety but different dosage forms (i.e., Tablet versus Injection), and only one retains the NME designation upon approval; in this case, the NDA for the Capsule form retained the NME designation.

[14] These two NDAs are for the same moiety but different dosage forms (i.e., Tablet versus Injection), and only one retains the NME designation upon approval; in this case, the NDA for the Capsule form retained the NME designation.

[15] This non-NME NDA was reviewed under the PDUFA NME Program. At the time of receipt, the active ingredient amifampridine had never been approved in the United States allowing for NME designation; however, at the time of approval, amifampridine 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
TEGSEDI (inotersen)	Akcea Therapeutics Inc.	Y	First	11.0	AP	11.0	Y♦♯
ZULRESSO (brexanolone)	Sage Therapeutics Inc.	Y	First	11.0	AP	11.0	Y♦♯
REVCOVI (elapegademase-lvlr)[16]	Leadiant Biosciences Inc.	Y	First	11.4	AP	11.4	Y♦
dolutegravir, lamivudine, and tenofovir disoproxil fumarate tablets	Macleods Pharmaceuticals Ltd.	N	First	5.7	CR	5.7	Y◊
			Sponsor	5.0		10.7	
			Second	6.0	TA	16.7	YΔ◊
efavirenz, lamivudine and tenofovir disoproxil fumarate tablets	Macleods Pharmaceuticals Ltd.	N	First	5.9	CR	5.9	Y
			Sponsor	0.1		6.0	
			Second	6.0	CR	12.0	YΔ◊
			Sponsor	0.2		12.1	
			Third	5.9	AP	18.0	YΔ◊
Submitted in FY 2017							
BRIXADI (buprenorphine)	Braeburn Pharmaceuticals Inc.	N	First	6.1	CR	6.1	Y
			Sponsor	5.2		11.3	
			Second	5.9	TA	17.2	YΔ

[16] The application was granted a priority review after a filing notification was sent to the sponsor. Per CDER regulations, the application retained the standard NME program review goal (i.e., 10 months after the 60-day filing date) but was designated as a priority application.

Table 2
FY 2019 Standard NDA and BLA Approvals (by Fiscal Year 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 2019							
VYNDAMAX (tafamidis)	Foldrx Pharmaceuticals Inc. Sub Pfizer Inc.	N	First	6.0	AP	6.0	Y♦
zinc sulfate	American Regent Inc.	N	First	9.2	AP	9.2	Y
RIOMET ER (metformin hydrochloride for extended-release oral suspension)	Sun Pharmaceutical Industries Ltd.	N	First	9.9	AP	9.9	Y
dolutegravir, lamivudine, and tenofovir alafenamide	Mylan Laboratories Ltd.	N	First	9.9	TA	9.9	Y◊
Submitted in FY 2018							
YUTIQ (fluocinolone acetonide intravitreal implant)	Eyepoint Pharmaceuticals Inc.	N	First	9.2	AP	9.2	Y
tranexamic acid	Exela Pharma Sciences LLC	N	First	9.3	AP	9.3	Y
TOLSURA (itraconazole)	Mayne Pharma International Pty Ltd.	N	First	9.8	AP	9.8	Y
KATERZIA (amlodipine benzoate)	Silvergate Pharmaceuticals Inc.	N	First	9.8	AP	9.8	Y
BAFIERTAM (monomethyl fumarate)	Banner Life Sciences LLC	N	First	9.9	TA	9.9	Y
DUAKLIR PRESSAIR (aclidinium bromide/formoterol fumarate dihydrate inhalation powder)	Circassia Ltd.	N	First	9.9	AP	9.9	Y
levothyroxine sodium injection	Fresenius Kabi Usa LLC	N	First	9.9	AP	9.9	Y
isopropyl alcohol	Zurex Pharma	N	First	9.9	AP	9.9	Y
QMIIZ ODT (meloxicam)	Tersera Therapeutics LLC	N	First	9.9	AP	9.9	Y
ANGIOMAX RTU (bivalirudin)	Maia Pharmaceuticals Inc.	N	First	9.9	AP	9.9	Y
KHAPZORY (levoleucovorin)	Acrotech Biopharma LLC	N	First	9.9	AP	9.9	Y
SLYND (drospirenone)	Exeltis Usa Inc.	N	First	9.9	AP	9.9	Y
SPY AGENT GREEN (indocyanine green for injection (usp))	Novadaq Technologies Ulc.	N	First	9.9	AP	9.9	Y
THIOLA EC (tiopronin)	Mission Pharmacal Co.	N	First	9.9	AP	9.9	Y
ACCRUFER (ferric maltol)	Shield Tx Uk Ltd.	Y	First	9.9	AP	9.9	Y♦
MYXREDLIN (insulin human in sodium chloride injection)	Baxter Healthcare Corp.	N	First	10.0	AP	10.0	Y
LOTEMAX SM (loteprednol etabonate)	Bausch And Lomb Inc.	N	First	10.0	AP	10.0	Y
ROCKLATAN (netarsudil and latanoprost ophthalmic solution)	Aerie Pharmaceuticals Inc.	N	First	10.0	AP	10.0	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
BIJUVA (estradiol and progesterone)	Therapeuticsmd Inc.	N	First	10.0	AP	10.0	Y
dolutegravir, lamivudine, and tenofovir disoproxil fumarate	Laurus Labs Ltd.	N	First	10.0	TA	10.0	Y
QTERNMET XR (dapagliflozin, saxagliptin, and metformin hydrochloride)	Astrazeneca Ab	N	First	10.0	AP	10.0	Y
TOSYMRA (sumatriptan)	Upsher Smith Laboratories Inc.	N	First	10.0	AP	10.0	Y
ZYKADIA (ceritinib)	Novartis Pharmaceuticals Corp.	N	First	10.0	AP	10.0	Y
TEMIXYS (lamivudine and tenofovir disoproxil fumarate)	Celltrion Inc.	N	First	10.0	AP	10.0	Y
Argatroban	Accord Healthcare Inc.	N	First	10.0	TA	10.0	Y
DRIZALMA SPRINKLE (duloxetine delayed-release capsules)	Sun Pharma Global Fze	N	First	10.0	AP	10.0	Y
HERCEPTIN HYLECTA (trastuzumab and hyaluronidase-oysk)	Genentech Inc.	N	First	10.0	AP	10.0	Y
NUCALA (mepolizumab)	Glaxosmithkline LLC	N	First	10.0	AP	10.0	Y
EVEKEO ODT (amphetamine sulfate)	Arbor Pharmaceuticals LLC	N	First	10.1	AP	10.1	Y
GLOPERBA (colchicine)	Avion Pharmaceuticals LLC	N	First	10.1	AP	10.1	Y
bendamustine	Hospira A Pfizer Co.	N	First	10.1	TA	10.1	Y
ADHANSIA XR (methylphenidate hydrochloride)	Purdue Pharma Lp.	N	First	10.1	AP	10.1	Y
BRYHALI (halobetasol propionate)	Bausch Health Americas Inc.	N	First	10.0	TA	10.0	Y
			Sponsor	0.0		10.0	
			Second	1.1	AP	11.1	Y▲
SEYSARA (sarecycline)	Almirall LLC	Y	First	11.4	AP	11.4	Y♦
CUTAQUIG (immune globulin subcutaneous (human)-hipp)	Octapharma Pharmazeutika Productionsges M.B.H	Y	First	11.5	AP	11.5	Y♦
ESPEROCT (antihemophilic factor (recombinant), glycopegylated-exei)	Novo Nordisk Inc.	Y	First	11.7	AP	11.7	Y♦
NAYZILAM (midazolam)	Ucb Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	0.5		10.5	
			Second	1.2	AP	11.7	YΔ
MOTEGRITY (prucalopride)	Shire Development LLC	Y	First	11.8	AP	11.8	Y♦
XEMBIFY (immune globulin subcutaneous (human))	Grifols therapeutics llc	Y	First	11.8	AP	11.8	Y♦
YUPELRI (revefenacin)	Mylan Ireland Ltd.	Y	First	11.9	AP	11.9	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
ASPARLAS (calaspargase pegol-mknl)	Servier Pharmaceuticals LLC	Y	First	11.9	AP	11.9	Y♦
IBSRELA (tenapanor)	Ardelyx Inc.	Y	First	12.0	AP	12.0	Y♦
SKYRIZI (risankizumab-rzaa)	Abbvie Inc.	Y	First	12.0	AP	12.0	Y♦
SYMPAZAN (clobazam)	Aquestive Therapeutics	N	First	10.0	TA	10.0	Y
			Sponsor	0.4		10.4	
			Second	1.7	AP	12.1	Y▲
tetracaine hydrochloride	Bausch Health Ireland Ltd.	N	First	8.9	CR	8.9	Y
			Sponsor	3.2		12.1	
			Second	0.5	AP	12.6	YΔ
INBRIJA (levodopa)	Acorda Therapeutics Inc.	N	First	12.6	AP	12.6	Y♯
BAQSIMI (glucagon)	Eli Lilly And Co.	N	First	12.9	AP	12.9	Y♯
READYPREP CHG (chlorhexidine gluconate)	Medline Industries Inc.	N	First	13.0	AP	13.0	Y♯
GVOKE (glucagon)	Xeris Pharmaceuticals Inc.	N	First	13.0	AP	13.0	Y♯
ORTIKOS (budesonide)	Sun Pharma Global Fze	N	First	10.1	TA	10.1	Y
			Sponsor	0.7		10.8	
			Second	1.9	TA	12.7	Y▲
			Sponsor	0.1		12.9	
			Third	1.7	AP	14.6	Y▲
VYLEESI (bremelanotide)	Amag Pharmaceuticals Inc.	Y	First	15.0	AP	15.0	Y♯
Ga-68-DOTATOC	Univ Iowa Hosps And Clinics Pet Imaging Center	Y	First	15.0	AP	15.0	Y♦♯
SUNOSI (solriamfetol)	Jazz Pharmaceuticals Ireland Ltd.	Y	First	15.0	AP	15.0	Y♦♯
WELCHOL (colesevelam hcl)	Daiichi Sankyo Inc.	N	First	9.8	CR	9.8	Y
			Sponsor	1.3		11.1	
			Second	6.0	AP	17.1	YΔ
JEUVEAU (prabotulinumtoxinA-xvfs)	Evolus Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	2.6		14.6	
			Second	6.0	AP	20.6	YΔ
OZOBAX (baclofen)	Metacel Pharmaceuticals LLC	N	First	10.1	CR	10.1	Y
			Sponsor	11.7		21.8	
			Second	5.7	CR	27.5	YΔ
			Sponsor	8.7		36.3	
			Third	6.1	AP	42.4	YΔ
Submitted in FY 2017							
calcium gluconate	HQ Specialty Pharma Corp.	N	First	13.0	AP	13.0	Y♯
DUOBRII (halobetasol propionate and tazarotene)	Bausch Health Americas Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	2.0		11.9	
			Second	8.3	AP	20.2	NΔ
Fulvestrant	Fresenius Kabi Usa LLC	N	First	9.9	TA	9.9	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Sponsor	8.7		18.6	
			Second	2.0	AP	20.6	Y▲
DSUVIA (sufentanil)	Acelrx Pharmaceuticals Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	6.7		16.7	
			Second	6.0	AP	22.7	YΔ
Fulvestrant	Teva Pharmaceuticals USA Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	15.8		25.7	
			Second	6.0	AP	31.7	YΔ
Fosaprepitant	Teva Pharmaceuticals USA	N	First	9.9	TA	9.9	Y
			Sponsor	16.7		26.6	
			Second	6.1	AP	32.7	YΔ
Submitted in FY 2016							
Argatroban	Aurobindo Pharma Ltd.	N	First	9.9	CR	9.9	Y
			Sponsor	3.9		13.8	
			Second	5.9	CR	19.7	YΔ
			Sponsor	2.4		22.1	
			Third	6.0	AP	28.1	YΔ
LICART (diclofenac epolamine)	Institut Biochimique Sa	N	First	9.9	CR	9.9	Y
			Sponsor	15.1		25.0	
			Second	5.8	AP	30.8	YΔ
EVENITY (romosozumab-aqqg)	Amgen Inc.	Y	First	11.8	CR	11.8	Y♦
			Sponsor	11.9		23.7	
			Second	9.0	AP	32.7	YΔ♯
Submitted in FY 2015							
DEXTENZA (dexamethasone)	Ocular Therapeutix Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	6.0		15.9	
			Second	5.7	CR	21.6	YΔ
			Sponsor	11.6		33.2	
			Third	5.1	AP	38.3	YΔ
EZALLOR (rosuvastatin)	Sun Pharma Global Fze	N	First	9.8	CR	9.8	Y
			Sponsor	23.9		33.7	
			Second	6.0	AP	39.7	YΔ
ASCENIV (immune globulin intravenous, human-sira)	Adma Biologics Inc.	Y	First	11.9	CR	11.9	
			Sponsor	26.1		38.0	
			Second	6.0	AP	44.0	YΔ♦
Submitted in FY 2014							
VAXELIS (inactivated poliovirus, haemophilus b conjugate [meningococcal protein conjugate] and hepatitis b [recombinant] vaccine)	MCM Vaccine Company	Y	First	14.7	CR	14.7	Y♦
			Sponsor	31.9		46.6	
			Second	5.7	AP	52.3	YΔ♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
JATENZO (testosterone undecanoate)	Clarus Therapeutics Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	31.6		41.6	
			Second	9.0	CR	50.6	YΔ
			Sponsor	6.2		56.8	
			Third	6.0	AP	62.8	YΔ
Submitted in FY 2013							
PRIMATENE MIST (epinephrine)	Armstrong Pharmaceuticals Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	25.2		35.2	
			Second	5.9	CR	41.1	YΔ
			Sponsor	16.4		57.6	
			Third	6.1	AP	63.7	YΔ
AVACLYR (acyclovir)	Fera Pharmaceuticals LLC	N	First	70.0	AP	70.0	N
Submitted in FY 2012							
ELEPSIA XR (levetiracetam)	Sun Pharma Advanced Research Co. Ltd.	N	First	10.0	CR	10.0	Y
			Sponsor	17.2		27.2	
			Second	12.7	CR	39.9	NΔ
			Sponsor	12.0		51.9	
			Third	5.9	CR	57.8	YΔ
			Sponsor	15.4		73.1	
			Fourth	5.6	AP	78.7	YΔ
Submitted in FY 2010							
MAVENCLAD (cladribine)[17]	Emd Serono Inc.	N	First	9.1	CR	9.1	Y♯
			Sponsor	87.1		96.2	
			Second	10.0	AP	106.2	Y
Submitted in FY 2007							
NOURIANZ (istradefylline)[18]	Kyowa Kirin Inc.	Y	First	10.1	NA	10.1	Y
			Sponsor	132.2		142.3	
			Second	6.0	AP	148.3	YΔ

[17] During the first review cycle, this application received a complete response. The sponsor subsequently withdrew the application and later re-submitted the full application as a new original. The submission after the withdrawal was subject to a Standard Original Review clock.

[18] This submission is a Type I New NME that was not reviewed under the NME Program Review timeline. The timeline went into effect on October 1, 2012.

Appendix B: Filed Application Numbers by Review Division

The tables below and on the pages that follow show the number of applications filed in FY 2019 for various application types and review designations broken out by review division. This reporting for PDUFA VI is required under section 103 of FDARA.

Original Applications Filed in FY 2019 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	1	8	0	0	2
Division of Anti-Infective Products	10	2	0	0	1
Division of Antiviral Products	5	4	0	0	1
Division of Bone, Reproductive, and Urologic Products	0	4	0	0	0
Division of Cardiovascular and Renal Products	4	7	0	0	0
Division of Dermatology and Dental Products	1	6	0	1	2
Division of Gastroenterology and Inborn Errors Products	4	5	0	1	2
Division of Hematology Products	4	4	3	3	0
Division of Medical Imaging Products	2	3	0	0	1
Division of Metabolism and Endocrinology Products	1	11	0	3	0
Division of Neurology Products	4	11	0	2	3
Division of Nonprescription Drug Products	0	2	0	0	0
Division of Oncology Products 1 (DOP1)	2	2	2	0	0
Division of Oncology Products 2 (DOP2)	5	0	0	0	1
Division of Psychiatry Products	1	3	0	0	0
Division of Pulmonary, Allergy, and Rheumatology Products	2	4	0	0	0
Division of Transplant and Ophthalmology Products	1	5	2	1	0
CDER Totals	47	81	7	11	13

Original Applications Filed in FY 2019 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	0	0
Office of Tissues and Advanced Therapies	0	0	3	0	0
Office of Vaccines Research and Review	0	0	2	2	0
CBER Totals	0	0	5	2	0
FDA Totals	47	81	12	13	13

Efficacy Supplements Filed in FY 2019 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	4	2
Division of Anti-Infective Products	5	6	0
Division of Antiviral Products	10	19	1
Division of Bone, Reproductive, and Urologic Products	1	6	0
Division of Cardiovascular and Renal Products	2	7	0
Division of Dermatology and Dental Products	2	5	4
Division of Gastroenterology and Inborn Errors Products	3	10	0
Division of Hematology Products	13	6	5
Division of Medical Imaging Products	0	2	0
Division of Metabolism and Endocrinology Products	3	33	0
Division of Neurology Products	6	16	0
Division of Nonprescription Drug Products	0	4	0
Division of Oncology Products 1 (DOP1)	11	11	1
Division of Oncology Products 2 (DOP2)	7	16	1
Division of Psychiatry Products	3	5	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Pulmonary, Allergy, and Rheumatology Products	8	16	3
Division of Transplant and Ophthalmology Products	0	1	0
CDER Totals	74	167	17
CBER Review Offices			
Office of Blood Research and Review	0	0	0
Office of Tissues and Advanced Therapies	0	6	0
Office of Vaccines Research and Review	0	4	0
CBER Totals	0	10	0
FDA Totals	74	177	17

Submissions with Special Designations Filed in FY 2019 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	1	0	1
Division of Anti-Infective Products	2	7	3	1
Division of Antiviral Products	0	3	2	6
Division of Bone, Reproductive and Urologic Products	0	0	0	0
Division of Cardiovascular and Renal Products	1	1	6	1
Division of Dermatology and Dental Products	0	1	1	1
Division of Gastroenterology and Inborn Errors Products	1	4	3	6
Division of Hematology Products	1	4	11	15
Division of Medical Imaging Products	0	0	0	0
Division of Metabolism and Endocrinology Products	0	0	1	2
Division of Neurology Products	2	5	7	2
Division of Nonprescription Drug Products	0	0	0	0
Division of Oncology Products 1 (DOP1)	3	2	0	5
Division of Oncology Products 2 (DOP2)	2	2	6	15
Division of Psychiatry Products	0	1	1	5

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
Division of Pulmonary, Allergy, and Rheumatology Products	0	0	1	2
Division of Transplant and Ophthalmology Products	0	1	2	0
CDER Totals	12	32	44	62
CBER Review Offices				
Office of Blood Research and Review	0	0	0	0
Office of Tissues and Advanced Therapies	0	2	1	2
Office of Vaccines Research and Review	0	0	0	1
CBER Totals	0	*2*	1	3
FDA Totals	12	34	45	65

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2019. BT designation is granted based on indication, and therefore, one submission may have more than one BT designation granted.

Appendix C: Analysis of Use of Funds

On August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

FDARA requires, in the annual performance reports of each of the human medical product user fee programs, specified analyses of the use of funds to include information such as the differences between aggregate numbers of applications and approvals, an analysis of performance enhancement goals, and the most common causes and trends affecting the ability to meet goals. FDARA also requires the issuance of corrective action reports (section 904).

A. Original Application Approval Cycle Summary

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(A) of the FD&C Act), pertaining to PDUFA, which requires FDA to include data showing the aggregate number of approvals that occurred during FY 2019. Data represent all the original NDA and BLA approvals that occurred during FY 2019, regardless of when the application was received. Data are presented by the type of application and performance goal, as well as whether the approval occurred on time or was overdue on the performance goal.

This table captures not only first cycle approvals, but also multiple cycle approvals. For applications that were approved after multiple cycles, the performance metric is counted for the last cycle where the approval was given. Approval counts also include applications that were given a tentative approval.

Figures provided in the table below are indicated in detail in Appendix A of this report, which provides a detailed review history of the NDAs and BLAs approved under PDUFA during FY 2019.[19]

[19] Performance is calculated only on the first cycle in which the application received an Approval or Tentative Approval. Any subsequent Tentative or Full approvals, after the first Tentative Approval action, will not affect the performance metric regardless of the fiscal year of the first Tentative Approval.

Approval Cycle Type	Performance Goal: Act on 90 Percent Within	Approval Count	On Time	Overdue	Percent On Time
First Cycle Priority NMEs & BLAs	6 months of filing date	35	35	0	**100%**
First Cycle Standard NMEs & BLAs	10 months of filing date	15	15	0	**100%**
First Cycle Priority Non-NME NDAs	6 months	14	13	1	**93%**
First Cycle Standard Non-NME NDAs	10 months	45*	44	1	**98%**

* During the first review cycle, this one application received a complete response. The sponsor subsequently withdrew the application and later re-submitted the full application as a new original. The submission after the withdrawal was subject to a Standard Original Review clock.

Approval Cycle Type	Performance Goal: Act on 90 Percent Within	Approval Count	On Time	Overdue	Percent On Time
Class 1 Resubmissions	2 months	0	0	0	**--**
Class 2 Resubmissions	6 months	22	21	1	**95%**
Total		**131**	**128**	**3**	**--***

* Performance is not calculated on combined goals.

B. Performance Enhancement Goals

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(B) of the FD&C Act), pertaining to PDUFA, which requires FDA to include relevant data to determine whether CDER and CBER have met performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the applicable fiscal year. A link to each performance enhancement goal completed under PDUFA VI can be found on FDA's website.[20]

For the purposes of this report, performance enhancement goals are defined as any non-review performance goal described in PDUFA with a specified goal date that falls within the applicable fiscal year.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
PDUFA FY18 Hiring Web Posting Quarter 4	10/14/2018	Y	10/9/2018	FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).

[20] www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Staff Training of Combination Product Review	12/31/2018	Y	6/22/2017	
Combination Product Contacts	12/31/2018	Y	9/12/2017	Combination Product Contacts (see www.fda.gov/combination-products/classification-and-jurisdictional-information/combination-product-contacts).
FY19 FDA Data Standards Action Plan Update Quarter 1	12/31/2018	Y	10/25/2018	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board).
Innovative Drug Approval Report on Rare Diseases Program	12/31/2018	Y	12/31/2018	Advancing Health Through Innovation: 2018 New Drug Therapy Approvals (see www.fda.gov/media/120357/download).
PDUFA FY19 Hiring Web Posting Quarter 1	1/14/2019	N	2/19/2019	Web posting was delayed. FDA has since established a new process and POCs to assure that updated hiring numbers are posted shortly after each quarter ends. FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
FY19 FDA Data Standards Action Plan Update Quarter 2	3/30/2019	Y	1/18/2019	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board).
SMG 4104 Inter-Center Consults for Review of Human Factors Information	3/31/2019	Y	2/12/2019	
Five-Year Financial Plan: Fiscal Years 2018-2019-2020-2021-2022: 2019 Update for PDUFA	3/31/2019	N	5/31/2019	FDA published the FY 2019 PDUFA Five-Year Financial Plan Update (i.e., Five-Year Financial Plan: Fiscal Years 2018-2019-2020-2021-2022: 2019 Update for the Prescription Drug User Fee Act Program (see www.fda.gov/media/127005/download)), in May 2019.
PDUFA FY19 Hiring Web Posting Quarter 2	4/14/2019	N	5/9/2019	Web posting was delayed. FDA has since established a new process and POCs to assure that updated hiring numbers are posted shortly after each quarter ends. FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
FY19 FDA Data Standards Action Plan Update Quarter 3	6/30/2019	Y	4/17/2019	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board).
Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments	6/30/2019	Y	6/7/2019	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (seewww.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
PDUFA FY19 Hiring Web Posting Quarter 3	7/14/2019	N	10/3/2019	Web posting was delayed. FDA has since established a new process and POCs to assure that updated hiring numbers are posted shortly after each quarter ends. FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).
Annual ESG and Standard Metrics - Submission Statistics FY19	9/30/2019	Y	12/4/2018	Submission Statistics (see www.fda.gov/industry/about-esg/submission-statistics).
2019 Public Meeting on Electronic Submissions and Data Standards	9/30/2019	Y	4/10/2019	2nd Public Meeting on PDUFA VI Electronic Submissions and Data Standards (see www.fda.gov/media/124614/download).
Characterizing FDA's Approach to Benefit-Risk Assessment throughout the Medical Product Life Cycle	9/30/2019	Y	5/16/2019	Public Meeting: Characterizing FDA's Approach to Benefit-Risk Assessment throughout the Medical Product Life Cycle (see healthpolicy.duke.edu/events/benefit-risk-framework-public-workshop).
Population Pharmacokinetics	9/30/2019	Y	7/11/2019	Population Pharmacokinetics (see www.fda.gov/regulatory-information/search-fda-guidance-documents/population-pharmacokinetics).
Guidance on Combination Product Bridging Studies	9/30/2019	N	N/A	FDA hopes the guidance will be published in the near future.
Draft Guidance for Industry, FDA Staff, and Other Stakeholders *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients*	9/30/2019	Y	9/30/2019	Draft guidance for industry, FDA staff, and other stakeholders *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients* (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients-guidance-industry-food-and).
Electronic Submissions and Data Standards Meeting Quarter 1	9/30/2019	Y	12/4/2018	
Electronic Submissions and Data Standards Meeting Quarter 2	9/30/2019	Y	3/19/2019	
Electronic Submissions and Data Standards Meeting Quarter 3	9/30/2019	Y	6/18/2019	
Electronic Submissions and Data Standards Meeting Quarter 4	9/30/2019	Y	9/24/2019	
FY19 Annual Discussion of IT Strategic Plan	9/30/2019	Y	12/31/2018	
FY19 FDA Data Standards Action Plan Update Quarter 4	9/30/2019	Y	7/31/2019	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board).
FY19 MIDD Selections and Meetings Quarter 1	9/30/2019	Y	10/5/2018	

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
FY19 MIDD Selections and Meetings Quarter 2	9/30/2019	Y	1/7/2019	
FY19 MIDD Selections and Meetings Quarter 3	9/30/2019	Y	3/25/2019	
FY19 MIDD Selections and Meetings Quarter 4	9/30/2019	Y	7/5/2019	
Initiate RWE Activities	9/30/2019	Y	12/6/2018	
MAPP for Conducting Combination Product Quality Assessment (MAPP 2017.7 and MAPP 5017.7)	9/30/2019	Y	9/27/2019	
MAPP 6701.1 *Procedures for DMEPA Intra-Center Consult to DMPP on Patient-Oriented Labeling Submitted with Human Factors Validation Study Protocols*	9/30/2019	Y	9/19/2019	MAPP 6701.1 *Procedures for DMEPA Intra-Center Consult to DMPP on Patient-Oriented Labeling Submitted with Human Factors Validation Study Protocols* (see www.fda.gov/media/131008/download).
Guidance for Industry *Instructions for Use - Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products - Content and Format*	9/30/2019	Y	7/10/2019	Guidance for industry *Instructions for Use - Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products - Content and Format* (see www.fda.gov/regulatory-information/search-fda-guidance-documents/instructions-use-patient-labeling-human-prescription-drug-and-biological-products-and-drug-device).
Complex Innovative Designs Pilot Program FY19 Meeting Quarter 1	9/30/2019	Y	11/8/2018	
Complex Innovative Designs Pilot Program FY19 Meeting Quarter 2	9/30/2019	Y	2/8/2019	
Complex Innovative Designs Pilot Program FY19 Meeting Quarter 3	9/30/2019	Y	5/3/2019	
Complex Innovative Designs Pilot Program FY19 Meeting Quarter 4	9/30/2019	Y	6/30/2019	
Implement Procedures for Human Factors Protocol Review	9/30/2019	Y	10/1/2018	
Update SOPP 8001.5 *Inter-Center Consultative Review Process* on April 8, 2019, to reflect the new ICCR process and SMG 4101	9/30/2019	Y	4/8/2019	
Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities	9/30/2019	Y	6/12/2019	Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities (see healthpolicy.duke.edu/events/advancing-development-and-implementation-analysis-data-standards-key-challenges-and).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Eleventh Annual Sentinel Initiative Public Workshop	9/30/2019	Y	4/4/2019	FDA's Sentinel Initiative – News and Events (see www.fda.gov/safety/fdas-sentinel-initiative/fdas-sentinel-initiative-news-and-events).
Update MAPP 6700.9 *FDA Posting of Potential Signals of Serious Risks Identified by the Adverse Event Reporting System*	9/30/2019	Y	9/10/2019	MAPP 6700.9 *FDA Posting of Potential Signals of Serious Risks Identified by the Adverse Event Reporting System* (see www.fda.gov/media/80214/download).
Update SOPP8429 *FDAA Section 921: Posting of Potential Signals of Serious Risk*	9/30/2019	Y	9/17/2019	
Enhancing the Incorporation of Patient Perspectives on Clinical Trials	9/30/2019	Y	3/18/2019	Enhancing the Incorporation of Patient Perspectives on Clinical Trials (see www.ctti-clinicaltrials.org/briefing-room/meetings/enhancing-incorporation-patient-perspectives-clinical-trials).
PDUFA Hiring Goals FY2019: 74 FTEs	9/30/2019	N	N/A	51 out of 74 required hires under PDUFA were completed. FDA intends to hire the remaining 23 FTEs as quickly as possible.

C. Common Causes and Trends Impacting Ability to Meet Goals

The following table addresses section 904(a)(1) of FDARA (section 736B(a)(5)(C) of the FD&C Act), pertaining to PDUFA, which requires FDA to identify the most common causes and trends of external or other circumstances affecting the ability of FDA, including CDER, CBER, and the Office of Regulatory Affairs, to meet the review time and performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

Cause or Trend	Impact on FDA's Ability to Meet Goals
Small number of Class 1 resubmissions for the original applications cohort	• Missing the goal date for a single resubmission resulted in dropping below the performance goal.
Large volume of formal PDUFA meeting requests	• Increasingly resource-intensive performance goals and workload, common across all user fee programs, strained the resources of the same set of key staff within relevant offices/divisions and contributed to the overall challenge of scheduling and completing meeting responses and meeting minutes on time. There were also logistical challenges in trying to schedule meetings within the goal dates around the relatively few signatories that needed to attend.
Federal government shutdown	• The federal government shutdown delayed publication of the FY 2019 update to the PDUFA Five-Year Financial Plan and contributed to the inability to meet the annual hiring goals.
Change in hiring web posting methodology	• A change in the methodology used to calculate metrics for the web posting, along with changes in the POC for some of the necessary data, led to late postings.

Cause or Trend	Impact on FDA's Ability to Meet Goals
Strong job market	• The job market in both the medical and pharmaceutical fields was very strong in FY 2019, and the federal unemployment rate remained low. This made it difficult to attract strong candidates and led to potential employees for user-fee positions of critical need receiving competing offers.
Non-competitive salaries for specialized talent	• Occupations represented by user-fee positions of critical need had large gaps in government pay compared to the private sector. This made it difficult to attract strong candidates and led to potential employees for user-fee positions of critical need receiving competing offers.
Lengthy hiring process	• In some cases, months elapsed between an interview and the extension of a tentative offer to a potential employee, which led to some potential employees declining offers.
Need for extensive cross-discipline discussion and coordination	• The need for extensive discussion across scientific disciplines and complex legal analysis resulted in the delayed publication of the draft guidance on bridging for drug-device and biologic-device combination products. FDA hopes the guidance will be published soon.

Appendix D: FY 2019 Corrective Action Report

On August 18, 2017, FDARA (Public Law 115-52) was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for drugs, biologics, medical devices, and biosimilar biological products, as well as to perform other purposes. Among the provisions of Title IX, section 904 of FDARA, FDA is required to publicly issue an analysis of its use of funds, which includes a corrective action report that details FDA's progress in meeting the review and performance enhancement goals identified in PDUFA VI for the applicable fiscal year.

If each of the review and performance enhancement goals for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application process.

For any of the review and performance enhancement goals during the applicable fiscal year that were not met, the corrective action report shall include a justification, as applicable, for the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts that FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year. Such a description of corrective efforts is not required by statute for review time goals, but FDA is providing this information regardless in an effort to be complete.

This report satisfies this reporting requirement.

Executive Summary

FY 2019 Review Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goal Dates	Corrective Action Plan
Review Goals	• Due to the low number of Class 1 resubmissions received (i.e., 7 total), missing the goal for a single application resulted in dropping below the PDUFA standard of 90 percent on time for Class 1 resubmissions for original applications.	• This reflects a single outlier scenario. FDA will continue to strive to meet all PDUFA review goal dates.
Procedural and Processing Goals	• There was a large volume of formal PDUFA meeting requests in FY 19. The number of requests has continued to rise each year in recent years.	• As part of a New Drugs Regulatory Program Modernization effort, FDA is executing a new drugs reorganization within CDER to better align and distribute resources.

FY 2019 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Guidances	• The draft guidance on bridging for drug-device and biologic-device combination products required extensive discussion across scientific disciplines, as well as complex legal analysis.	• When completed, the guidance will be published.
Website Publishing	• A change in the methodology used to calculate metrics for the posting, along with changes in the POCs for some of the necessary data, led to late postings.	• The new methodology has been established, as well as primary and secondary POCs for the hiring data.
Human Capital/Hiring	• The federal government shutdown led to a significant lapse in operations. • A strong job market and non-competitive salaries compared to the private sector made it harder to attract qualified candidates. • A lengthy hiring process led to some potential employees accepting other offers.	• FDA is expanding the use of the 21st Century Cures Act hiring authority to more effectively hire specialized talent. • FDA is increasing its talent sourcing activities to improve its recruitment and outreach.
Reporting	• FDA published the FY 2019 PDUFA Five-Year Financial Plan Update in May 2019. Publication was delayed by the government shutdown.	• Barring another government shutdown, there should be no delay in publishing the FY 2020 update to the PDUFA Five-Year Financial Plan.

PDUFA Review Goals

The following section addresses section 904(a)(2)(B) of FDARA (section 736B(c)(2)(A) of the FD&C Act), which requires FDA to provide a justification for the determination of review goals missed during FY 2019, and a description of the circumstances and any trends related to missed review goals.

This section 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.

This section includes all PDUFA VI goals as they pertains to receipts/filed submissions in FY 2019.

I. FY 2019 Review Goal Performance

A. *Summary of Performance*

FDA missed the PDUFA goal date for the 90 percent on time review of Class 1 resubmissions of original applications.

B. *Justification*

Because of the low number of Class 1 resubmissions received (i.e., 7 total), missing the goal for a single application resulted in dropping below the PDUFA goal of 90 percent on time.

C. *FY 2020 Corrective Actions*

This reflects a single outlier scenario. FDA will continue to strive to meet all PDUFA review goal dates.

II. FY 2019 Procedural and Processing Performance

A. *Summary of Performance*

FDA missed the following procedural goals related to formal meeting management:

- Meeting request response for Type A, B (EOP), and C
- Meeting scheduling for Type A, B, B (EOP), and C
- Final written response for Type A, B, B (EOP), and C
- Meeting preliminary response for Type B (EOP)

B. *Justification*

In FY 2019, FDA received 3,771 formal PDUFA meeting requests. This number is up again from FY 2018 and has continued to rise steadily each year for the past 7 years in a row. There were logistical challenges with finding time to schedule all these meetings for the relatively few signatories who must attend. Other contributing factors in missing meeting management goals included increasing workloads in other user fee areas such as IND and marketing application submissions.

C. *FY 2020 Corrective Actions*

FDA has engaged in a New Drugs Regulatory Program Modernization effort, which includes a reorganization of OND within CDER. This ongoing effort, among other things, will re-align new drug therapeutic areas and flatten the organization to improve operational excellence and promote consistency. This change will result in an increased number of signatories who can attend and sign-off on formal meetings, hopefully addressing some of the logistical scheduling issues. The reorganization also includes a centralization of the Regulatory Project Management discipline, which is intended in part to promote and facilitate consistency and efficiency in processes and performance. The reorganization will create greater efficiency and enhance FDA's ability to meet the PDUFA meeting goals.

PDUFA Performance Enhancement Goals

The following section addresses section 904(a)(2) of FDARA (section 736B(c)(2) of the FD&C Act), which requires FDA to provide a justification for missed performance enhancement goals and a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year (included here under the heading "FY 2020 Corrective Actions").

This section presents non-review performance goals cited in the PDUFA VI Commitment Letter with required completion dates in FY 2019. For the purposes of this report, *performance enhancement goals* are defined as any non-review performance goal with a specified deadline as named in the PDUFA Commitment Letter. Performance enhancement goals with specified completion dates in FY 2020 through FY 2022 will be covered in subsequent corrective action reports.

I. Guidances

A. *Summary of Performance*

The PDUFA goal date for publishing a draft guidance on bridging for drug-device and biological-device combination products was missed.

B. *Justification*

Preparation and clearance of the guidance has required extensive discussion within FDA. In particular, ensuring that the guidance would be useful required a careful assessment of what type of information could advance the interest of improving predictability for industry while at the same time ensuring that reviews were appropriately rigorous. In addition, the guidance raised complex legal issues involving regulatory authorities across FDA, and extensive effort was needed to ensure it was aligned with, and did not undermine, important regulatory and legal frameworks.

C. *FY 2020 Corrective Actions*

The guidance will be published as soon as completed.

II. Website Publishing

A. *Summary of Performance*

FDA missed the PDUFA goal date for posting on the web the FY 2018 first, second, and third quarter hiring data.

B. *Justification*

In 2019, FDA implemented a new methodology for the purpose of these postings that defines a "hire" as "someone who has been confirmed as on board by the date indicated

in a full-time position at the noted Center." Using this new methodology, FDA can provide clearer and more precise data that are easier to obtain and report and are more closely aligned with what the commitment intended. This led to some confusion with compiling the correct quarterly hiring data, which contributed to delays in FDA's data reporting. In addition, several POCs for hiring data left the Agency, which also contributed to continuing delays in receiving and aggregating the data.

C. *FY 2020 Corrective Actions*

The methodology for the calculations is now well established, as is the new process for obtaining and posting the data. Additionally, primary and secondary POCs for the data have been established.

III. Human Capital/Hiring

A. *Summary of Performance*

FDA missed the PDUFA goal for hiring in FY 2019. Specifically, 51 out of 74 (69%) employees were hired.

B. *Justification*

FY 2019 was interrupted by the longest federal government shutdown in history (35 days). The shutdown slowed down all of FDA's business operations, including the hiring process. At the same time, FDA continued to compete in a very strong job market in both the medical and pharmaceutical fields, and the national unemployment rate remained at a 50-year low. The demand for occupations of critical need represented by user fee positions led to large gaps in government pay compared to the private sector. These factors made it difficult for FDA to attract strong candidates for user fee positions of critical need in support of the drug review process and/or regulation of medical products. In some cases, tentative offers were extended, but candidates chose to pursue other opportunities outside FDA. There were other instances when months elapsed between an interview and the tentative offer to a potential employee. This led to some potential employees declining FDA offers.

C. *FY 2020 Corrective Actions*

FDA continues to expand the use of the hiring authority granted under the 21st Century Cures Act to bring on specialized talent, including physicians, at more competitive salaries. This should help FDA compete in the current job market; however, it will not fully close the gap with the private sector.

Additionally, FDA will increase talent sourcing activities in support of recruitment and outreach, aligning positions of critical need with hiring managers' program priorities, including PDUFA positions. This streamlined approach within human resources will generate partnerships with hiring managers to promote user fee positions. FDA will also continue to work on making the overall hiring process more efficient.

IV. Reporting

A. *Summary of Performance*

FDA missed the PDUFA goal for publishing an update to the PDUFA Five-Year Financial Plan.

B. *Justification*

FDA published the FY 2019 PDUFA Five-Year Financial Plan Update in May 2019. Publication was delayed by the government shutdown.

C. *FY 2020 Corrective Actions*

Assuming there is no government shutdown in 2020, there should not be a delay in publishing the FY 2020 update to the PDUFA Five-Year Financial Plan. In addition, FDA has concurrently been working to streamline internal processes to speed publishing and mitigate the risk of missing the timelines regardless of external factors (e.g., a government shutdown).

Appendix E: Definitions of Key Terms

A. The phrase *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. Review Performance Goal Extensions

1. Major Amendments

   a. 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.]

   b. 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 Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

   c. 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.]

   d. Only one extension can be given per review cycle.

   e. Consistent with the underlying principles articulated in the Good Review Management Principles and Practices for PDUFA Products guidance,[21] 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.

2. Inspection of Facilities Not Adequately Identified in an Original Application or Supplement

   a. All original applications, including those in the "Program," and supplements are expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

   b. If, during FDA's review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list, the goal date may be extended.

      i. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by 3 months.

[21] https://www.fda.gov/media/99140/download

ii. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by 2 months.

C. A *resubmitted original application* is an applicant's complete response to an action letter addressing all identified deficiencies.

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

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences not previously reported with the product, are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform 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 and Type B(EOP) 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, 70 days for Type B(EOP) 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. Preliminary responses to sponsor questions contained in the background package for Type B(EOP) meetings should be sent to the sponsor no later than 5 calendar days prior to the meeting date.

I. 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.

J. *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.

K. Type B meetings include pre-IND meetings and pre-NDA/BLA meetings, while Type B(EOP) meetings are reserved for certain End-of-Phase 1 meetings (i.e., for 21 CFR part 312 subpart E or 21 CFR part 314 subpart H or similar products) and End-of-Phase 2/pre-Phase 3 meetings. Meetings regarding REMS or postmarketing requirements that occur outside the context of the review of a marketing application will also generally be considered Type B meetings.

L. A *Type C Meeting* is any other type of meeting.

M. 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.

N. IT-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 PDUFA.
2. *Standards-base*" 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, postmarket 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 postmarket surveillance and risk management activities as covered under the process for the review of human drug applications.

O. 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.

P. 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.

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Department of Health and Human Services
Food and Drug Administration

This report was prepared by FDA's Office of Planning in collaboration with the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). For information on obtaining additional copies, contact:

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