FY 2020

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's or the Agency's) fiscal year (FY) 2020 Prescription Drug User Fee Act (PDUFA) performance report. This report marks the 28th year of PDUFA and the third year of PDUFA VI (which covers FY 2018 through FY 2022).

This report presents updated data on FDA's progress in meeting FY 2019 performance goals, preliminary data on FDA's progress in meeting FY 2020 review performance goals, and data on other commitments under PDUFA VI as of September 30, 2020.

FY 2020 turned out to be a unique year, creating unforeseen challenges and obstacles due to the COVID-19 pandemic. Despite an increased workload, the use of expedited development and review pathways for new therapeutics to address the public health emergency, and a remote workforce, FDA rose to the challenge and maintained its high level of performance in meeting PDUFA goals and initiatives.

FDA continues its longstanding commitment to meeting all PDUFA performance goals related to human drug review. In FY 2020, 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 2021, FDA will continue to enhance the program's staffing and strengthen efforts to improve the program's performance while maintaining a focus on ensuring that safe, effective, and high-quality new drugs and biological products are reviewed in an efficient and predictable time frame.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

ARIA – Active Risk Identification and Analysis
BEST – Biologics Effectiveness and Safety Initiative
BLA – Biologics License Application
BT – Breakthrough Therapy
BQP – Biomarkers Qualification Program
BTD – Breakthrough Therapy-Designated
CBER – Center for Biologics Evaluation and Research
CDER – Center for Drug Evaluation and Research
CE – Continuing Education
CID – Complex Innovative Design
COA – Clinical Outcome Assessment
DDT – Drug Development Tool
EHR – Electronic Health Record
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
FTE – Full-Time Equivalent
FY – Fiscal Year (October 1 to September 30)
IMEDS – Innovation in Medical Evidence Development and Surveillance
IND – Investigational New Drug
IT – Information Technology
MAPP – Manual of Policies and Procedures
MIDD – Model-Informed Drug Development
NDA – New Drug Application
NISS – Newly Identified Safety Signal (NISS)
NME – New Molecular Entity
OC – Office of the Commissioner
ORA – Office of Regulatory Affairs

PD – Position Description

PDUFA – Prescription Drug User Fee Act

POC – Point of Contact

RDT – Rare Diseases Team

REMS – Risk Evaluation and Mitigation Strategy

RMAT – Regenerative Medicine Advanced Therapies

RWE – Real-World Evidence

SOP – Standard Operating Procedure

SOPP – Standard Operating Policy and Procedure

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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 has been 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 fiscal year (FY) 2018 to FY 2022 period, detailed in a document commonly known as the PDUFA VI Commitment Letter.[1]

This report summarizes FDA's performance results in meeting PDUFA goals and commitments for FY 2019 and FY 2020. Specifically, this report updates performance data for submissions received in FY 2019 (initially reported in the FY 2019 PDUFA Performance Report)[2] and presents preliminary data on FDA's progress in meeting FY 2020 goals. Updates on FDA's accomplishments related to additional PDUFA VI commitments for FY 2020 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 2020, 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 and standard NDAs and BLAs received in FY 2019 decreased compared to the estimated median approval times for priority and standard NDAs and BLAs received in FY 2018. The preliminary data show that the percentage of priority and standard applications filed in FY 2019 and approved during the first review cycle were 73 percent and 68 percent, respectively.

Achievements in FY 2020

[1] www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.
[2] www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/ucm2007449.htm.
[3] The median approval time is estimated because an application can receive an approval after multiple review cycles, thus impacting the median approval time for all applications in a given receipt cohort. Some applications may be approved several years after their original receipt.

In March 2020, FDA experienced the unexpected onset of a public health emergency, the impact of which continued through the remainder of that fiscal year. The COVID-19 pandemic resulted in a shift to 100 percent virtual work for the majority of the Agency's staff. The Agency appropriately shifted limited resources to prioritize work focused on addressing the pandemic. Also, the Agency experienced a significant increase of 17 percent in PDUFA workload. For example, in FY 2020, there was a 24 percent increase in formal meeting requests alone. Despite all this, FDA is on track to meet or exceed all its review performance goals for the FY 2020 cohort.

Review Performance Results

The FY 2019 cohort had a workload of 2,916 goal closing actions. FDA met or exceeded the 90 percent performance level for 11 of the 12 review performance goals for FY 2019.

For the FY 2020 cohort, FDA had completed 2,006 actions as of September 30, 2020. FDA is currently meeting or exceeding 12 of the 12 review performance goals for FY 2020. With 1,420 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed all 12 review performance goals for FY 2020.

Procedural and Processing Performance Results

For the FY 2019 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 10,196 actions. FDA met or exceeded the performance level for 9 of the 20 procedural and processing goals for FY 2019.

For the FY 2020 cohort, FDA is currently meeting or exceeding 7 of the 20 procedural and processing goals. With 1,322 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 7 of the 20 procedural and processing goal commitments for FY 2020.

Additional PDUFA VI Commitments

During FY 2020, FDA made significant progress implementing other important PDUFA VI commitments, including enhancing patient input and benefit-risk assessments in regulatory decision-making, enhancing regulatory science, exploring the use of real-world evidence, enhancing regulatory decision tools to support drug development and review, enhancing and modernizing FDA's drug safety system, and improving the efficiency of human drug review through the required electronic submission 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 2020, including the following:

- Published guidances addressing combination products, the collection of patient and caregiver input on drug development, drug development tools, and complex innovative trial design,
- Published a final report on the assessment of FDA-sponsor communication practices during the IND stage of drug/biologic development, and
- Held public meetings to discuss use of real-world evidence, patient-focused drug development, the use of Sentinel (FDA's medical product safety surveillance system), and financial transparency and efficiency.

Table of Contents

Introduction

On August 18, 2017, the President signed the FDA 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 the Food and Drug Administration (FDA or the Agency) with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biological products. In return forthis funding, 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 time frames.

Since the enactment of PDUFA I in 1992, FDA has used PDUFA resources to significantly reduce the time needed to evaluate new drugs and biological products without compromising its rigorous standards for a demonstration of safety, efficacy, and quality of these products 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 FDA's website.[4]

Information Presented in This Report

This report presents PDUFA performance and workload information for two different types of goals: (1) the review of applications and other submissions pertaining to human drugs and biological products 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 the final performance results for the FY 2019 cohort of submissions based on actions completed in FY 2019 and FY 2020. In addition, this report includes the preliminary performance results for the FY 2020 cohort of submissions that had actions completed or due for completion in FY 2020. Final performance for the FY 2020 cohort will be presented in the FY 2021 PDUFA Performance Report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2020.

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

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

- The following terminology is used throughout this document:

    - *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 for that fiscal year. 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 FDA's 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 by FDA. 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. For these submissions, FDA's performance data 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-

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

time goals tend to have a larger percentage of reviews completed by the end of the fiscal year, and these submissions types' preliminary performance data are a more reliable indicator of their final performance results. However, submission types (e.g., standard NME NDA/BLA) with longer (e.g., within 10 months of the 60-day filing date) review-time goals tend to have a smaller percentage of reviews completed, and these submission types' preliminary performance data are a less reliable indicator of their final performance results.

- Final performance results for FY 2019 submissions are 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 results for FY 2020 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2020, excluding actions pending within the PDUFA goal date. Submission types with a current performance result 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 results) 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 2020 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, 2020.

- 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 chemical, pharmacological, medical, biopharmaceutical, and statistical. 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 being met.
- **Source:** www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.

PDUFA Review Goals

Review Workload: FY 2015 to FY 2020

In the table below, preliminary workload numbers from FY 2020 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements. FDA noted a large increase in the number of original priority NMEs and BLAs, original priority non-NME NDAs submissions, Class 2 resubmitted NDAs and BLAs, priority NDA and BLA efficacy supplements, Class 2 resubmitted NDA and BLA efficacy supplements, and NDA and BLA manufacturing supplements requiring prior approval in FY 2020.

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 15	FY 16	FY 17	FY 18	FY 19*	FY 20	FY 15 to FY 19 5-Year Average	FY 20 Compared to 5-Year Average
Original Priority NMEs and BLAs	25	23	31	48	44	53	34	56%
Original Standard NMEs and BLAs	32	24	22	22	35	31	27	15%
Original Priority Non-NME NDAs	9	12	24	16	16	22	15	47%
Original Standard Non-NME NDAs	84	72	81	69	68	52	75	-31%
Class 1 Resubmitted NDAs and BLAs	7	5	8	9	8	5	7	-29%
Class 2 Resubmitted NDAs and BLAs	37	31	49	50	41	57	42	36%
Priority NDA and BLA Efficacy Supplements	52	54	78	97	81	116	72	61%
Standard NDA and BLA Efficacy Supplements	136	145	173	177	197	180	166	8%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	0	3	3	3	4	3	3	0%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	11	11	11	11	2	20	9	122%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	765	842	968	992	973	1,191	908	31%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,614	1,475	1,540	1,610	1,450	1,696	1,538	10%

* FY 2019 numbers were changed to reflect updates to the data presented in the FY 2019 PDUFA Performance Report.

Final FY 2019 Review Goal Performance Results

The final FY 2019 review goal performance results are presented in the table below. The final performance results for submission types that met the goal (i.e., 90 percent or more actions were completed by the goal date) are shown in bold text. FDA met or exceeded the 90 percent performance level for 11 of the 12 review performance goals in FY 2019.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2019 Performance
Original Priority NMEs and BLAs	6 months of filing date	44 of 44 on time	**100%**
Original Standard NMEs and BLAs	10 months of filing date	33 of 33 on time	**100%**
Original Priority non-NME NDAs	6 months	16 of 16 on time	**100%**
Original Standard non-NME NDAs	10 months	67 of 68 on time	**99%**
Class 1 Resubmitted NDAs and BLAs	2 months	7 of 8 on time	88%
Class 2 Resubmitted NDAs and BLAs	6 months	37 of 41 on time	**90%**
Priority NDA and BLA Efficacy Supplements	6 months	78 of 81 on time	**96%**
Standard NDA and BLA Efficacy Supplements	10 months	178 of 196 on time	**91%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	4 of 4 on time	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	2 of 2 on time	**100%**
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	953 of 973 on time	**98%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,436 of 1,450 on time	**99%**

Final FY 2019 Review Goal Performance Details

The following tables detail the final performance data for the FY 2019 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 the goal date 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 2019 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	44	44	0	100%
Standard NMEs & BLAs	10 months of filing date	35	33	0	100%*
Priority Non-NME NDAs	6 months	16	16	0	100%
Standard Non-NME NDAs	10 months	68	67	1	99%

* Two NMEs are still pending within goal. This table represents data as of September 30, 2020.

Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	8	7	1	88%
Class 2	6 months	41	37	4	90%

Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	81	78	3	96%
Standard	10 months	197	178	18	91%*

* One efficacy supplement is still pending within goal. This table represents data as of September 30, 2020.

Resubmitted Efficacy Supplements

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	4	4	0	100%
Class 2	6 months	2	2	0	100%

Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	973	953	20	98%

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Not Required	6 months	1,450	1,436	14	99%

Preliminary FY 2020 Review Goal Performance Results

The preliminary FY 2020 review goal performance results are 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 the goal date or pending past the goal date). The current performance results for submission types with a greater proportion of reviews completed will be more representative of the final performance results. The *highest possible final performance* is the best potential final performance result, which accounts for actions pending within the PDUFA goal date.

- The current performance results 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, 2020, are shown in bold text. FDA is currently meeting or exceeding the 90 percent performance level for all 12 review performance goals.

- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance results presented in the Highest Possible Final Performance column. FDA has the potential to meet or exceed the 90 percent performance level for all 12 review performance goals.

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2020 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	18 of 48 complete	6 months of filing date	**94%**	98%
Original Standard NMEs and BLAs	1 of 31 complete	10 months of filing date	**100%**	100%
Original Priority non-NME NDAs	8 of 12 complete	6 months	**100%**	100%
Original Standard non-NME NDAs	7 of 52 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	5 of 5 complete	2 months	**100%**	100%
Class 2 Resubmitted NDAs and BLAs	30 of 57 complete	6 months	**90%**	95%
Priority NDA and BLA Efficacy Supplements	58 of 105 complete	6 months	**100%**	100%
Standard NDA and BLA Efficacy Supplements	54 of 180 complete	10 months	**100%**	100%

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2020 Current Performance	Highest Possible Final Performance
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 of 3 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	11 of 20 complete	6 months	**91%**	95%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	812 of 1,191 complete	4 months	**98%**	98%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,000 of 1,696 complete	6 months	**99%**	99%

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

Preliminary FY 2020 Review Goal Performance Details

The following detailed performance information for the FY 2020 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 the goal date 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

Original 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	48	17	1	30	94%	98%
Standard NMEs & BLAs	10 months of filing date	31	1	0	30	100%	100%
Priority Non-NME NDAs	6 months	12	8	0	4	100%	100%
Standard Non-NME NDAs	10 months	52	7	0	45	100%	100%
Review Priority Undesignated*	N/A	15	--	--	15	--	--
Total		158	33	1	124	--	--

* 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	5	5	0	0	100%	100%
Class 2	6 months	57	27	3	27	90%	95%

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	105	58	0	47	100%	100%
Standard	10 months	180	54	0	126	100%	100%
Review Priority Undesignated*	N/A	11	--	--	11	--	--

* 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	3	2	0	1	100%	100%
Class 2	6 months	20	10	1	9	91%	95%

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	1,191	793	19	379	98%	98%
Prior Approval Not Required	6 months	1,696	990	10	696	99%	99%
Review Priority Undesignated*	N/A	0	--	--	0	--	--

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

PDUFA Procedural and Processing Goals and Commitments

Procedural and Processing Workload: FY 2015 to FY 2020

The FY 2020 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 2020.

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 2019 and FY 2020) 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 2019 performance and 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.

Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request Type	FY 15	FY 16	FY 17	FY 18	FY 19*	FY 20	FY 15 to FY 19 5-Year Average	FY 20 Compared to 5-Year Average
Type A Meeting Requests	121	135	175	146	153	279**	146	91%
Type B Meeting Requests	1,664	1,738	1,850	1,609	1,725	2,390	1,717	39%
Type B (EOP) Meeting Requests	--	--	--	343	343	346	--†	--†
Type C Meeting Requests	1,237	1,372	1,391	1,403	1,550	1,663	1,391	20%
Type A Meetings Scheduled	107	123	159	127	130	244**	129	89%
Type B Meetings Scheduled	1,204	1,183	1,293	945	936	877	1,112	-21%
Type B (EOP) Meetings Scheduled	--	--	--	324	325	316	--†	--†
Type C Meetings Scheduled	603	596	660	640	732	684	646	6%
Type A Written Response	--	--	--	6	6	13	--†	--†
Type B Written Response	382	469	482	578	719	1,384	526	163%
Type B (EOP) Written Response	--	--	--	14	11	25	--†	--†
Type C Written Response	546	658	652	686	728	877	654	34%

Submission/Request Type	FY 15	FY 16	FY 17	FY 18	FY 19*	FY 20	FY 15 to FY 19 5-Year Average	FY 20 Compared to 5-Year Average
Type B (EOP) Preliminary Response	--	--	--	303	305	300	--†	--†
Meeting Minutes	1,517	1,500	1,679	1,541	1,638	1,511	1,575	-4%
Responses to Clinical Holds	161	232	193	199	197	264	196	35%
Major Dispute Resolutions	15	17	20	23	28	35	21	67%
Special Protocol Assessments	231	215	173	160	158	149	187	-20%
Review of Proprietary Names Submitted During IND Phase	178	158	176	159	212	223	177	26%
Review of Proprietary Names Submitted with NDA/BLA	213	202	255	228	230	250	226	11%
Human Factors Protocol Submissions	--	--	--	--	70	79	--†	--†

* FY 2019 numbers were changed to reflect updates to the data presented in the FY 2019 PDUFA Performance Report.
** Some meeting requests and the subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 101 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 2021 PDUFA Performance Report.
† Because of changing reporting requirements, no past average is presented for this area.

Final FY 2019 Procedural and Processing Performance Results

The table below presents the final performance results for FY 2019 submissions in meeting goals related to meeting management, procedural responses, and procedural notifications. The final performance results for submission types that met the goal (i.e., 90 percent or more reviews were completed by the goal date) are shown in bold text. FDA exceeded the performance level for 9 of the 20 procedural and processing goals in FY 2019.

Submission/Request Type	Goal: 90 Percent	Total	FY 2019 Performance
Type A Meeting Requests	Respond within 14 days	137 of 153 on time	**90%**
Type B Meeting Requests	Respond within 21 days	1,577 of 1,725 on time	**91%**
Type B (EOP) Meeting Requests	Respond within 14 days	282 of 343 on time	82%
Type C Meeting Requests	Respond within 21 days	1,375 of 1,550 on time	89%
Type A Meetings Scheduled	Schedule within 30 days	92 of 130 on time	71%
Type B Meetings Scheduled	Schedule within 60 days	613 of 936 on time	65%
Type B (EOP) Meetings Scheduled	Schedule within 70 days	247 of 325 on time	76%
Type C Meetings Scheduled	Schedule within 75 days	553 of 732 on time	76%

Submission/Request Type	Goal: 90 Percent	Total	FY 2019 Performance
Type A Written Response	Respond within 30 days	4 of 6 on time	67%
Type B Written Response	Respond within 60 days	581 of 719 on time	81%
Type B (EOP) Written Response	Respond within 70 days	8 of 11 on time	73%
Type C Written Response	Respond within 75 days	591 of 728 on time	81%
Preliminary Response for Type B (EOP) Meetings	Issue no later than 5 days prior to meeting date	264 of 305 on time	87%
Meeting Minutes	Issue within 30 days after meeting date	1,506 of 1,634 on time	**92%**
Responses to Clinical Holds	Respond within 30 days	189 of 197 on time	**96%**
Major Dispute Resolutions	Respond within 30 days	27 of 28 on time	**96%**
Special Protocol Assessments	Respond within 45 days	149 of 158 on time	**94%**
Review of Proprietary Names Submitted During IND Phase	Review within 180 days	203 of 212 on time	**96%**
Review of Proprietary Names Submitted with NDA/BLA	Review within 90 days	225 of 230 on time	**98%**

Submission/Request Type	Goal: 50 Percent	Total	FY 2019 Performance
Human Factors Protocol Submissions	Respond within 60 days	62 of 70 on time	**89%**

Final FY 2019 Procedural and Processing Goal Performance Details

The following tables detail the final performance data for the FY 2019 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 the goal date 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 2019 PDUFA Performance Report.

Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests	Respond within 14 days	153	137	16	90%
Type B Meeting Requests	Respond within 21 days	1,725	1,577	148	91%
Type B (EOP) Meeting Requests	Respond within 14 days	343	282	61	82%
Type C Meeting Requests	Respond within 21 days	1,550	1,375	175	89%
Type A Meetings Scheduled	Schedule within 30 days	130	92	38	71%
Type B Meetings Scheduled	Schedule within 60 days	936	613	323	65%
Type B (EOP) Meetings Scheduled	Schedule within 70 days	325	247	78	76%
Type C Meetings Scheduled	Schedule within 75 days	732	553	179	76%
Type A Written Response	Respond within 30 days	6	4	2	67%
Type B Written Response	Respond within 60 days	719	581	138	81%
Type B (EOP) Written Response	Respond within 70 days	11	8	3	73%
Type C Written Response	Respond within 75 days	728	591	137	81%
Preliminary Response for Type B (EOP) Meetings	Issue no later than 5 days prior to meeting date	305	264	41	87%
Meeting Minutes	Issue within 30 days after meeting date	1,638	1,506	128	92%†

* 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.
† Four meeting minutes are still pending within goal. This table represents data as of September 30, 2020.

Responses to Clinical Holds

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	197	189	8	96%

Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	28	27	1	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	Percent on Time
Respond to 90 percent within 45 days	158	149	9	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	Percent on Time
Submitted During IND Phase	Review and respond within 180 days	212	203	9	96%
Submitted with NDA/BLA	Review and respond within 90 days	230	225	5	98%

Human Factor Protocol Submissions

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Percent on Time
Human Factors Protocol Submissions	Respond within 60 days	70	62	8	89%

Preliminary FY 2020 Procedural and Processing Performance Results

The table below presents preliminary performance results for FY 2020 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 the goal date or pending past the goal date). *Highest possible final performance* is the best potential final performance result, which accounts for actions pending within the PDUFA goal date.
- The current performance results for submission types that are meeting the performance goal as of September 30, 2020, are shown in bold text. FDA is currently meeting or exceeding the performance level for 7 of the 20 procedural and processing goals. If all pending submissions are reviewed on time, FDA has the potential to meet 7 of the 20 goals, as seen in the Highest Possible Final Performance column.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2020 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	198 of 279 complete	Respond within 14 days	83%	88%
Type B Meeting Requests	2,350 of 2,390 complete	Respond within 21 days	**92%**	92%
Type B (EOP) Meeting Requests	341 of 346 complete	Respond within 14 days	82%	83%
Type C Meeting Requests	1,630 of 1,663 complete	Respond within 21 days	89%	89%
Type A Meetings Scheduled	154 of 244 complete	Schedule within 30 days	69%	81%
Type B Meetings Scheduled	836 of 877 complete	Schedule within 60 days	74%	75%
Type B (EOP) Meetings Scheduled	307 of 316 complete	Schedule within 70 days	79%	80%
Type C Meetings Scheduled	646 of 684 complete	Schedule within 75 days	78%	79%
Type A Written Response	12 of 13 complete	Respond within 30 days	75%	77%
Type B Written Response	1,210 of 1,384 complete	Respond within 60 days	82%	85%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2020 Current Performance	Highest Possible Final Performance
Type B (EOP) Written Response	19 of 25 complete	Respond within 70 days	79%	84%
Type C Written Response	695 of 877 complete	Respond within 75 days	79%	83%
Preliminary Response for Type B (EOP) Meetings	261 of 300 complete	Issue no later than 5 days prior to meeting date	81%	84%
Meeting Minutes	1,122 of 1,511 complete	Issue within 30 days after meeting date	**92%**	94%
Responses to Clinical Holds	235 of 264 complete	Respond within 30 days	**96%**	96%
Major Dispute Resolutions	33 of 35 complete	Respond within 30 days	88%	89%
Special Protocol Assessments	128 of 149 complete	Respond within 45 days	**96%**	97%
Review of Proprietary Names Submitted During IND Phase	133 of 223 complete	Review and respond within 180 days	**98%**	99%
Review of Proprietary Names Submitted with NDA/BLA	206 of 250 complete	Review and respond within 90 days	**100%**	100%

Submission/Request Type	Progress	Goal: 70 Percent	FY 2020 Current Performance	Highest Possible Final Performance
Human Factors Protocol Submissions	71 of 79 complete	Respond within 60 days	**90%**	91%

Preliminary FY 2020 Procedural and Processing Goal Performance Details

The following detailed performance information for FY 2020 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 the goal date 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	279	164	34	81	83%	88%
Type B Meeting Requests	Respond within 21 days	2,390	2,163	187	40	92%	92%
Type B (EOP) Meeting Requests	Respond within 14 days	346	281	60	5	82%	83%
Type C Meeting Requests	Respond within 21 days	1,663	1,450	180	33	89%	89%
Type A Meetings Scheduled†	Schedule within 30 days	244	107	47	90	69%	81%
Type B Meetings Scheduled	Schedule within 60 days	877	621	215	41	74%	75%
Type B (EOP) Meetings Scheduled	Schedule within 70 days	316	243	64	9	79%	80%
Type C Meetings Scheduled	Schedule within 75 days	684	504	142	38	78%	79%
Type A Written Response	Respond within 30 days	13	9	3	1	75%	77%
Type B Written Response	Respond within 60 days	1,384	998	212	174	82%	85%
Type B (EOP) Written Response	Respond within 70 days	25	15	4	6	79%	84%
Type C Written Response	Respond within 75 days	877	547	148	182	79%	83%
Preliminary Response for Type B (EOP) Meetings	Issue no later than 5 days prior to meeting date	300	212	49	39	81%	84%
Meeting Minutes	Issue within 30 days after meeting date	1,511	1,035	87	389	92%	94%

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

† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 101 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 2021 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	264	225	10	29	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	35	29	4	2	88%	89%

* 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	149	123	5	21	96%	97%

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
15	14	1	0	0	16

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 and respond within 180 days	223	131	2	90	98%	99%
Proprietary Names Submitted with NDA/BLA	Review and respond within 90 days	250	205	1	44	100%*	100%*

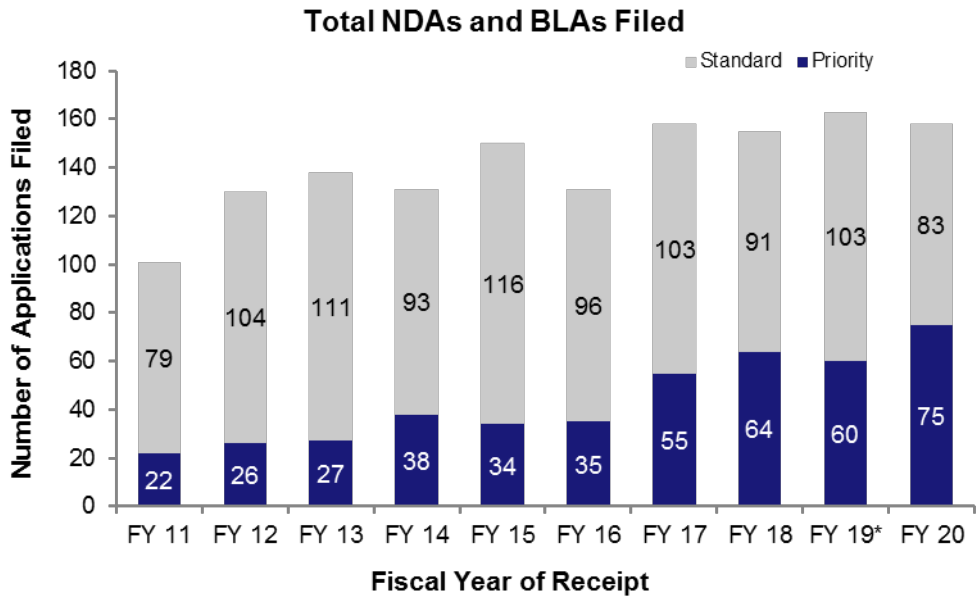
* The reported percentage is rounded up from 99.5%.

Human Factors Protocol Submissions

Submission Type	Goal: 70 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	79	64	7	8	90%	91%

PDUFA Trend Graphs

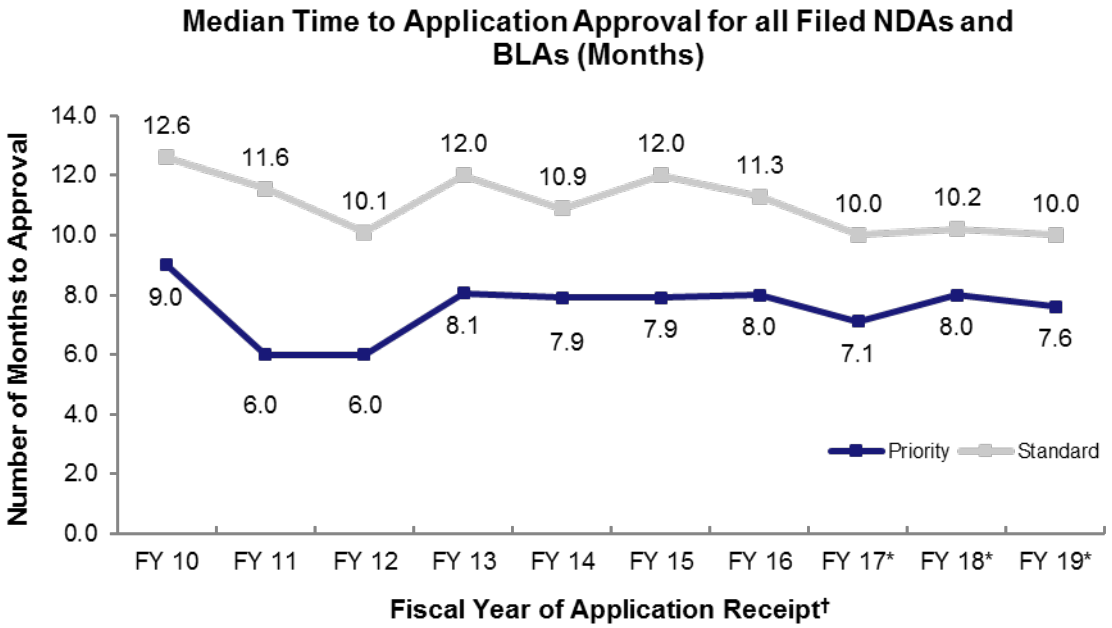
The number of NDAs and BLAs filed from FY 2011 to FY 2020 is presented in the graph below. The total number of all original applications (NDAs and BLAs) filed in FY 2020 decreased slightly from the number filed in FY 2019, and the total number of priority applications filed reached a new high in FY 2020.



* FY 2019 numbers were changed to reflect updates to the data presented in the FY 2019 PDUFA Performance Report.

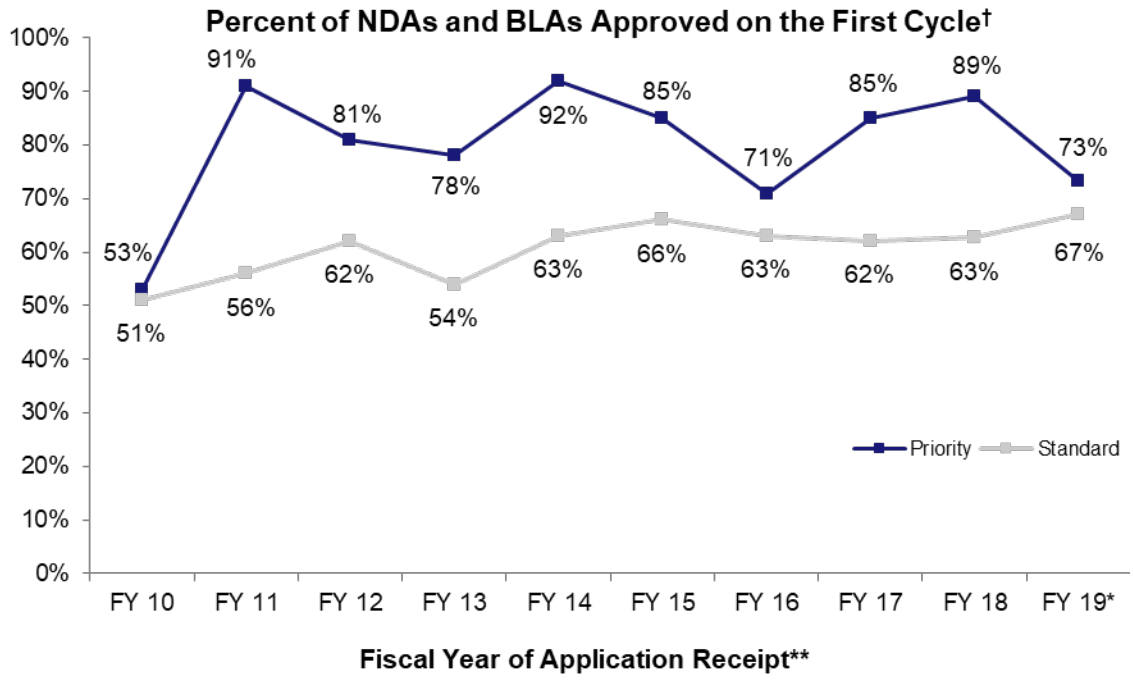
The median total times to approval for priority and standard applications received from FY 2010 through FY 2019 are presented in the graph below.[7] The data represented in the graph are updated based on the approvals reported in Appendix A. FY 2020 data are too preliminary to estimate the median approval 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. The 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.
† The 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 2010 to FY 2019. These percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals increased in FY 2018 and FY 2019. For the FY 2019 cohort, which is still preliminary, 67 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications decreased in FY 2019, with 73 percent of approved priority applications being approved on the first cycle. The FY 2020 data are too preliminary to estimate the percent of first-cycle approvals.



* First-cycle approvals are still possible for FY 2019 standard applications, so the data are preliminary.
† The data were changed to reflect upates to the data presented in the FY 2019 PDUFA Performance Report.
** The data represented in this graph re based on the approvals reported in Appendix A.

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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 2020 on commitments in Sections I.I-K of the Commitment Letter. 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 2020 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 2020 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 FY 2020, including attending and assessing FDA-sponsor meetings and conducting post-meeting surveys and interviews with FDA review teams and sponsors (I.I.1.a). • FDA published the final report on the assessment of FDA-sponsor communication practices during the IND stage of drug/biologic development on June 17, 2020 (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-assessment-fda-sponsor-communication-practices-during-ind-stage-drugbiologic-development) (I.I.1.a). • FDA hosted a public meeting to present and discuss the findings of the report.

I.I.2 Ensuring Sustained Success of Breakthrough Therapy Program	• Under the Breakthrough Therapy (BT) Program,[9] FDA:
	  ○ Received 140 BT Designation Requests.
	  ○ Granted 66 BT Designation Requests.
	  ○ Approved 27 original and 8 supplemental marketing applications for BT-Designated (BTD) products.[10]
	• Under the Regenerative Medicine Advanced Therapies (RMAT) Program, FDA:
	  ○ Received 34 RMAT Designation Requests.
	  ○ Granted 11 RMAT Designation Requests.
	  ○ Granted no approvals for RMAT-Designated products.

I.I.3 Early Consultation on the Use of New Surrogate Endpoints	• FDA developed and fully implemented the internal process for the new Type C novel surrogate endpoint meeting. To date, FDA has had approximately nine requests for this new meeting type involving products by both Centers.
I.I.4 Advancing Drug Development of Drugs for Rare Diseases	• The Center for Drug Evaluation and Research's (CDER's) Rare Diseases Team (RDT) held meetings with the Center for Biologics Evaluation and Research (CBER) to coordinate efforts in documenting FDA's progress in advancing the development of drugs for rare diseases through review of applications/submissions, training, and stakeholder engagement activities. • In FY 2020, CDER's RDT was consulted or contributed to rare diseases programs in the majority of the Office of New Drugs

[9] www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm.

[10] Note that BTD approvals are tracked and posted on the FDA.gov website by calendar year (see www.fda.gov/drugs/nda-and-bla-approvals/breakthrough-therapy-approvals). However, the BT approval numbers included in this PDUFA report are reflective of FY 2020.

	review divisions. • At an annual training on Advancing Rare Disease Drug Development Through Innovative Thinking and Collaboration held in May 2020, a record 417 FDA staff were in attendance. The theme of the training was *Breaking Through the Silos*, focusing on regulatory and scientific considerations in rare disease drug development to increase an understanding of trial considerations in rare disease research to drug review practices. • Further, as part of training, in FY 2020, CDER's RDT initiated the Rare Disease Quarterly series, focusing on promoting awareness and sharing knowledge regarding drug development for rare diseases across the Centers. • In FY 2020, CDER's RDT launched the Zebragram, a monthly internal newsletter, distributed across FDA, highlighting innovative approaches to rare disease drug development, precedent-setting regulatory decisions, publications, and important upcoming rare disease events. • As part of furthering consistency (specifically with other regulatory agencies), CDER's RDT administers the International Rare Diseases Cluster, which includes FDA, European Medicines Agency, and Health Canada. Health Canada was added as a standing cluster participant in March 2020. Cluster meetings were held regularly to discuss rare disease product-specific and general topics to facilitate alignment across scientific evaluation requirements and drug development. Since the inception of the International Rare Diseases Cluster in September 2016, 43 cluster meetings have been held, covering approximately 124 agenda topics. • CDER's RDT continues to work on cross-cutting guidances regarding key issues for the Center concerning rare disease drug development. • CBER's Rare Disease Program continued the series of case study presentations of flexibility in the review of biological products as a CBER Rare Disease Coordinating Committee meeting activity. • CBER continues to track rare disease-related stakeholder engagement activities. In FY 2020, CBER staff participated in a minimum of 113 outreach activities intended to support development of biological products for rare diseases. These activities included presentations (60%), publications (19%), and poster/abstracts (21%). • In January 2020, CBER issued three rare disease-related final guidance documents regarding the development of gene therapy products. • On March 3, 2020, CBER held a public workshop, titled *Facilitating End-to-end Development of Individualized Therapeutics*, to foster the development of gene therapies and phage therapies for the treatment of rare diseases that affect one or a very small number of patients. • CBER continued to collaborate with CDER and the Office of Orphan Products Development in activities to advance the development of drugs and biological products for rare diseases, such as in planning for and providing the annual rare disease training for FDA review staff on May 28, 2020, and the public meeting *FDA Rare Disease Day 2020: Supporting the Future of Rare Disease Product Development* on February 24, 2020.
I.I.5 Advancing Development of Drug-Device and Biologic-Device Combination	• FDA continues to expand its hiring and enhance its training of staff to develop the capacity and capability to review

Products Regulated by CBER and CDER	combination products effectively across the Centers (I.I.5.a). • FDA published an independent contractor's final report of an assessment of combination drug products. The report included best practices and areas of improvement regarding submission procedures for human factors protocols and the review and submission of combination product applications (see Assessment of Combination Product Review Practices in PDUFA VI at www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-assessment-combination-product-review-practices-pdufa-vi) (I.I.5.g). • In December 2019, FDA published the draft guidance for industry *Bridging for Drug-Device and Biologic-Device Combination Products* (see www.fda.gov/media/133676/download) (I.I.5.h.i).
I.I.6 Enhancing Use of Real World Evidence for Use in Regulatory Decision-Making	• FDA satisfied the commitment to complete the public workshop *A Framework for Regulatory Use of Real-World Evidence (RWE)* in September 2017, and the Agency continues to host public meetings on RWE such as the two-day public workshop *Establishing a High-Quality Real-World Data Ecosystem* in July 2020 and *Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines* on September 17-18, 2020. (PI.I.6.a). • FDA satisfied the commitment to initiate RWE activities in FY 2017 and continues to oversee additional demonstration projects and activities aimed at addressing evolving concerns and considerations in the use of RWE for regulatory decision-making. FY 2020-funded projects focused on improving methods for using electronic health records (PI.I.6.b). • FDA announced a funding opportunity in FY 2020 to solicit research on how to improve RWE for regulatory decision-making; 31 proposals were received, and 4 grants were awarded after scientific review. • FDA established an Intra-Departmental Delegation of Authority with the NIH to seek proposals—and funded two supplements in FY 2020 to existing NIH-funded trials—to better understand how current ethical and human subject protection frameworks can be applied to the use of RWE.

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

Commitment Title	FY 2020 Accomplishments
I.J.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	• FDA made progress on hiring goals related to strengthening staff capacity to facilitate development and use of patient-focused methods to inform drug development and regulatory decisions. In addition, FDA held monthly cross-disciplinary meetings to discuss reviews, guidances, and process changes; and staff provided presentations at several internal meetings and public meetings with a high attendance by FDA staff (I.J.1.a). • FDA continued the Standard Core Clinical Outcomes and Endpoints Grant Program that funds the development of core outcome sets in a variety of clinical divisions. The grant program also increases the familiarity and understanding of the Clinicial Outcome Assessment (COA) development within the divisions. As part of this program, 2 public meetings were held. (I.J.1.a). • In June 2020, FDA published a final guidance for industry, FDA staff, and other stakeholders entitled *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input*, describing approaches for collecting comprehensive and representative patient and caregiver input on the burden of disease and current therapy (see www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input) (I.J.1.b.v). • FDA gathered input from patients, patient advocates, academic researchers, expert practitioners, industry, and other stakeholders on COAs and on methods to better incorporate these assessments into endpoints that are considered significantly robust for regulatory decision-making (I.J.1.b.v). • FDA maintained and enhanced its repository of publicly available tools and resources for stakeholders (I.J.1.c).
I.J.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• FDA is in the process of developing guidance on the benefit-risk assessment for new drugs and biological products (I.J.2.c). • FDA awarded a contract to a third party to conduct an evaluation of the implementation of the benefit-risk framework in the human drug review program (I.J.2.d). • FDA published a manuscript entitled *FDA's Benefit–Risk Framework for Human Drugs and Biologics: Role in Benefit–Risk Assessment and Analysis of Use for Drug Approvals* (see doi.org/10.1007/s43441-020-00203-6). • FDA is participating in the CIOMS Working Group XII on Benefit-Risk Balance for Medicinal Products (see cioms.ch/working-groups/working-group-xii/).
I.J.3 Advancing Model-Informed Drug Development	• FDA selected proposals on a quarterly basis for which model-informed drug development (MIDD) would be needed to assess uncertainties regarding dosing, duration, and patient selection

	to help inform decision-making (I.J.3.c.ii).
	• The Office of Clinical Pharmacology conducted 13 industry meetings from October 2019 to September 2020 related to nine applications.
	• FDA will develop its regulatory science and review expertise and capacity in MIDD approaches. This staff will support the highly specialized evaluation of model-based strategies and development efforts (I.J.3.a).
	• The Office of Clinical Pharmacology launched the inaugural MIDD Education Seminar series designed to provide staff with a foundational understanding of MIDD approaches and their application in drug development and clinical practice (I.J.3.a).
	  ○ Inaugural MIDD Seminar Series, The Role of Model-Informed Drug Discovery and Development in Enhancing Public Health-State of the Art, Innovation or Disruptions, Dr. Stephan Schmidt, University of Florida, March 4, 2020, 163 attendees
	  ○ Pharmacometrics for Clinical Therapeutics: An Opportunity to Democratize the Science and Tooling in Quantitative Pharmacology, Dr. Vijay Ivaturi, University of Maryland, July 20, 2020, 161 attendees
	• The Office of Clinical Pharmacology also provided continuing education (CE) for staff through MIDD Science Rounds, yearly update, September 9, 2020, 117 CE, 772 attendees (I.J.3.a).
	• 20 scientific papers were published by FDA staff on the topic of advancing MIDD.

I.J.4 Enhancing Capacity to Review Complex Innovative Designs	• FDA developed staff capacity to enable processes to facilitate the appropriate use of complex adaptive, Bayesian, and other novel clinical trial designs (I.J.4.a).
	• FDA conducted four CE lectures for the Complex Innovative Design (CID) Seminar Series.
	• FDA reviewed and selected proposals on a quarterly basis that were prioritized based on trial design features and therapeutic areas of unmet need (I.J.4.b.ii):
	  ○ Received five CID meeting requests in FY 2020
	  ○ Reviewed six CID meeting requests in FY 2020
	  ○ Granted two CID meeting requests in FY 2020
	• FDA presented trial designs developed through the program as case studies at four professional meetings (I.J.4.b.iii).
	• FDA published a final guidance for industry entitled *Adaptive Design Clinical Trials for Drugs and Biologics* in December 2019 (I.J.4.d).
	• FDA revised, per public comment, the draft guidance for industry entitled *Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products* (published September 2019).
	• FDA completed a draft CID meeting process standard operating procedure (SOP) (I.J.4.e).

I.J.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• FDA developed an Analysis Data Standards training and resources site to provide statisticians/analysts with guidance, training, and standard processes for an efficient and effective application review (I.J.5.e). • In December 2019, FDA developed a Standard Operating Procedure related to the CID meeting program. The pilot is ongoing, and FDA will continue to revise the SOP accordingly (I.J.5.e). • FDA developed training videos on various topics related to Clinical Data Interchange Standards Consortium data

	standards (ADaM and SDTM) (I.J.5.a). • FDA participated in the review and development of Therapeutic Area User Guides and technical specification documents. (I.J.5.b). • FDA presented at five public workshops and conferences sponsored by standards development organizations. (I.J.5.d).
I.J.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• FDA administers three qualification programs (biomarkers (BQP), clinical outcome assessments, and animal models for use under the animal rule). Although the enhancement focused on biomarkers, the three programs work together in the development of interrelated process and policy. • BQP experienced continued interest and growth, with over 60 projects under development. In FY 2020, the program reviewed 19 submissions (13 Letters of Intent and six Qualification Plans). • BQP continued its extensive public engagement with key stakeholder groups (i.e., the FNIH Biomarkers Consortium, the Critical Path Institute, and the Innovative Medicines Initiative). Staff were invited to speak at over 20 scientific conferences. • FDA published a final guidance for industry and FDA staff on the qualification process for drug development tools, on November 25, 2020 (see www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-process-drug-development-tools-guidance-industry-and-fda-staff) (I.J.6.d). • FDA is developing the Evidentiary Framework guidance and a Biomarker Qualification Analytics guidance (I.J.6.d).

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

Commitment Title	FY 2020 Accomplishments
I.K.1 Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System, and Integration into FDA Pharmacovigilance Activities	• Expand sources of data and enhance core capabilities (I.K.1.a) : FDA has been involved in the following actions: ○ Created a 5-year strategic plan to improve access to electronic health records (EHRs) and incorporate advanced analytics. ○ Added the National Patient-Centered Clinical Research Network (see pcornet.org/) and TriNetX (see trinetx.com/) to Sentinel; many other resources are available in the Sentinel Operations Center and the Innovation Center. ○ The Innovation Center is developing a new EHR-based distributed data network. ○ The Biologics Effectiveness and Safety Initiative (BEST) developed and operated by CBER (1) commenced the use of EHRs for post-market surveillance, (2) expanded BEST'saccess to multiple sources covering more than 50 million patients, (3) expanded BEST's access to administrative claims data sources (covering more than 200 million patients) with reduced data lag, (4) expanded BEST's access to on-demand, ad-hoc programming capabilities to

	accommodate simple and complex studies, (5) commenced the use of linked claims-EHR data sources covering more than 5 million patients to provide the capability for phenotype development and other activities. ○ BEST is utilizing new technologies such as machine learning and Natural Language Processing to extract more clinical information from EHR data sources to improve surveillance capabilities. ○ The BEST Initiative has built working relationships with scientific leaders in the field of pharmacoepidemiology and related fields, including participants from academia, industry, and other government agencies, to use their expertise as consultants and to utilize its resources to implement the most advanced and optimal methods and practices for the surveillance of medical products. • Enhance communication with sponsors and the public on methodologies for Sentinel queries (I.K.1.b): FDA completed the following actions: ○ Formalized the existing policies and processes for sponsor notifications in Manual of Policies and Procedures (MAPP) 6701.4 (see www.fda.gov/media/141216/download). ○ Continued to post all results, analytic packages, and analysis tools. ○ Hosted the Sentinel annual meeting with public trainings on tool use. ○ Developed a public website for the BEST Initiative (www.bestinitiative.org/) to post the initiative's work products for public view and access. • Facilitate public and sponsor access to Sentinel (I.K.1.c): FDA completed the following actions: ○ Shared the analytic center with Innovation in Medical Evidence Development and Surveillance (IMEDS). ○ Supported 15 IMEDS queries. (IMEDS benefits from FDA's routinely curated data network and incurs only marginal costs for queries.) ○ Held the annual Sentinel public workshops, with public training on tools (I.K.1.d). ○ Developed and posted sponsor notification MAPP 6701.4 (I.K.1.e) (see www.fda.gov/media/141216/download). • Facilitate integration of Sentinel into the human drug review program (I.K.1.f). FDA has been involved in the following actions: ○ Integrated into the approval letter the Active Risk Identification and Analysis (ARIA) sufficiency process, which is now integral to original and supplemental drug reviews. ○ Developed ARIA templates to improve the consistency of implementation. ○ Revised the postmarketing requirements industry guidance. ○ Developed a six-part, module-based, online training program to ensure that staff have a working knowledge of Sentinel, can identify when Sentinel can inform important regulatory questions, and are able to consistently participate in use of Sentinel to evaluate safety issues (I.K.1.g). ○ CBER revised its standard operating policy and

	procedure (SOPP) for developing postmarketing requirements and commitments (SOPP 8415) to formalize Sentinel sufficiency assessments in the drug review program (see https://www.fda.gov/media/90591/download). ○ CBER prepared a draft SOPP to formalize the manufacturer notification process before the protocol or final report of biologic products' safety and effectiveness studies are posted to the BEST website. This SOPP is in the final stage of being formally approved. • Analyze and report on FDA's use of Sentinel for regulatory purposes (I.K.1.h): FDA did the following: ○ Made ongoing updates to three web pages describing ongoing queries completed queries and regulatory impacts. ○ Made ongoing updates to the "Assessing ARIA's Ability to Evaluate a Safety Concern" web page containing ARIA sufficiency memos. (see www.sentinelinitiative.org/assessments/aria-overview/assessing-arias-ability-evaluate-safety-concern). ○ Reported on FDA's use of ARIA at four different public meetings. ○ Published lessons learned about ARIA sufficiency and next steps for improving distributed data networks in an article entitled *Using and improving distributed data networks to generate actionable evidence: the case of real-world outcomes in the Food and Drug Administration's Sentinel system (*see academic.oup.com/jamia/article/27/5/793/5819225).
I.K.2 Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs	• FDA published MAPP 4121.3 *Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal (NISS*) and launched the Lifecycle Safety Signal Tracker in CDER's Nexus to track NISS in April 2020 (I.K.2.a). • 600-plus CDER staff members have been trained on the NISS MAPP and on the Lifecycle Safety Signal Tracker (I.K.2.a). • FDA analyzed data and found 97.4 percent of application holders were notified, to the extent practicable, not less than 72 hours before the public posting of a safety notice under section 921 of the Food and Drug Administration Amendments Act of 2007 since Q3 (2019) and as described in MAPP 6700.9 and SOP 8420 (I.K.2.b.2).

Section II: Enhancing the Management of User Fee Resources

Commitment Title	FY 2020 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• FDA published an independent evaluation of the PDUFA resource capacity planning adjustment methodology to assess changes in the resource and capacity needs of the human drug review program (II.A.3). The report was published on April 6, 2020 (see www.fda.gov/media/136606/download).

II.B Financial Transparency and Efficiency	• FDA published the FY 2020 PDUFA Five-Year Financial Plan Update in March 2020 (see www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) (II.B.2). • FDA held a public meeting June 22, 2020, regarding this plan (see FDA's Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments web page at 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 2020 Accomplishments
III.A Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity	• The Agency implemented iBAPS as the position management system of record in 2018, and all funded vacancies are now captured and monitored in this central system. eClass was launched in 2018 as a central repository and position description (PD) management system. The Agency currently has over 2800 PDs within the classification tool that allows standardized PDs to be used and provides easy access to classified PDs to reduce the administrative burden.
III.B Augmentation of Hiring Staff Capacity and Capability	• Corporate recruiting has been deployed as an agency best practice by delivering the most qualified candidates for FDA mission-critical positions to the hiring manager. • The human resources contract support staff augmentation was awarded in 2017 and has continued each year thereafter. An additional inter-agency agreement with the Office of Personnel Management was awarded in 2019 to provide an additional human resources support mechanism for staff augmentation for the Agency.
III.C Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Program	• The Scientific Staffing Office was established in 2017. A scientist was appointed as the Associate Director for Scientific Staffing, and recruiters provide specialized placement and recruiting in FDA-related scientific fields. The fully staffed team was installed because of its expertise in recruiting in science and related fields. Through the team's affiliations and partnerships with academia and professional organizations, it is able to develop extensive resources to the Centers, as well as to professional job seekers in FDA-related scientific fields.
III.D Set Clear Goals for Human Drug Review Program Hiring	• FDA's FY 2020 hiring goal was for 58 FTEs, and 48 FTEs were onboarded (which was 83 percent of the FY 2020 hiring goal) (III.D.2). • FDA's hiring progress against this goal was posted on FDA's website (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data) (III.D.2). • During FY 2020, FDA additionally onboarded 16 FY 2019 FTEs, making progress towards FY 2019's outstanding hiring goal (which is at 93 percent of FY 2019 hiring goals) (III.D.2).

III.E Comprehensive and Continuous Assessment of Hiring and Retention	• FDA published the HR Interim Report on June 5, 2020, and held a public meeting on July 30, 2020 (see www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report) (III.E.2).

Section IV: Information Technology Goals

Goal	FY 2020 Accomplishments
IV.B Improve the Predictability and Consistency of PDUFA Electronic Submission Processes	• FDA maintained its targets for and its measure of the Electronic Submissions Gateway's (ESG's) overall availability. • FDA maintained target time frames (1) for the expected submission upload duration(s) and (2) between key milestones and notifications. • FDA maintained its submission upload status (e.g., successfully processed or rejected) to sender/designated contacts. • FDA maintained its ESG operational status on its public website. • FDA maintained its submission instructions to use in the event of an ESG service disruption. • Through quarterly meetings, FDA invited industry to provide feedback and participate in user acceptance testing and provided ample advance notification on systems and process changes. • FDA maintained metrics on its quarterly ESG performance and its monthly volume of submissions on its public website.
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 (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress) (IV.C.4) • FDA planned a public meeting entitled Electronic Submissions and Data Standards for April 22, 2020; however, the meeting was canceled due to COVID-19 (IV.C.2). • FDA updated the data standards and action plan on a quarterly basis (IV.C.5).

Additional PDUFA VI Review Program Reporting

Hiring and Placement of New PDUFA VI Staff at FDA

FY 2020'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 web page.[11] 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.

Rationale for PDUFA Program Changes

FDARA amended the FD&C Act to require the reporting of certain information relating to PDUFA program changes in the annual performance report starting with FY 2020.

Specifically, section 903(a) of FDARA added section 736(b)(4) to the FD&C Act, which requires the annual PDUFA performance report to include the following:

(A) data, analysis, and discussion of the changes in the number of full-time equivalents (FTEs) hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 and the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, the Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC);

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes; and

(C) for each of the CDER, CBER, ORA, and OC, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

The information below fulfills these reporting requirements.

A. Changes in the number of FTEs hired as agreed in the PDUFA VI Commitment Letter and the number of FTEs funded by budget authority at FDA by division within CDER, CBER, ORA, and OC

This section addresses the requirement to provide data, an analysis, and a discussion of the changes in the number of FTEs hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 and the number of FTEs funded by budget authority at the FDA by each division within CDER, CBER, ORA, and OC.

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

Changes in the number of FTEs hired as agreed upon in the PDUFA VI Commitment Letter

FDA is committed to hiring 230 FTEs from FY 2018 to FY 2022 as agreed upon in the PDUFA VI Commitment Letter. FDA has successfuly hired 193 FTEs of the 230 FTEs (84 percent) as of December 19, 2020. The data in the following table shows the total number of FTEs hired towards the FY 2019 and FY 2020 hiring targets as agreed upon in the PDUFA VI Commitment Letter and the change in the number of FTE hires from FY 2019 to FY 2020.

The hiring of FTEs decreased from FY 2019 to FY 2020 due to the hiring goal targets decreasing from 74 FTEs in FY 2019 to 58 FTEs in FY 2020. FDA has successfully fulfilled 96 percent of its hiring target for FY 2019 and 88 percent of its hiring target for FY 2020 as of December 19, 2020. With a total of 37 FTEs remaining to hire through FY 2022, FDA will continue hiring new FTEs to meet its commitments as agreed upon in the PDUFA VI Commitment Letter.

Number of FTEs Hired as Agreed in the PDUFA VI Commitment Letter

Center	FY 2019 Hires*	FY 2020 Hires*	Change in Number of FTE Hires
CDER	57	39	-18
CBER	8	7	-1
ORA	0	0	0
OC/Other	6	5	-1

* A *hire* is defined as someone who has been confirmed as on board by the date indicated in a full-time position at the noted Center. Although some hires are recruited from outside the Center/FDA, a hire can also be a current Center/FDA employee who is changing positions within the Agency.

Number of FTEs funded by budget authority at FDA by division within CDER, CBER, ORA, and OC

The data in the table below show the change from FY 2019 to FY 2020 in the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, ORA, and OC. This table reflects the number of FTEs funded by budget authority for the PDUFA VI program. For this table, *budget authority* refers to FDA's non-user fee annual appropriations. To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," the information in this table is broken down to the office level for the Centers, ORA, and OC. FDA uses a 2080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2020 and the previous year, FY 2019, are presented and compared to show the change in the number of FTEs over the last 2 fiscal years committed to PDUFA work. The number of FTEs funded by budget authority for FY 2019 are those FTEs as of September 30, 2019. The number of FTEs funded by budget authority for FY 2020 are those FTEs as of September 30, 2020.

FDA reported a decrease in overall FTEs in FY 2020 compared to FY 2019. The decrease in reported FTEs was attributable to the impacts of COVID-19-related efforts. Although FDA saw

a decrease in reported FTEs in FY 2020, FDA will continue to increase staff to address the PDUFA VI program workload.

Center and Office	Number of PDUFA Program FTEs Funded by Budget Authority*		Change in Number of PDUFA Program FTEs Funded by Budget Authority
	FY 2019	FY 2020	
CDER			
Office of Communications	6.7	0.4	-6.3
Office of Compliance	36.9	28.5	-8.4
Office of the Center Director	2.9	0.8	-2.1
Office of Executive Programs	12.8	0.4	-12.4
Office of Generic Drugs	2.2	3.3	1.1
Office of Medical Policy	18.4	10.1	-8.3
Office of Management	5.2	1.3	-3.9
Office of New Drugs	142.1	157.3	15.2
Office of Pharmaceutical Quality	106.1	68.2	-37.9
Office of Regulatory Policy	23.0	6.5	-16.5
Office of Surveillance and Epidemiology	33.0	5.0	-28.0
Office of Strategic Planning	6.6	4.4	-2.2
Office of Information Management and Technology	0.4	0.1	-0.3
Office of Translational Sciences	66.2	55.4	-10.8
Other Offices	3.7	2.7	-1.0
WCF	49.8	43.2	-6.6
CDRH			
Office of Product Evaluation and Quality	7.7	1.6	-6.1
Office of Management	0.0	0.1	0.1
Office of Science and Engineering Laboratories	0.6	0.3	-0.3
WCF	0.7	0.8	0.1
CBER			
Office of Biostatistics and Epidemiology	20.1	17.9	-2.2

Office of Blood Research and Review	4.9	4.6	-0.3
Office of Compliance and Biologics Quality	17.4	19.4	2.0
Office of Tissues and Advanced Therapies	55.7	57.1	1.4
Office of Vaccines Research and Review	85.7	84.8	-0.9
Office of Communication Outreach and Development	13.9	11.1	-2.8
Office of the Center Director	20.7	17.3	-3.4
Office of Management	23.5	19.2	-4.3
Other Offices	1.9	1.8	-0.1
WCF	0.7	33.1	32.4
OC			
OC Immediate Office	6.6	4.4	-2.2
Office of the Chief Counsel	15.1	14.9	-0.2
Office of the Chief Scientist	8.8	9.9	1.1
Office of Clinical Policy and Programs	8.1	22.0	13.9
Office of External Affairs	5.1	5.0	-0.1
Office of Health Informatics	1.3	1.7	0.4
Office of International Programs	3.1	0.1	-3.0
Office of Operations	7.8	8.8	1.0
Office of Policy Legislation and International Affairs	11.0	11.5	0.5
Office of Special Medical Programs	22.4	0.2	-22.2
WCF	18.3	17.1	-1.2
ORA			
Office of Pharmaceutical Quality Operations	89.1	89.9	0.8
WCF	8.8	8.6	-0.2

* This table includes PDUFA program FTE calculated through working capital fund (WCF) assessments for certain centrally administered services provided to CDER, CBER, ORA, and OC. Because many employees under OC and WCF do not report time, an average cost per OC and WCF FTE was applied to derive the number of PDUFA program FTEs funded by budget authority.

B. Changes in the fee revenue amounts and costs for the review process

Section 903(a) of FDARA amended the FD&C Act to require FDA to provide data, an analysis, and a discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes. Accordingly, the table below provides data for the PDUFA fee revenue amounts and process costs for FY 2019 and FY 2020, as well as the changes in these amounts from FY 2019 to FY 2020. Relevant information about the data provided is as follows:

- *Fee Revenue Amounts* represent FDA's net collection of human drug user fees.
- *Review Process Costs* represents FDA's total expenditure of the PDUFA program.
- Numbers are provided for both the most recent fiscal year (FY 2020) and the prior fiscal year (FY 2019). Although FDARA does not explicitly require this data, they do provide relevant context necessary to interpret the required information.

In FY 2020, FDA had net collections of $1.020 billion in prescription drug user fees, spent $1.075 billion in user fees for the human drug review process, and carried a cumulative balance of $194 million forward for future fiscal years. Detailed financial information for the PDUFA user fee program can be found in the FY 2020 PDUFA Financial Report.

The process for setting the annual target revenue is set forth in the statute. For FY 2020, the base revenue amount is $1,001,479,592. The FY 2020 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity palnning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional FTE positions to support PDUFA VI initiatives. The revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the FY 2020 amount is adjusted to provide for additional direct costs yielding a total adjusted fee revenue amount of $1,074,714,059, which funds PDUFA VI initiatives.

In FY 2020, PDUFA costs increased by approximately $41 million from FY 2019. The increase in PDUFA costs was attributed to growth in payroll and operating costs. The payroll cost increase is attributable to payroll cost inflation and salary increases due to Centers and Offices converting employees under CURES Authority pay bands.

Changes in the Fee Revenue Amounts and Review Process Costs

Fiscal Year	FY 2019	FY 2020	Change from FY 2019 to FY 2020
Net Fiscal Year Collections	$1,015,152,012	$1,020,229,037	1%
Review Process Costs	$1,430,338,888	$1,471,144,928	3%

C. Number of Employees for Whom Time Reporting Is Required

Section 903(a) of FDARA amended the FD&C Act to require FDA to provide—for CDER, CBER, ORA, and OC—the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, the table below provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2020.

These data reflect time reporting across all employees in each entity, rather than only those engaged in PDUFA program activities.

Time Reporting Requirements for FY 2020

Center	FTEs for Whom Time Reporting Is Required	FTEs for Whom Time Reporting Is Not Required
CDER	5,256	15
CBER	1,119	8
ORA	3,106	1,682
OC	483	1,479

Appendices

Appendix A: List of Approved Applications

This appendix includes detailed review histories of the NDA and BLA submissions approved under PDUFA VI in FY 2020. 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 the NDA and BLA submissions approved prior to FY 2020 can be found in the appendices of the earlier PDUFA performance reports.[12]

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 may 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 *tazemetostat* on page A-3 was received on May 23, 2019, and had an 8-month review goal date of January 23, 2020, 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 in This Appendix

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[13]

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

FY 2020 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 2020							
TUKYSA (tucatinib)	SEATTLE GENETICS Inc.	Y	First	3.9	AP	3.9	Y♦
TABRECTA (capmatinib)	NOVARTIS PHARMACEUTICAL Corp.	Y	First	4.9	AP	4.9	Y♦
QINLOCK (ripretinib)	DECIPHERA PHARMACEUTICALS LLC	Y	First	5.1	AP	5.1	Y♦
RETEVMO (selpercatinib)	LOXO ONCOLOGY Inc.	Y	First	5.2	AP	5.2	Y♦
GAVRETO (pralsetinib)	BLUEPRINT MEDICINES Corp.	Y	First	5.4	AP	5.4	Y♦
JELMYTO (mitomycin)	UROGEN PHARMA Ltd.	N	First	5.9	AP	5.9	Y
XYWAV (calcium, magnesium, potassium, and sodium oxybates)	JAZZ PHARMACEUTICALS Inc.	N	First	6.0	AP	6.0	Y
TAZVERIK (tazemetostat)	EPIZYME Inc.	N	First	6.0	AP	6.0	Y
ZEPZELCA (lurbinectedin)	JAZZ PHARMACEUTICALS IRELAND Ltd.	Y	First	6.0	AP	6.0	Y♦
TIVICAY PD (dolutegravir)	VIIV HEALTHCARE Co.	N	First	6.0	AP	6.0	Y
XELJANZ (tofacitinib)	PFIZER Inc.	N	First	6.0	AP	6.0	Y
ONUREG (azacitidine)	CELGENE Corp.	N	First	6.0	AP	6.0	Y
TEPEZZA (teprotumumab-TRBW)	HORIZON THERAPEUTICS IRELAND DAC	Y	First	6.5	AP	6.5	Y♦
INQOVI (decitabine and cedazuridine)	OTSUKA PHARMACEUTICAL Co. Ltd.	Y	First	6.9	AP	6.9	Y♦
RUKOBIA (fostemsavir)	VIIV HEALTHCARE Co.	Y	First	7.0	AP	7.0	Y♦
MONJUVI (tafasitamab-CXIX)	MORPHOSYS US Inc.	Y	First	7.0	AP	7.0	Y♦
TECARTUS (brexucabtagene autoleucel)	KITE PHARMA Inc.	Y	First	7.4	AP	7.4	Y♦
VILTEPSO (viltolarsen)	NIPPON SHINYAKU Co. Ltd.	Y	First	8.0	AP	8.0	Y♦
LAMPIT (nifurtimox)	BAYER HEALTHCARE PHARMACEUTICALS Inc.	Y	First	8.0	AP	8.0	Y♦
DETECTNET (copper cu 64 dotatate injection)	RADIOMEDIX Inc.	Y	First	8.0	AP	8.0	Y♦
BLENREP (belantamab mafodotin-BLMF)	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT Ltd. ENGLAND	Y	First	8.0	AP	8.0	Y♦
Submitted in FY 2019							
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)	VERTEX PHARMACEUTICALS Inc.	Y	First	3.1	AP	3.1	Y♦

[13] Under PDUFA VI, a major amendment can be received any time 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.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
ENHERTU (fam-trastuzumab deruxtecan- NXKI)	DAIICHI SANKYO Inc.	Y	First	3.7	AP	3.7	Y♦
BRUKINSA (zanubrutinib)	BEIGENE USA Inc.	Y	First	4.6	AP	4.6	Y♦
OXBRYTA (voxelotor)	GLOBAL BLOOD THERAPEUTICS Inc.	Y	First	5.0	AP	5.0	Y♦
PADCEV (enfortumab vedotin)	ASTELLAS PHARMA US Inc.	Y	First	5.1	AP	5.1	Y♦
ERVEBO (Ebola Zaire Vaccine, Live)	MERCK SHARP & DOHME Corp.	Y	First	5.1	AP	5.1	Y♦
GIVLAARI (givosiran)	ALNYLAM PHARMACEUTICALS Inc.	Y	First	5.6	AP	5.6	Y♦
potassium phosphates	FRESENIUS KABI USA LLC	N	First	6.0	AP	6.0	Y
TALICIA (omeprazole magnesium, amoxicillin and rifabutin)	REDHILL BIOPHARMA Ltd.	N	First	6.0	AP	6.0	Y
ADAKVEO (crizanlizumab-TMCA)	NOVARTIS PHARMACEUTICALS CORPORATION	Y	First	6.0	AP	6.0	Y♦
DIFICID (fidaxomicin)	CUBIST PHARMACEUTICALS LLC	N	First	6.1	AP	6.1	Y
PEMAZYRE (pemigatinib)	INCYTE Corp.	Y	First	6.6	AP	6.6	Y♦
AYVAKIT (avapritinib)	BLUEPRINT MEDICINES Corp.	Y	First	6.9	AP	6.9	Y♦
KOSELUGO (selumetinib)	ASTRAZENECA PHARMACEUTICALS LP.	Y	First	6.9	AP	6.9	Y♦
REBLOZYL (luspatercept – AAMT)	CELGENE CORPORATION	Y	First	7.2	AP	7.2	Y♦
TISSUEBLUE (brilliant blue g ophthalmic solution)	DUTCH OPHTHALMIC RESEARCH CENTER INTERNATIONAL BV	Y	First	7.7	AP	7.7	Y♦
TAUVID (flortaucipir f18 injection)	AVID RADIOPHARMACEUTICALS Inc.	Y	First	7.9	AP	7.9	Y♦
BEOVU (brolucizumab-DBLL)	NOVARTIS PHARMACEUTICALS CORPORATION	Y	First	8.0	AP	8.0	Y♦
Artesunate	AMIVAS LLC	Y	First	8.0	AP	8.0	Y♦
Artesunate	LA JOLLA PHARMACEUTICAL Co.	N[14]	First	8.0	TA	8.0	Y♦
Tazemetostat	EPIZYME Inc.	Y	First	8.1	AP	8.1	Y♦
NURTEC ODT (rimegepant)	BIOHAVEN PHARMACEUTICAL HOLDING Co. Ltd.	Y	First	8.1	AP	8.1	Y♦
ZX008 (fenfluramine)	ZOGENIX Inc.	N	First	9.0	AP	9.0	Y♯
NOURESS (cysteine hydrochloride injection)	EXELA PHARMA SCIENCES LLC	N	First	9.0	AP	9.0	Y♯

[14] Non-NME NDA reviewed under the NME program. At time of receipt, the active ingredient artesunate had never been approved in the United States, allowing for NME designation; however, at time of approval, artesunate 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
EVRYSDI (risdiplam)	GENENTECH Inc.	Y	First	10.5	AP	10.5	Y♯♦
FETROJA (cefiderocol)	SHIONOGI Inc.	Y	First	11.0	AP	11.0	Y♯♦
SCENESSE (afamelanotide)	CLINUVEL Inc.	Y	First	11.0	AP	11.0	Y♯♦
VYONDYS 53 (golodirsen)	SAREPTA THERAPEUTICS Inc.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	3.3		11.3	
			Second	0.5	AP	11.8	Y▲
TRODELVY (sacituzumab govitecan-HZIY)	IMMUNOMEDICS Inc.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	10.5		18.5	
			Second	4.7	AP	23.2	YΔ
Submitted in FY 2017							
VESICARE LS (solifenacin succinate)	ASTELLAS PHARMA US Inc.	N	First	6.0	CR	6.0	Y
			Sponsor	27.0		33.0	
			Second	6.0	AP	39.0	YΔ

FY 2020 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 2020							
atropine sulfate	ACCORD HEALTHCARE Inc.	N	First	6.0	AP	6.0	Y
PHESGO (pertuzumab, trastuzumab, and hyaluronidase-ZZXF)	GENENTECH Inc.	N	First	6.4	AP	6.4	Y
XTANDI (enzalutamide)	ASTELLAS PHARMA US Inc.	N	First	9.2	AP	9.2	Y
PULMOTECH MAA (kit for the preparation of technetium tc99m albumin aggregated injection)	CIS BIO INTERNATIONAL	N	First	9.3	AP	9.3	Y
DARZALEX FASPRO (daratumumab and hyaluronidase-FIHJ)	JANSSEN BIOTECH Inc.	N	First	9.7	AP	9.7	Y
ALKINDI SPRINKLE (hydrocortisone)	DIURNAL Ltd.	N	First	10.0	AP	10.0	Y
LYUMJEV (insulin lispro-AABC)	ELI LILLY AND COMPANY	N	First	10.0	AP	10.0	Y
Methotrexate	ACCORD HEALTHCARE Inc.	N	First	10.0	AP	10.0	Y
QWO (collagenase clostridium histolyticum-AAES)	ENDO GLOBAL AESTHETICS Ltd.	N	First	10.0	AP	10.0	Y
QDOLO (tramadol hydrochloride)	ATHENA BIOSCIENCE LLC	N	First	10.1	AP	10.1	Y
SARCLISA (isatuximab-IRFC)	SANOFI-AVENTIS US LLC	Y	First	10.1	AP	10.1	Y♦
ENSPRYNG (satralizumab-MWGE)	GENENTECH Inc.	Y	First	12.0	AP	12.0	Y♦
SOGROYA (somapacitan-BECO)	NOVO NORDISK Inc.	Y	First	12.0	AP	12.0	Y♦
UPLIZNA (inebilizumab-CDON)	VIELA BIO	Y	First	12.0	AP	12.0	Y♦
VYEPTI (eptinezumab-JJMR)	LUNDBECK SEATTLE BIOPHARMACEUTICALS Inc.	Y	First	12.0	AP	12.0	Y♦
SEMGLEE (insulin glargine injection)	MYLAN PHARMACEUTICALS Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	9.4		19.4	
			Second	6.0	CR	25.4	Y△
			Sponsor	3.6		29.0	
			Third	5.9	AP	34.8	Y△
Submitted in FY 2019							
IBRANCE (palbociclib)	PFIZER Inc.	N	First	9.0	AP	9.0	Y
PROCYSBI (cysteamine bitartrate)	HORIZON PHARMA USA Inc.	N	First	9.0	AP	9.0	Y
dolutegravir, lamivudine, and tenofovir disoproxil fumarate	CELLTRION Inc.	N	First	9.6	TA	9.6	Y◊
EXSERVAN (riluzole)	AQUESTIVE THERAPEUTICS	N	First	9.7	AP	9.7	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
CONJUPRI (levamlodipine)	CSPC OUYI PHARMACEUTICAL CO Ltd.	N	First	9.7	AP	9.7	Y
UPNEEQ (oxymetazoline hydrochloride)	RVL PHARMACEUTICALS Inc.	N	First	9.8	AP	9.8	Y
MONOFERRIC (ferric derisomaltose)	PHARMACOSMOS AS	N	First	9.9	AP	9.9	Y
Tralement	AMERICAN REGENT Inc.	N	First	9.9	AP	9.9	Y
QUZYTTIR (cetirizine)	JDP THERAPEUTICS LLC	N	First	9.9	AP	9.9	Y
ARALZO (tazarotene)	BAUSCH HEALTH AMERICAS Inc.	N	First	9.9	AP	9.9	Y
BONSITY (teriparatide)	ALVOGEN MALTA OPERATIONS Ltd.	N	First	9.9	AP	9.9	Y
SECUADO (asenapine)	HISAMITSU PHARMACEUTICAL Co. Inc.	N	First	9.9	AP	9.9	Y
AMZEEQ (minocycline)	FOAMIX PHARMACEUTICALS Inc.	N	First	9.9	AP	9.9	Y
ZILXI (minocycline)	FOAMIX PHARMACEUTICALS Inc.	N	First	9.9	AP	9.9	Y
DURYSTA (bimatoprost)	ALLERGAN Inc.	N	First	10.0	AP	10.0	Y
ELYXYB (celecoxib)	DR REDDYS LABORATORIES Ltd.	N	First	10.0	AP	10.0	Y
FERRIPROX (deferiprone)	CHIESI USA Inc.	N	First	10.0	AP	10.0	Y
AVNU (ferric pyrophosphate citrate)	ROCKWELL MEDICAL Inc.	N	First	10.0	AP	10.0	Y
BIORPHEN (phenylephrine hydrochloride)	ETON PHARMACEUTICALS	N	First	10.0	AP	10.0	Y
FENSOLVI (leuprolide acetate)	TOLMAR INTERNATIONAL Ltd.	N	First	10.0	AP	10.0	Y
ORIAHNN (elagolix, estradiol and norethindrone acetate capsules; elagolix capsules)	ABBVIE Inc.	N	First	10.0	AP	10.0	Y
WYNZORA (calcipotriene and betamethasone dipropionate)	MC2 THERAPEUTICS Ltd.	N	First	10.0	AP	10.0	Y
IMPEKLO (clobetasol propionate)	MYLAN PHARMACEUTICALS Inc.	N	First	10.0	AP	10.0	Y
EMERPHED (ephedrine sulfate)	NEXUS PHARMACEUTICALS Inc.	N	First	10.0	AP	10.0	Y
levonorgestrel/ethinyl estradiol	EXELTIS USA Inc.	N	First	10.1	AP	10.1	Y
TRIJARDY XR (empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets)	BOEHRINGER INGELHEIM PHARMACEUTICALS Inc.	N	First	10.1	AP	10.1	Y
BYNEFEZIA PEN (octreotide acetate)	SUN PHARMACEUTICAL INDUSTRIES Ltd.	N	First	10.1	AP	10.1	Y
VUMERITY (diroximel fumarate)	BIOGEN	N	First	9.9	TA	9.9	Y
			Sponsor	0.0		9.9	
			Second	0.6	AP	10.5	Y▲

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
DOJOLVI (triheptanoin)	ULTRAGENYX PHARMACEUTICAL Inc.	Y	First	11.0	AP	11.0	Y♦
DAYVIGO (lemborexant)	EISAI Inc.	Y	First	11.8	AP	11.8	Y♦
UBRELVY (ubrogepant)	ALLERGAN SALES LLC	Y	First	11.9	AP	11.9	Y♦
MENQUADFI(Meningococcal (Groups A, C, Y, W) Conjugate Vaccine)	SANOFI PASTEUR Inc.	Y	First	11.9	AP	11.9	Y♦
REYVOW (lasmiditan)	ELI LILLY AND Co.	Y	First	12.0	AP	12.0	Y♦
AKLIEF (trifarotene)	GALDERMA LABORATORIES LP.	Y	First	12.0	AP	12.0	Y♦
NEXLETOL (bempedoic acid)	ESPERION THERAPEUTICS Inc.	Y	First	12.0	AP	12.0	Y♦
NEXLIZET (bempedoic acid/ezetimibe)	ESPERION THERAPEUTICS Inc.	N[15]	First	12.0	AP	12.0	Y♦
ONGENTYS (opicapone)	NEUROCRINE BIOSCIENCES Inc.	Y	First	12.0	AP	12.0	Y♦
ISTURISA (osilodrostat)	RECORDATI RARE DISEASES Inc.	Y	First	12.0	AP	12.0	Y♦
XCOPRI (cenobamate)	SK LIFE SCIENCE Inc.	Y	First	12.0	AP	12.0	Y♦
WINLEVI (clascoterone)	CASSIOPEA SPA	Y	First	12.0	AP	12.0	Y♦
AUDENZ (Influenza A (H5N1) Monovalent Vaccine, Adjuvanted)	SEQIRUS Inc.	Y	First	12.0	AP	12.0	Y♦
ZEPOSIA (ozanimod)	CELGENE INTERNATIONAL II SARL	Y	First	12.1	AP	12.1	Y♦
REDITREX (methotrexate)	CUMBERLAND PHARMACEUTICALS Inc.	N	First	12.7	AP	12.7	Y♯
ADVIL DUAL ACTION WITH ACETAMINOPHEN (ibuprofen/acetaminophen)	GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS US LLC	N	First	12.9	AP	12.9	Y♯
VALTOCO (diazepam)	NEURELIS Inc.	N	First	13.0	AP	13.0	Y♯
EXEM FOAM (air polymer-type A)	GISKIT BV	Y	First	13.0	AP	13.0	Y♯♦
CERIANNA (fluoroestradiol f18)	ZIONEXA US Corp.	Y	First	14.7	AP	14.7	Y♯♦
BYFAVO (remimazolam)	ACACIA PHARMA Ltd.	Y	First	14.9	AP	14.9	Y♯♦
vasopressin	AMERICAN REGENT Inc.	N	First	10.0	TA	10.0	Y
			Sponsor	4.2		14.2	
			Second	2.0	AP	16.2	Y▲
CYSTADROPS	RECORDATI RARE	N	First	10.1	CR	10.1	Y

[15] The applicant submitted two NDAs for the same new moiety (bempedoic acid), but one of the NDAs is in combination with a currently marketed drug (bempedoic acid vs. bempedoic acid and ezetimibe). Only one NDA retains the NME designation upon approval; in this case, the NDA for the bempedoic acid alone retained the NME designation.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
(cysteamine)	DISEASES Inc.		Sponsor	1.0		11.1	
			Second	5.7	AP	16.8	Y△
BREZTRI AEROSPHERE (budesonide, glycopyrrolate, and formoterol fumarate)	ASTRAZENECA AB	N	First	10.0	CR	10.0	Y
			Sponsor	3.8		13.8	
			Second	6.0	AP	19.8	Y△
Submitted in FY 2018							
HEMADY (dexamethasone)	DEXCEL PHARMA TECHNOLOGIES Ltd.	N	First	12.9	AP	12.9	Y♯
ABSORICA LD (isotretinoin)	SUN PHARMACEUTICAL INDUSTRIES Ltd.	N	First	14.6	AP	14.6	N♯
PIZENSY (lactitol)	BRAINTREE LABORATORIES Inc.	Y	First	14.7	AP	14.7	Y♯♦
CAPLYTA (lumateperone)	INTRA-CELLULAR THERAPIES Inc.	Y	First	14.8	AP	14.8	Y♯♦
fluorescein sodium and benoxinate hydrochloride	BAUSCH HEALTH IRELAND Ltd.	N	First	9.8	CR	9.8	Y
			Sponsor	4.9		14.7	
			Second	2.8	AP	17.5	Y△
bendamustine hydrochloride	SLAYBACK PHARMA LLC	N	First	9.5	CR	9.5	Y
			Sponsor	0.5		10.0	
			Second	2.5	CR	12.5	Y△
			Sponsor	5.0		17.4	
			Third	4.6	TA	22.0	Y△
cyclophosphamide	INGENUS PHARMACEUTICALS LLC	N	First	9.7	CR	9.7	Y
			Sponsor	0.2		9.9	
			Second	5.7	CR	15.6	Y△
			Sponsor	0.7		16.3	
			Third	5.8	AP	22.1	Y△
GIMOTI (metoclopramide)	EVOKE PHARMA Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	8.6		18.6	
			Second	6.0	AP	24.6	Y△
KYNMOBI (apomorphine)	SUNOVION PHARMACEUTICALS Inc.	N	First	10.1	CR	10.1	Y
			Sponsor	9.7		19.8	
			Second	6.0	AP	25.8	Y△
BAFIERTAM (monomethyl fumarate)	BANNER LIFE SCIENCES LLC	N	First	9.9	TA	9.9	Y
			Sponsor	13.8		23.7	
			Second	3.6	AP	27.3	Y△
BARHEMSYS (amisulpride)	ACACIA PHARMA Ltd.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	1.0		13.0	
			Second	5.9	CR	18.9	Y△
			Sponsor	3.8		22.7	
			Third	6.1	AP	28.8	Y△
XARACOLL (bupivacaine HCl)	INNOCOLL PHARMACEUTICALS	N	First	9.9	CR	9.9	Y
			Sponsor	14.9		24.8	

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Second	6.1	AP	30.9	N△
OLINVYK (oliceridine)	TREVENA Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	15.2		27.2	
			Second	6.0	AP	33.2	Y△
Submitted in FY 2017							
NUMBRINO (cocaine hydrochloride)	CODY LABORATORIES Inc. A WHOLLY OWNED SUBSIDIARY OF LANNETT Co. Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	11.0		20.9	
			Second	6.7	AP	27.6	N△
ANJESO (meloxicam)	BAUDAX BIO Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	4.1		14.0	
			Second	5.9	CR	19.9	Y△
			Sponsor	9.0		28.9	
			Third	2.1	AP	31.0	Y▲
ABBOJECT SYRINGE (epinephrine)	HOSPIRA Inc.	N	First	9.9	TA	9.9	Y
			Sponsor	21.2		31.1	
			Second	2.0	AP	33.1	Y▲
PEMFEXY (pemetrexed)	EAGLE PHARMACEUTICALS Inc.	N	First	9.9	TA	9.9	Y
			Sponsor	21.4		31.3	
			Second	2.0	TA	33.3	Y▲
			Sponsor	2.0		35.3	
			Third	2.0	AP	37.3	Y▲
SEVENFACT (Coagulation Factor VIIa (Recombinant))	LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES S.A.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	23.9		35.9	
			Second	5.7	AP	41.6	Y△
Pemetrexed	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA Inc.	N	First	9.1	CR	9.1	Y
			Sponsor	3.9		13.0	
			Second	5.0	CR	18.0	Y△
			Sponsor	19.9		37.9	
			Third	6.0	AP	43.9	Y△
Submitted in FY 2016							
Pemetrexed	DR REDDYS LABORATORIES Ltd.	N	First	10.0	CR	10.0	Y
			Sponsor	9.4		19.4	
			Second	5.8	CR	25.2	Y△
			Sponsor	6.8		32.0	
			Third	6.0	CR	38.0	Y△
			Sponsor	2.0		40.0	
			Fourth	5.8	CR	45.8	Y△
			Sponsor	3.3		49.1	
			Fifth	6.0	TA	55.1	Y△
Submitted in FY 2015							

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
romidepsin	TEVA PHARMACEUTICALS USA Inc.	N	First	9.5	CR	9.5	Y
			Sponsor	6.9		16.4	
			Second	5.1	CR	21.5	Y△
			Sponsor	23.9		45.4	
			Third	5.2	CR	50.6	Y△
			Sponsor	0.6		51.2	
			Fourth	3.7	AP	54.9	Y△
XEGLYZE (abametapir)	DR REDDYS LABORATORIES SA	Y	First	11.6	CR	11.6	Y♦
			Sponsor	38.4		50.0	
			Second	8.4	AP	58.4	Y♯△
PHEXXI (lactic acid, citric acid, and potassium bitartrate)	EVOFEM Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	42.9		52.8	
			Second	5.9	AP	58.7	Y△
MYCAPSSA (octreotide)	CHIASMA Inc.	N	First	10.1	CR	10.1	Y
			Sponsor	44.4		54.5	
			Second	6.0	AP	60.5	Y△
Submitted in FY 2014							
Cabazitaxel	FRESENIUS KABI USA LLC	N	First	10.0	CR	10.0	Y
			Sponsor	46.8		56.8	
			Second	6.0	TA	62.8	Y△
Bortezomib	DR REDDYS LABORATORIES Ltd.	N	First	9.5	CR	9.5	Y
			Sponsor	11.2		20.7	
			Second	5.4	CR	26.0	Y△
			Sponsor	36.0		62.0	
			Third	5.1	AP	67.1	Y△
Submitted in FY 2013							
[F-18] FLUORODOPA (fdopa)	FEINSTEIN INSTITUTE MEDICAL RESEARCH	Y	First	12.0	CR	12.0	Y♦
			Sponsor	25.8		37.8	
			Second	9.1	CR	46.9	Y♯△
			Sponsor	30.8		77.7	
			Third	6.0	AP	83.7	Y△
Submitted in FY 2012							
GENOSYL (nitric oxide)	VERO BIOTECH	N	First	9.9	CR	9.9	Y
			Sponsor	60.9		70.8	
			Second	6.1	CR	76.9	Y△
			Sponsor	4.9		81.8	
			Third	6.0	AP	87.8	Y△
TWIRLA (levonorgestrel and ethinyl estradiol)	AGILE THERAPEUTICS Inc.	N	First	10.1	CR	10.1	Y
			Sponsor	52.4		62.5	
			Second	5.9	CR	68.4	Y△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Sponsor	16.8		85.2	
			Third	9.0	AP	94.2	Y♯△
Submitted in FY 2010							
MILPROSA (progesterone)	FERRING PHARMACEUTICALS Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	59.9		59.9	
			Second	9.0	CR	68.9	Y♯△
			Sponsor	35.2		104.1	
			Third	6.0	AP	110.0	Y△

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 2020 for various application types and review designations broken out by review division. This reporting for PDUFA VI is required under section 736B(a) of the FD&C Act.

Original Applications Filed in FY 2020 by Review Division/Office

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CDER Review Divisions					
Division of Anesthesiology, Addition Medicine, and Pain Medicine	0	7	0	1	1
Division of Anti-Infectives	3	3	0	0	1
Division of Antivirals	6	6	2	0	0
Division of Cardiology and Nephrology	2	9	0	0	1
Division of Dermatology and Dentistry	2	2	0	4	1
Division of Diabetes, Lipid Disorders, and Obesity	1	3	1	0	0
Division of Gastroenterology	0	1	0	0	0
Division of General Endocrinology	0	3	0	1	1
Division of Hematologic Malignancies I	2	1	0	0	1
Division of Hematologic Malignancies II	2	2	2	0	1
Division of Hepatology and Nutrition	0	0	0	0	0
Division of Imaging and Radiation Medicine	1	1	0	0	2
Division of Neurology I	3	0	1	0	1
Division of Neurology II	0	4	0	0	0
Division of Non-Malignant Hematology	3	1	1	2	1
Division of Non-Prescription Drugs I	0	2	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0	0
Division of Non-Prescription Drugs III	0	0	0	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Oncology I	4	4	1	2	0
Division of Oncology II	6	4	2	0	1
Division of Oncology III	1	1	0	0	1
Division of Ophthalmology	0	1	0	1	0
Division of Psychiatry	1	7	0	0	0
Division of Pulmonology, Allergy, and Critical Care	0	1	0	0	0
Division of Rare Diseases and Medical Genetics	3	1	1	0	1
Division of Rheumatology and Transplant Medicine	3	2	0	1	0
Division of Urology, Obstetrics, and Gynecology	0	4	0	0	1
CDER Totals	*43*	*70*	*11*	*12*	*15*
CBER Review Offices					
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	0	0	6	1	0
Office of Vaccines Research and Review	0	0	0	0	0
CBER Totals	*0*	*0*	*6*	*1*	*0*
FDA Totals	**43**	**70**	**17**	**13**	**15**

Efficacy Supplements Filed in FY 2020 by Review Division/Office

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Review Divisions			
Division of Anesthesiology, Addition Medicine, and Pain Medicine	0	8	1
Division of Anti-Infectives	3	11	1
Division of Antivirals	4	18	0
Division of Cardiology and Nephrology	2	7	2
Division of Dermatology and Dentistry	1	8	0
Division of Diabetes, Lipid Disorders, and Obesity	3	7	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Gastroenterology	0	2	0
Division of General Endocrinology	1	2	0
Division of Hematologic Malignancies I	7	0	0
Division of Hematologic Malignancies II	6	7	1
Division of Hepatology and Nutrition	0	1	0
Division of Imaging and Radiation Medicine	1	3	0
Division of Neurology I	1	7	1
Division of Neurology II	3	11	1
Division of Non-Malignant Hematology	3	6	0
Division of Non-Prescription Drugs I	0	2	0
Division of Non-Prescription Drugs II	0	2	0
Division of Non-Prescription Drugs III	0	0	0
Division of Oncology I	16	10	1
Division of Oncology II	10	7	2
Division of Oncology III	25	7	0
Division of Ophthalmology	0	0	0
Division of Psychiatry	2	7	0
Division of Pulmonology, Allergy, and Critical Care	6	1	1
Division of Rare Diseases and Medical Genetics	0	6	0
Division of Rheumatology and Transplant Medicine	7	10	0
Division of Urology, Obstetrics, and Gynecology	0	5	0
CDER Totals	*101*	*155*	*11*
CBER Review Offices			
Office of Blood Research and Review	0	0	0
Office of Tissues and Advanced Therapies	2	14	0
Office of Vaccines Research and Review	2	11	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CBER Totals	*4*	*25*	*0*
FDA Totals	**105**	**180**	**11**

Submissions with Special Designations Filed in FY 2020 by Review Division/Office

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
CDER Review Divisions				
Division of Anesthesiology, Addition Medicine, and Pain Medicine	0	1	1	0
Division of Anti-Infectives	0	2	3	2
Division of Antivirals	0	7	2	1
Division of Cardiology and Nephrology	0	1	2	6
Division of Dermatology and Dentistry	1	1	2	4
Division of Diabetes, Lipid Disorders, and Obesity	0	0	2	0
Division of Gastroenterology	0	0	0	1
Division of General Endocrinology	0	0	3	1
Division of Hematologic Malignancies I	0	0	4	6
Division of Hematologic Malignancies II	4	1	6	1
Division of Hepatology and Nutrition	0	0	0	2
Division of Imaging and Radiation Medicine	0	1	1	1
Division of Neurology I	2	3	4	0
Division of Neurology II	0	1	1	0
Division of Non-Malignant Hematology	0	0	3	4
Division of Non-Prescription Drugs I	0	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0
Division of Non-Prescription Drugs III	0	0	0	0
Division of Oncology I	2	3	3	7
Division of Oncology II	4	1	7	10

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
Division of Oncology III	1	2	2	6
Division of Ophthalmology	0	0	1	0
Division of Psychiatry	0	0	1	3
Division of Pulmonology, Allergy, and Critical Care	0	1	1	4
Division of Rare Diseases and Medical Genetics	1	3	4	2
Division of Rheumatology and Transplant Medicine	0	1	1	3
Division of Urology, Obstetrics, and Gynecology	0	0	0	0
CDER Totals	*15*	*29*	*54*	*64*
CBER Review Offices				
Office of Blood Research and Review	0	0	0	0
Office of Tissues and Advanced Therapies	0	1	6	4
Office of Vaccines Research and Review	0	0	0	0
CBER Totals	*0*	*1*	*6*	*4*
FDA Totals	**15**	**30**	**60**	**68**

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2020. BT designation is granted based on indication, and, therefore, one submission may have more than one BT designation granted.

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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. In addition, FDARA (specifically, section 904) requires the issuance of corrective action reports.

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 2020. Data represent all the original NDA and BLA approvals that occurred during FY 2020, 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 when 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 2020.[16]

[16] 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	36	36	0	**100%**
First Cycle Standard NMEs & BLAs	10 months of filing date	28	28	0	**100%**
First Cycle Priority non-NME NDAs	6 months	12	12	0	**100%**
First Cycle Standard non-NME NDAs	10 months	43	42	1	**98%**
Class 1 Resubmissions	2 months	2	2	0	**100%**
Class 2 Resubmissions	6 months	27	25	2	**93%**
Total		**148**	**145**	**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.[17]

For 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.

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

The table below represents FDA's FY 2019 updated performance.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
PDUFA FY 2019 Hiring Web Posting Quarter 4	10/14/2019	N	10/18/2019	FDARA Hiring Data (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)

The table below represents FDA's FY 2020 performance.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
FY 2020 PDUFA Hiring Goals	10/15/2019	N	N/A	FDA's FY 2020 hiring goal was for 58 FTEs, and 48 FTEs were onboarded (83 percent of the FY 2020 hiring goal)
CY 2019 FDA Data Standards Action Plan - Quarter 4	12/31/2019	Y	11/6/2019	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board) FDA Resources for Data Standards (see www.fda.gov/industry/fda-resources-data-standards)
PDUFA FY 2020 Hiring Web Posting - Quarter 1	1/14/2020	N	1/17/2020	FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
Innovative Drug Approval Report on Rare Diseases Program	1/30/2020	Y	1/6/2020	Innovation in New Drug Approvals of 2019 Advances Patient Care Across a Broad Range of Diseases (see www.fda.gov/news-events/fda-voices/innovation-new-drug-approvals-2019-advances-patient-care-across-broad-range-diseases)
CY 2020 FDA Data Standards Action Plan - Quarter 1	3/30/2020	Y	2/12/2020	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board) FDA Resources for Data Standards (see www.fda.gov/industry/fda-resources-data-standards)
2020 Annual Update to 5-Year Plan	3/31/2020	Y	3/31/2020	User Fee Five-Year Financial Plans (see www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans)
Interim Assessment for Hiring and Retention	3/31/2020	N	6/5/2020	FDA Interim Hiring and Retention Assessment Report (see www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report)
PDUFA FY 2020 Hiring Web Posting - Quarter 3	4/14/2020	Y	4/13/2020	FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
FY 2020 Financial Public Meetings	6/30/2020	Y	6/22/2020	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (see www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and)
Interim Public Meeting for Hiring and Retention	6/30/2020	N	7/30/2020	FDA PDUFA Hiring and Retention Interim Assessment Public Meeting (see www.fda.gov/drugs/news-events-human-drugs/fda-pdufa-hiring-and-retention-interim-assessment-public-meeting-07302020-07302020)
CY 2020 FDA Data Standards Action Plan - Quarter 2	6/30/2020	Y	4/26/2020	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board) FDA Resources for Data Standards (see www.fda.gov/industry/fda-resources-data-standards)
PDUFA FY 2020 Hiring Web Posting - Quarter 4	7/14/2020	Y	7/6/2020	FDARA Hiring Data (see www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
Communication During Drug Development Independent Assessment	9/30/2020	Y	6/17/2020	Assessment of FDA-Sponsor Communication Practices During the IND Stage of Drug/Biologic Development (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-assessment-fda-sponsor-communication-practices-during-ind-stage-drugbiologic-development)
Combination Products Independent Assessment	9/30/2020	Y	8/28/2020	Assessment of Combination Product Review Practices in PDUFA VI (see www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-assessment-combination-product-review-practices-pdufa-vi)
Drafting PFDD Guidance - Fit-for-Purpose COAs	9/30/2020	N	N/A	
Report on Enhancing Patient Engagement in Trials	9/30/2020	Y	3/18/2019	Enhancing the Incorporation of Patient Perspectives in Clinical Trials: Meeting Summary (see www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/meeting_summary_-_enhancing_incorporation_of_patient_perspectives_-_final.pdf)
BRA Draft Guidance	9/30/2020	N	N/A	FDA aims to publish the guidance in the near future.
FY 2020 MIDD Selections and Meetings - Quarter 1	9/30/2020	Y	10/4/2019	
FY 2020 MIDD Selections and Meetings - Quarter 2	9/30/2020	Y	1/6/2020	
FY 2020 MIDD Selections and Meetings - Quarter 3	9/30/2020	Y	4/3/2020	
FY 2020 MIDD Selections and Meetings - Quarter 4	9/30/2020	Y	7/6/2020	

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Innovative Trial Design Pilot Program FY 2020 Meetings - Quarter 1	9/30/2020	Y	10/31/2019	
Innovative Trial Design Pilot Program FY 2020 Meetings - Quarter 2	9/30/2020	Y	3/31/2020	
Innovative Trial Design Pilot Program FY 2020 Meetings - Quarter 3	9/30/2020	Y	5/7/2020	
Innovative Trial Design Pilot Program FY 2020 Meetings - Quarter 4	9/30/2020	Y	7/30/2020	
MAPP and SOP Templates for Evaluating Complex Clinical Trial Design	9/30/2020	Y	12/31/2019	
Revising or Developing MAPPs and SOPs on Biomarker Qualification Process	9/30/2020	Y	9/30/2020	
Guidance on Evidentiary Standards (Draft Guidance)	9/30/2020	N	N/A	FDA aims to publish this guidance in the near future.
Develop Sentinel Sponsor Notification MAPPs (MAPP 6701.4)	9/30/2020	Y	8/17/2020	MAPP 6701.4 *Notifying Applicants of Sentinel Analyses and Results* (see www.fda.gov/media/141216/download)
Integrating Sentinel into Pharmacovigilance Activities (ARIA Templates)	9/30/2020	Y	8/16/2019	
Integrating Sentinel into Pharmacovigilance Activities (Training)	9/30/2020	Y	9/24/2020	
Electronic Submissions and Data Standards FY 2020 Meeting - Quarter 1	9/30/2020	Y	12/3/2019	
Electronic Submissions and Data Standards FY 2020 Meeting - Quarter 2	9/30/2020	Y	3/4/2020	
Electronic Submissions and Data Standards FY 2020 Meeting - Quarter 3	9/30/2020	Y	6/2/2020	
Electronic Submissions and Data Standards FY 2020 Meeting - Quarter 4	9/30/2020	N	N/A	
Annual Public Meeting FY 2020 for IT Strategic Plan	9/30/2020	N	N/A	This meeting was jointly canceled by FDA and industry.
Annual ESG and Standard Metrics - Submission Statistics FY 2020	9/30/2020	Y	12/31/2019	Electronic Submissions Gateway: About ESG Submission Statistics (see www.fda.gov/industry/about-esg/submission-statistics)
FY 2020 Annual Discussion of IT	9/30/2020	Y	12/3/2019	

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Strategic Plan				
CY 2020 FDA Data Standards Action Plan - Quarter 3	9/30/2020	Y	7/29/2020	Data Standards Program Strategic Plan and Board (see www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board) FDA Resources for Data Standards (see www.fda.gov/industry/fda-resources-data-standards)
New Adjustment Report	9/30/2020	Y	4/6/2020	Resource Capacity Planning and Modernized Time Reporting (see www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting) Independent Evaluation of the PDUFA and BsUFA Resource Capacity Planning Adjustment Methodology (see www.fda.gov/media/136606/download)

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 ORA, 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
COVID-19 health pandemic	• The COVID-19 health pandemic required FDA to shift resources towards addressing the health emergency, which impacted the goals that were eventually missed. The volume of COVID-19-related meeting requests also substantially increased FDA's meeting-related workload. Additionally, circumstances surrounding the COVID-19 health pandemic led some new FDA hires to extend their start dates, thereby contributing to missing the hiring goal.
Federal government shutdown	• The FY 2019 federal government shutdown delayed the start of the contract for the Interim Assessment of Hiring and Retention, contributing to the delay in the publication of the report.
Change in hiring web posting methodology	• A change in the methodology used to calculate metrics for the hiring web posting was made in FY 2019 and took some time to be established, which contributed to the short delay in posting two quarterly hiring web postings.
Loss of points of contact for hiring data	• The loss of several Agency points of contact also contributed to short delays in clearing hiring data for two quarterly web postings.
Security clearance for new hires	• The federal hiring process requires clearances (e.g., security and ethics) to finalize the onboarding process, which led to some delays in onboarding and subsequent declinations, requiring the reinitiation of the recruitment process.
Cross-cutting topics in major dispute	• Multiple cross-cutting topics that raised complex policy and scientific issues took time to address, causing FDA to miss the Major Dispute Resolution goal.

Appendix D: FY 2020 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 2020 Review Goal Performance

Goal Type	Circumstances and Trends Impacting FDA's Ability to Meet Goal Dates	Corrective Action Plan

Procedural and Processing Goals	• **Meeting management goals**:
	  ○ 4,678 meeting requests in FY 2020
	  ○ 24% increase in meeting requests from FY 2019
	  ○ Large increase in COVID-19 related submissions adding to overall workload
	  ○ Limited resources
	• **Major Dispute Resolution goal**:
	  ○ Multiple cross-cutting topics that raised complex policy and scientific issues
	  ○ Increased COVID-19 workload and appropriate prioritization on addressing the public health emergency
		• FDA anticipates that once the pandemic ends, formal PDUFA meeting volume may return to pre-COVID levels and we anticipate that our limited resources will be able to address other important issues such as formal disputes in a more timely manner.

FY 2020 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Guidances	• Three guidances were missed this year due to the COVID-19 health pandemic. Resources needed to expedite the development and clearance of these guidances were instead directed to the pandemic.	• The draft guidances related to patient input, benefit-risk, and biomarker qualification. These will be published when complete.
Website Publishing	• A change in the methodology used to calculate metrics for posting was made in FY 2019 and took some time to be established, which contributed to the short delay in posting. • The loss of several agency POCs also contributed to the delay.	• The new methodology has been fully established, as well as new primary and secondary POCs for the hiring data.
Human Capital/Hiring	• Delays in clearing selected candidates led to subsequent delays in onboarding as well as some declinations. • Circumstances surrounding the COVID-19 health pandemic led some candidates to extend their start dates.	• Expanded use of the hiring authority granted under the 21st Century Cures Act should leave more time for the clearance process and to make alternative selections should selected candidates decline.
Reporting	• The start of the contract for the Interim Assessment of Hiring and Retention was delayed by the FY 2019 government shutdown. • The assessment was also delayed by COVID-19 pandemic, which prevented timely report review by key staff.	• The Interim Assessment of Hiring and Retention was published on June 5, 2020.
Public Meetings	• Two public meetings were delayed due to the COVID-19 health pandemic. • Industry and FDA jointly agreed to cancel the FY 2020 Annual Public Meeting for the IT Strategic Plan to focus on addressing the COVID-19 health pandemic.	• The public meeting for the Interim Assessment of Hiring and Retention was held on July 30, 2020. • The fourth quarter 2020 meeting on enhancing transparency and accountability of FDA electronic submission and data standards activities is slated to be held in the first quarter of 2021.

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 2020, 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 pertain to receipts/filed submissions in FY 2020.

I. FY 2020 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)
- Major dispute resolutions

B. *Justification*

Meeting management goals:

In FY 2020, FDA received 4,678 formal PDUFA meeting requests, compared to 3,771 in FY 2019. That represents a 24 percent increase from FY 2019, whereas in previous years the trend has been an average increase of 6 percent per year. Many meeting requests were for COVID-19 treatments, including new indications for approved drugs and new drug development. Unfortunately, the Agency did not receive a correlating number of new resources to address this significant increase in meeting volume. In addition, the onset of the COVID-19 pandemic (which contributed to the dramatic increase in workload), required the Agency to prioritize COVID-19 related submissions, utilizing our limited resources in order to appropriately address the public health emergency. The increased workload, pandemic focus, and limited resources resulted in difficulty achieving the meeting management goals.

Major Dispute Resolution goals:

There were a number of New Drug-related formal disputes this year that involved cross-cutting topics raising complex policy and scientific issues that took extra time to resolve. In addition, with the increased COVID-19 workload and appropriate prioritization on addressing the public health emergency, some of the timelines for disputes were missed.

C. *FY 2021 Corrective Actions*

As we continue to appropriately prioritize and address the COVID-19 pandemic, we anticipate that once the pandemic ends, formal PDUFA meeting volume may return to pre-COVID levels and we anticipate that our limited resources will be able to address other important issues such as formal disputes in a more timely manner.

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 2021 Corrective Actions").

This section presents non-review performance goals cited in the PDUFA VI Commitment Letter with required completion dates in FY 2020. 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 2021 through FY 2022 will be covered in subsequent corrective action reports.

I. Guidances

A. *Summary of Performance*

The PDUFA goal dates for the following guidances were missed:

- Draft guidance describing approaches to identifying and developing measures for an identified set of impacts to facilitate collection of meaningful patient input in clinical trials.
- Draft guidance on FDA's benefit-risk assessment for new drugs and biologics.
- Draft guidance on general evidentiary standards for biomarker qualification to be supplemented with focused guidance on specific biomarker uses and contexts.

B. *Justification*

- Approaches to impact metrics draft guidance: The guidance describing approaches to identifying and developing measures for an identified set of impacts to facilitate collection of meaningful patient input in clinical trials was delayed due to departure of senior staff and then the shifting of agency priorities related to COVID-19. The pandemic utilized the reviewers working on the Patient Focused Drug Development (PFDD) guidance to consult on trial changes, to review submissions, and to help draft COVID-19 specific guidances. These guidances included the Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment (see www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-covid-19-related-symptoms-outpatient-adult-and-adolescent-subjects-clinical-trials-drugs), which was published in September, and the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public

Health Emergency (see www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency), which was published in March 2020. The latter guidance has been updated multiple times, with the most recent update being January 27, 2021.

- Benefit-risk draft guidance: A significant contributing factor for the delay in issuing a draft guidance on FDA's benefit-risk assessment for new drugs and biologics has been the COVID-19 pandemic, which began early in the document clearance process. The increased workload and critical priorities introduced by the pandemic resulted in delays in engaging in the comprehensive review and discussions that are a necessary part of development of a guidance on such a complex, multi-disciplinary topic.

- Biomarker qualification draft guidance: The draft guidance on general evidentiary standards for biomarker qualification was delayed because the working group developing the guidance included expertise from review divisions heavily impacted by the COVID-19 pandemic; pandemic work was prioritized over the guidance.

C. *FY 2021 Corrective Actions*

- Approaches to impact metrics draft guidance: The draft guidance for describing approaches to identifying and developing measures for an identified set of impacts to facilitate collection of meaningful patient input in clinical trials will be published as soon as it is completed.

- Benefit-risk draft guidance: The completion of the draft guidance on FDA's benefit-risk assessment for new drugs and biologics remains a strong priority for FDA. The document is being finalized for issuance.

- Biomarker qualification draft guidance: The draft guidance on general evidentiary standards for biomarker qualification will be published as soon as it is completed.

II. Website Publishing

A. *Summary of Performance*

FDA missed the PDUFA goal date for posting on the web the FY 2019 fourth and FY 2020 first 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 2021 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 2020. Specifically, 48 out of 58 (83%) employees were hired.

B. *Justification*

The FDA FY 2020 PDUFA hiring goals were not met; however, candidates were identified and selected for all positions. The federal hiring process requires clearances (e.g., security and ethics) to finalize the onboarding process which led to some delays in onboarding and subsequent declinations, requiring the reinitiation of the recruitment process. The time-to-hire has been further impacted by the COVID-19 pandemic by requiring FDA to maximize candidate flexibilities to include extended start dates to accommodate candidates' individual circumstances.

C. *FY 2021 Corrective Actions*

As FDA continues to use the hiring authority granted under the 21st Century Cures Act to advance hiring, hiring managers continue to focus on prioritizing the completion of the recruitment and selection process by the third quarter of the fiscal year. By doing so, this will increase FDA's ability to identify alternative selections should a candidate decide to decline the offer as well as allow additional time for the various clearance processes.

Due to the COVID-19 pandemic, FDA had to quickly transition its recruitment process to incorporate virtual platforms as an essential outreach strategy to build external candidate talent pools. Thus, hiring managers will continue to increase their use of social media and other innovative recruitment tools to enhance recruitment and outreach in support of user fee hiring goals.

IV. Reporting

A. Summary of Performance:

FDA missed the PDUFA goal date for publishing the Interim Assessment of Hiring and Retention.

B. Justification:

The government shutdown delayed by several months the award for the contract under which this assessment was performed. Additionally, the onset of the COVID-19 pandemic prevented timely report review by key staff from Office of Operations, CDER and CBER.

C. FY 2021 Corrective Actions:

The assessment was published on June 5, 2020.

V. Public Meetings

A. Summary of Performance:

- FDA missed the PDUFA goal date for holding a public meeting on the Interim Assessment of Hiring and Retention.
- FDA did not hold a quarterly meeting in the fourth quarter of 2020 on enhancing transparency and accountability of FDA electronic submission and data standards activities.
- The FY 2020 Annual Public Meeting for the IT Strategic Plan was not held.

B. Justification:

- The COVID-19 pandemic made it difficult to find a date for the public meeting on the Interim Assessment of Hiring and Retention prior to the goal date on which key senior leadership could attend. Likewise, COVID-19 priorities delayed the fourth quarter 2020 meeting with industry related to electronic submission and data standards.
- The FY 2020 Annual Public Meeting for the IT Strategic Plan was initially scheduled within goal, but industry and FDA jointly agreed to cancel it to focus on addressing the COVID-19 pandemic.

C. FY 2021 Corrective Actions:

- The public meeting on the Interim Assessment of Hiring and Retention was held on July 30, 2020.
- The fourth quarter 2020 meeting on enhancing transparency and accountability of FDA electronic submission and data standards activities is slated to be held in the first quarter of 2021.

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,[18] 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.

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

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.
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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