Performance Report to Congress

Prescription Drug User Fee Act

FY 2022

Executive Summary

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and authorized the Food and Drug Administration (FDA or 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 2021 and FY 2022. Specifically, this report updates performance data for submissions received in FY 2021 (initially reported in the FY 2021 PDUFA Performance Report)[2] and presents preliminary data on FDA's progress in meeting FY 2022 goals. Updates on FDA's accomplishments related to additional PDUFA VI commitments for FY 2022 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 2022, the number and characteristics of applications filed by review division, and definitions of key terms used in this report. In addition, descriptions of the various submission types are included on page 4 of this report.

The estimated[3] median approval times for priority NDAs and BLAs received in FY 2021 remained approximately the same compared to the estimated median approval times for priority NDAs and BLAs received in FY 2020. The preliminary data show that the percentage of priority and standard applications filed in FY 2021 and approved during the first review cycle were 69 percent and 55 percent, respectively.

[1] http://www.fda.gov/media/99140/download.
[2] http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.
[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.

A. Achievements in FY 2022

In FY 2022, although the Agency continued to appropriately allocate resources to work focused on the pandemic, according to preliminary data, FDA met or exceeded all 12 of its review performance goals. For example, 100 percent of current performance goals were achieved for Original Priority new molecular entities (NMEs) and BLAs, Original Standard NMEs and BLAs, and Priority and Standard non-NME NDAs.

B. Review Performance Results

The FY 2021 cohort had a workload of 3,539 goal closing actions. FDA met or exceeded the 90 percent performance level for 10 of the 12 review performance goals, and with submissions still pending within goal, FDA has the potential to meet or exceed 11 of the 12 review performance goals for FY 2021.

For the FY 2022 cohort, FDA had completed 1,755 actions as of September 30, 2022. FDA is currently meeting or exceeding 12 of the 12 review performance goals for FY 2022. With 1,372 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 12 of the 12 review performance goals for FY 2022.

C. Procedural and Processing Performance Results

For the FY 2021 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 11,392 actions. FDA met or exceeded the performance level for 8 of the 20 procedural and processing goals for FY 2021.

For the FY 2022 cohort, FDA is currently meeting or exceeding 6 of the 20 procedural and processing goals. With 1,275 submissions 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 2022.

D. Additional PDUFA VI Commitments

During FY 2022, FDA made significant progress implementing all other remaining PDUFA VI commitments, including enhancing patient input and benefit-risk assessments in regulatory decision-making, enhancing regulatory science, enhancing regulatory decision tools to support drug development and review, enhancing and modernizing FDA's drug safety system, and enhancing transparency of FDA's electronic submission and data standards activities. These achievements, as well as information about FDA's hiring and retention accomplishments, are detailed in this report.

To highlight just a few of these achievements, there were several important PDUFA commitments completed in FY 2022, including the following:

FDA's rare disease programs launched the Accelerating Rare disease Cures Program and engaged in numerous internal and external educational and collaborative activities to advance the development of medical products for rare diseases.

- Guidance documents were published on patient-oriented labeling and patient focused drug development.

- Public workshops or meetings were held on rare disease related topics, model-informed drug development, and patient-focused drug development.

- Enhancements were made to the Sentinel System that facilitated public and sponsor access to the system.

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Acronym List

ARIA	Active Risk Identification and Analysis
BLA	Biologics License Application
BT	Breakthrough Therapy
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CID	Complex Innovative Design
DRDMG	Division of Rare Diseases and Medical Genetics
EOP	End of Phase
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)
IND	Investigational New Drug
IT	Information Technology
NCATS	National Center for Advancing Translational Sciences
NDA	New Drug Application
NIH	National Institutes of Health
NME	New Molecular Entity
NORD	National Organization for Rare Disorders
NPC	Niemann-Pick Type C
OC	Office of the Commissioner
OCP	Office of Combination Products

OND	Office of New Drugs
ORA	Office of Regulatory Affairs
ORPURM	Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
OTS	Office of Translational Sciences
PDUFA	Prescription Drug User Fee Act
PFDD	Patient-Focused Drug Development
RDT	Rare Diseases Team
REMS	Risk Evaluation and Mitigation Strategy
WCF	Working Capital Fund

I. 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 continued to provide the Food and Drug Administration (FDA or Agency) with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biological products. In commitments tied to this 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.[1]

A. 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 2021 cohort of submissions based on actions completed in FY 2021 and FY 2022. In addition, this report includes the preliminary performance results for the FY 2022 cohort of submissions that had actions completed or due for completion in FY 2022. Final performance for the FY 2022 cohort will be presented in the FY 2023 PDUFA Performance Report and will include actions for

[1] http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

submissions still pending within the PDUFA goal date as of September 30, 2022.

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

- 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 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 Biosimilar User Fee Act (BsUFA) Performance Reports located on FDA's website.[2]

- 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[3] 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

[2] http://www.fda.gov/about-fda/user-fee-performance-reports/bsufa-performance-reports.
[3] http://www.fda.gov/media/99140/download.

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 time goals tend to have a larger percentage of reviews completed by the end of the fiscal year, and these submission 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 within the reporting period, and these submission types' preliminary performance data are a less reliable indicator of their final performance results.

- Final performance results for FY 2021 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 2022 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2022, 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 2022 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, 2022.

- 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:** http://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

II. PDUFA Review Goals

A. Review Workload: FY 2017 to FY 2022

In the table below, preliminary workload numbers from FY 2022 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements, and the workload numbers for the previous 5 years are presented. FDA saw an increase between FY 2021 and FY 2022 in the number of Class 1 and Class 2 resubmitted NDAs and BLAs.

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.

Table 1. Workload for Applications and Submissions

Submission Type	FY 17	FY 18	FY 19	FY 20	FY 21*	FY 22	FY 17 to FY 21 5-Year Average	FY 22 Compared to 5-Year Average
Original Priority NMEs and BLAs	31	48	44	54	52	44**	46	-4%
Original Standard NMEs and BLAs	22	22	35	29	29	29	27	7%
Original Priority Non-NME NDAs	24	16	16	14	22	18**	18	0%
Original Standard Non-NME NDAs	81	69	68	59	72	43	70	-39%
Class 1 Resubmitted NDAs and BLAs	8	9	8	5	5	7	7	0%
Class 2 Resubmitted NDAs and BLAs	49	50	41	57	51	60	50	20%
Priority NDA and BLA Efficacy Supplements	78	97	81	112	100	84**	94	-11%
Standard NDA and BLA Efficacy Supplements	173	177	197	195	173	159	183	-13%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3	3	4	3	3	1	3	-67%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	11	11	2	20	10	8	11	-27%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	968	992	973	1,168	1,243	1,233	1,069	15%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,540	1,610	1,450	1,717	1,779	1,441	1,619	-11%

* FY 2021 numbers were changed to reflect updates to the data presented in the FY 2021 PDUFA Performance Report.

** Some applications have not yet received a review priority designation. There were 7 undesignated NMEs and BLAs counted as Priority NMEs and BLAs, 11 undesignated non-NME NDAs counted as Priority non-NME NDAs, and 15 undesignated efficacy supplements counted as Priority NDA and BLA Efficacy Supplements in the table above. Performance results in all categories may change once designations are made for these applications, and the table will then be updated accordingly, as appropriate, in the FY 2023 PDUFA Performance Report.

B. Final FY 2021 Review Goal Performance Results

The final FY 2021 review goal performance results are presented in the table below. The final performance results for submission types that met or exceeded 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 2021.

Table 2. FY 2021 Final Review Goal Performance Results

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2021 Performance
Original Priority NMEs and BLAs	6 months of filing date	51 of 52 on time	**98%**
Original Standard NMEs and BLAs	10 months of filing date	24 of 26 on time	**92%**
Original Priority Non-NME NDAs	6 months	20 of 22 on time	**91%**
Original Standard Non-NME NDAs	10 months	67 of 72 on time	**93%**
Class 1 Resubmitted NDAs and BLAs	2 months	4 of 5 on time	80%
Class 2 Resubmitted NDAs and BLAs	6 months	48 of 51 on time	**94%**
Priority NDA and BLA Efficacy Supplements	6 months	90 of 100 on time	**90%**
Standard NDA and BLA Efficacy Supplements	10 months	160 of 172 on time	**93%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	3 of 3 on time	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	10 of 10 on time	**100%**
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	1,189 of 1,243 on time	**96%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,706 of 1,779 on time	**96%**

C. Final FY 2021 Review Goal Performance Details

The following tables detail the final performance data for the FY 2021 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 2021 PDUFA Performance Report.

Table 3. FY 2021 Original Applications

Original Application Type	Goal: Act on 90 Percent	Filed	On Time	Overdue	Percent on Time
Priority NMEs & BLAs	6 months of filing date	52	51	1	98%
Standard NMEs & BLAs	10 months of filing date	29	24	2	92%*
Priority Non-NME NDAs	6 months	22	20	2	91%
Standard Non-NME NDAs	10 months	72	67	5	93%

* Three standard NMEs and BLAs are pending within goal as of September 30, 2022.

Table 4. FY 2021 Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	5	4	1	80%
Class 2	6 months	51	48	3	94%

Table 5. FY 2021 Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	100	90	10	90%
Standard	10 months	173	160	12	93%*

* One standard efficacy supplement is pending within goal as of September 30, 2022.

Table 6. FY 2021 Resubmitted Efficacy Supplements

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

Table 7. FY 2021 Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	1,243	1,189	54	96%
Prior Approval Not Required	6 months	1,779	1,706	73	96%

D. Preliminary FY 2022 Review Goal Performance Results

The preliminary FY 2022 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, 2022, are shown in bold text. FDA is currently meeting or exceeding the 90 percent performance level for 12 of the 12 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 12 of the 12 review performance goals.

Table 8. FY 2022 Preliminary Review Goal Performance Results

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2022 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	7 of 37 complete	6 months of filing date	**100%**	100%
Original Standard NMEs and BLAs	0 of 29 complete	10 months of filing date	--	100%
Original Priority Non-NME NDAs	4 of 7 complete	6 months	**100%**	100%
Original Standard Non-NME NDAs	7 of 43 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	7 of 7 complete	2 months	**100%**	100%
Class 2 Resubmitted NDAs and BLAs	32 of 60 complete	6 months	**100%**	100%
Priority NDA and BLA Efficacy Supplements	45 of 69 complete	6 months	**98%**	99%
Standard NDA and BLA Efficacy Supplements	28 of 159 complete	10 months	**96%**	99%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	1 of 1 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 of 8 complete	6 months	**100%**	100%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	785 of 1,233 complete	4 months	**96%**	97%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	833 of 1,441 complete	6 months	**98%**	99%

E. Preliminary FY 2022 Review Goal Performance Details

The following detailed performance information for the FY 2022 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).

Table 9. FY 2022 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	37	7	0	30	100%	100%
Standard NMEs & BLAs	10 months of filing date	29	0	0	29	--	100%
Priority Non-NME NDAs	6 months	7	4	0	3	100%	100%
Standard Non-NME NDAs	10 months	43	7	0	36	100%	100%
Review Priority Undesignated*	N/A	18	--	--	18	--	--
Total		134	18	0	116	--	--

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

Table 10. FY 2022 Resubmitted Original Applications

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Class 1	2 months	7	7	0	0	100%	100%
Class 2	6 months	60	32	0	28	100%	100%

Table 11. FY 2022 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	69	44	1	24	98%	99%
Standard	10 months	159	27	1	131	96%	99%
Review Priority Undesignated*	N/A	15	--	--	15	--	--

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

Table 12. FY 2022 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	1	1	0	0	100%	100%
Class 2	6 months	8	6	0	2	100%	100%

Table 13. FY 2022 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	1,233	750	35	448	96%	97%
Prior Approval Not Required	6 months	1,441	820	13	608	98%	99%
Review Priority Undesignated*	N/A	0	--	--	0	--	--

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

III. PDUFA Procedural and Processing Goals and Commitments

A. Procedural and Processing Workload: FY 2017 to FY 2022

The FY 2022 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 2022.

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 2021 and FY 2022) data to previous years' data, it is important to combine both Type B meeting categories. This new category also included a new meeting metric, Preliminary Response for Type B(EOP) Meetings. Meeting type definitions and other terms can be found in Appendix E. The table shows updated final FY 2021 performance and presents new reporting required under PDUFA VI.

Beginning in FY 2020, FDA committed to establish timelines for the review and comment on protocols for Human Factors studies of combination drug-device and biologic-device products. This additional goal is reflected in the number of procedural and processing goals reported.

Table 14. Meeting Management, Procedural Responses, and Procedural Notifications Workload

Submission/Request Type	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021*	FY 2022	FY 2017 to FY 2021 5-Year Average	FY 2022 Compared to 5-Year Average
Type A Meeting Requests	175	146	153	182	178	284**	167	70%
Type B Meeting Requests	1,850	1,609	1,725	2,438	2,332	2,145	1,991	8%
Type B(EOP) Meeting Requests	--	343	343	350	347	307	--	--
Type C Meeting Requests	1,391	1,403	1,550	1,716	1,706	1,648	1,553	6%
Type A Meetings Scheduled	159	127	130	147	143	231**	141	64%
Type B Meetings Scheduled	1,293	945	936	869	741	768	957	-20%
Type B(EOP) Meetings Scheduled	--	324	325	322	282	261	--	--
Type C Meetings Scheduled	660	640	732	699	648	637	676	-6%
Type A Written Response	--	6	6	13	11	18	--	--
Type B Written Response	482	578	719	1,430	1,451	1,281	932	37%
Type B(EOP) Written Response	--	14	11	23	49	36	--	--

Submission/Request Type	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021*	FY 2022	FY 2017 to FY 2021 5-Year Average	FY 2022 Compared to 5-Year Average
Type C Written Response	652	686	728	905	918	915	778	18%
Preliminary Response for Type B(EOP) Meetings	--	303	305	309	271	241	--	--
Meeting Minutes	1,679	1,541	1,638	1,515	1,363	1,305	1,547	-16%
Responses to Clinical Holds	193	199	197	261	275	344	225	53%
Major Dispute Resolutions	20	23	28	35	14	13	24	-46%
Special Protocol Assessments	173	160	158	148	150	166	158	5%
Review of Proprietary Names Submitted During IND Phase	176	159	212	224	211	191	196	-3%
Review of Proprietary Names Submitted During NDA/BLA Phase	255	228	230	255	223	208	238	-13%
Human Factors Protocol Submissions	--	--	70	79	79	59	--	--

* FY 2021 numbers were changed to reflect updates to the data presented in the FY 2021 PDUFA Performance Report.

** Some meeting requests and the subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 76 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 2023 PDUFA Performance Report.

† Because of changing reporting requirements, no past average is presented for this area.

B. Final FY 2021 Procedural and Processing Performance Results

The table below presents the final performance results for FY 2021 submissions in meeting goals related to meeting management, procedural responses, and procedural notifications. The final performance results for submission types that met or exceeded the goal (e.g., 90 percent or more reviews were completed by the goal date) are shown in bold text. FDA exceeded the performance level for 8 of the 20 procedural and processing goals in FY 2021.

Table 15. FY 2021 Final Procedural and Processing Performance Results

Submission/Request Type	Goal: 90 Percent	Total	FY 2021 Performance
Type A Meeting Requests	Respond within 14 days	166 of 178 on time	**93%**
Type B Meeting Requests	Respond within 21 days	2,089 of 2,332 on time	**90%**
Type B(EOP) Meeting Requests	Respond within 14 days	296 of 347 on time	85%
Type C Meeting Requests	Respond within 21 days	1,551 of 1,706 on time	**91%**

Submission/Request Type	Goal: 90 Percent	Total	FY 2021 Performance
Type A Meetings Scheduled	Schedule within 30 days	114 of 143 on time	80%
Type B Meetings Scheduled	Schedule within 60 days	595 of 741 on time	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	228 of 282 on time	81%
Type C Meetings Scheduled	Schedule within 75 days	536 of 648 on time	83%
Type A Written Response	Respond within 30 days	9 of 11 on time	82%
Type B Written Response	Respond within 60 days	1,009 of 1,451 on time	70%
Type B(EOP) Written Response	Respond within 70 days	26 of 49 on time	53%
Type C Written Response	Respond within 75 days	692 of 918 on time	75%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	226 of 271 on time	83%
Meeting Minutes	Issue within 30 days after meeting date	1,264 of 1,363 on time	**93%**
Responses to Clinical Holds	Respond within 30 days	257 of 275 on time	**93%**
Major Dispute Resolutions	Respond within 30 days	12 of 14 on time	86%
Special Protocol Assessments	Respond within 45 days	144 of 150 on time	**96%**
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	202 of 211 on time	**96%**
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	214 of 223 on time	**96%**
Human Factors Protocol Submissions	Respond within 60 days	24 of 79 on time	30%

C. Final FY 2021 Procedural and Processing Performance Details

The following tables detail the final performance data for the FY 2021 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 2021 PDUFA Performance Report.

Table 16. FY 2021 Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests	Respond within 14 days	178	166	12	93%
Type B Meeting Requests	Respond within 21 days	2,332	2,089	243	90%
Type B(EOP) Meeting Requests	Respond within 14 days	347	296	51	85%
Type C Meeting Requests	Respond within 21 days	1,706	1,551	155	91%
Type A Meetings Scheduled	Schedule within 30 days	143	114	29	80%
Type B Meetings Scheduled	Schedule within 60 days	741	595	146	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	282	228	54	81%
Type C Meetings Scheduled	Schedule within 75 days	648	536	112	83%
Type A Written Response	Respond within 30 days	11	9	2	82%
Type B Written Response	Respond within 60 days	1,451	1,009	442	70%
Type B(EOP) Written Response	Respond within 70 days	49	26	23	53%
Type C Written Response	Respond within 75 days	918	692	226	75%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	271	226	45	83%
Meeting Minutes	Issue within 30 days after meeting date	1,363	1,264	99	93%

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

Table 17. FY 2021 Responses to Clinical Holds

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	275	257	18	93%

Table 18. FY 2021 Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	14	12	2	86%

* 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.

Table 19. FY 2021 Special Protocol Assessments

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	150	144	6	96%

Table 20. FY 2021 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
19	16	2	1	0	23

Table 21. FY 2021 Drug/Biological Product Proprietary Names

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	211	202	9	96%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	223	214	9	96%

Table 22. FY 2021 Human Factors Protocol Submissions

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Human Factors Protocol Submissions	Respond within 60 days	79	24	55	30%

D. Preliminary FY 2022 Procedural and Processing Performance Results

The table below presents preliminary performance results for FY 2022 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, 2022, are shown in bold text. FDA is currently meeting or exceeding the performance level for 6 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.

Table 23. FY 2022 Preliminary Procedural and Processing Performance Results

Submission/Request Type	Progress	Goal: 90 Percent	FY 2022 Current Performance	Highest Possible Final Performance
Type A Meeting Requests	212 of 284 complete	Respond within 14 days	89%	92%
Type B Meeting Requests	2101 of 2145 complete	Respond within 21 days	**90%**	90%
Type B(EOP) Meeting Requests	303 of 307 complete	Respond within 14 days	89%	89%
Type C Meeting Requests	1608 of 1648 complete	Respond within 21 days	**90%**	90%
Type A Meetings Scheduled	154 of 231 complete	Schedule within 30 days	71%	81%
Type B Meetings Scheduled	714 of 768 complete	Schedule within 60 days	76%	77%
Type B(EOP) Meetings Scheduled	250 of 261 complete	Schedule within 70 days	84%	85%
Type C Meetings Scheduled	607 of 637 complete	Schedule within 75 days	82%	83%
Type A Written Response	17 of 18 complete	Respond within 30 days	82%	83%
Type B Written Response	1084 of 1281 complete	Respond within 60 days	66%	71%
Type B(EOP) Written Response	30 of 36 complete	Respond within 70 days	67%	72%
Type C Written Response	748 of 915 complete	Respond within 75 days	76%	80%
Preliminary Response for Type B(EOP) Meetings	192 of 241 complete	Issue no later than 5 days prior to meeting date	**90%**	92%
Meeting Minutes	959 of 1305 complete	Issue within 30 days after meeting date	**93%**	95%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2022 Current Performance	Highest Possible Final Performance
Responses to Clinical Holds	330 of 344 complete	Respond within 30 days	88%	89%
Major Dispute Resolutions	10 of 13 complete	Respond within 30 days	80%	85%
Special Protocol Assessments	149 of 166 complete	Respond within 45 days	**96%**	96%
Proprietary Name Submitted During IND Phase	103 of 191 complete	Review and respond within 180 days	54%	75%
Proprietary Name Submitted During NDA/BLA Phase	161 of 208 complete	Review and respond within 90 days	**96%**	97%
Human Factors Protocol Submissions	51 of 59 complete	Respond within 60 days	59%	64%

E. Preliminary FY 2022 Procedural and Processing Performance Details

The following detailed performance information for FY 2022 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*).

Table 24. FY 2022 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	284	188	24	72	89%	92%
Type B Meeting Requests	Respond within 21 days	2,145	1,893	208	44	90%	90%
Type B(EOP) Meeting Requests	Respond within 14 days	307	270	33	4	89%	89%
Type C Meeting Requests	Respond within 21 days	1,648	1,450	158	40	90%	90%
Type A Meetings Scheduled	Schedule within 30 days	231	110	44	77	71%	81%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type B Meetings Scheduled	Schedule within 60 days	768	540	174	54	76%	77%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	261	210	40	11	84%	85%
Type C Meetings Scheduled	Schedule within 75 days	637	499	108	30	82%	83%
Type A Written Response	Respond within 30 days	18	14	3	1	82%	83%
Type B Written Response	Respond within 60 days	1,281	713	371	197	66%	71%
Type B(EOP) Written Response	Respond within 70 days	36	20	10	6	67%	72%
Type C Written Response	Respond within 75 days	915	568	180	167	76%	80%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	241	173	19	49	90%	92%
Meeting Minutes	Issue within 30 days after meeting date	1,305	896	63	346	93%	95%

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

† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 76 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 2023 PDUFA Performance Report.

Table 25. FY 2022 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	344	291	39	14	88%	89%

Table 26. FY 2022 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	13	8	2	3	80%	85%

* 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.

Table 27. FY 2022 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	166	143	6	17	96%	96%

Table 28. FY 2022 Special Protocol Assessments Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
14	13	1	0	0	15

Table 29. FY 2022 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 Name Submitted During IND Phase	Review and respond within 180 days	191	56	47	88	54%	75%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	208	154	7	47	96%	97%

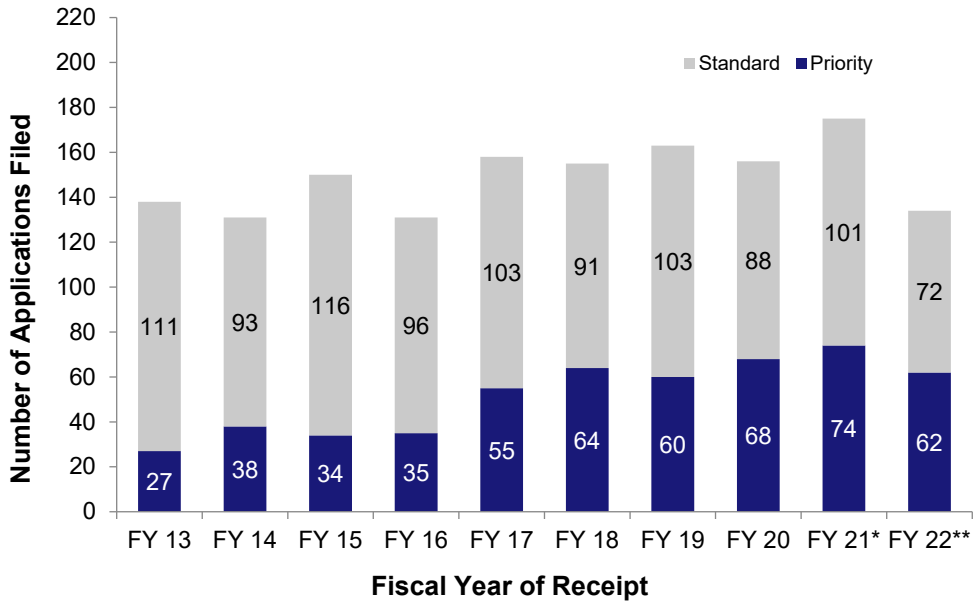
Table 30. FY 2022 Human Factors Protocol Submissions

Submission Type	Goal: 90 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	59	30	21	8	59%	64%

IV. PDUFA Trend Graphs

The number of NDAs and BLAs filed from FY 2013 to FY 2022 is presented in the graph below. The total number of all original applications (NDAs and BLAs) filed in FY 2022 decreased from the number filed in FY 2021, and the total number of priority applications filed decreased in FY 2022.

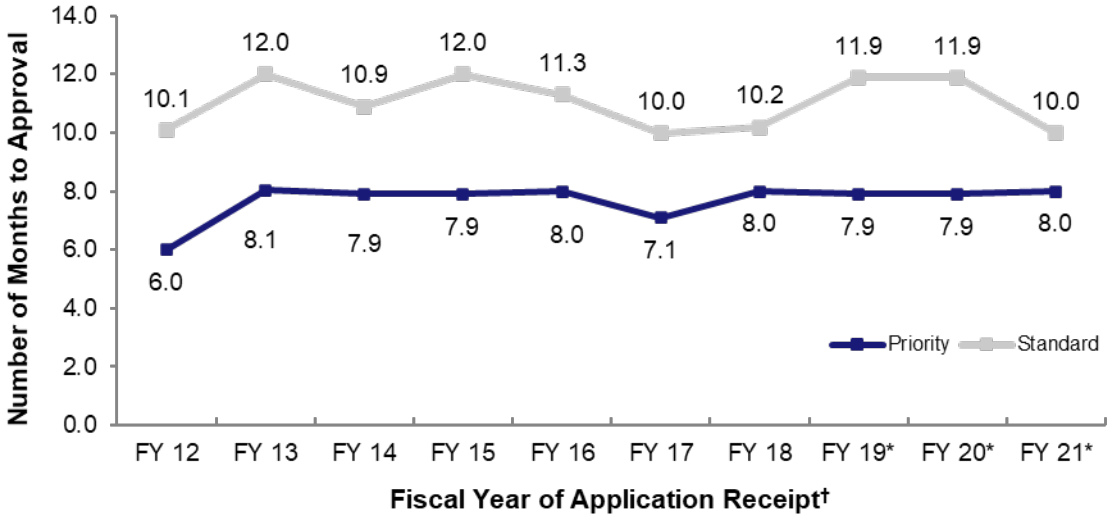
Figure 1. Total NDAs and BLAs Filed



* FY 2021 numbers were changed to reflect updates to the data presented in the FY 2021 PDUFA Performance Report.
** Some applications filed in FY 2022 have not yet received a review priority designation. The undesignated NDAs and BLAs are counted as Priority NDAs and BLAs. In the FY 2023 PDUFA Performance Report, designations may change, and the table will be updated accordingly.

The median total times to approval for priority and standard applications received from FY 2012 through FY 2021 are presented in the graph below.[4] The data represented in the graph are updated based on the approvals reported in Appendix A. FY 2022 data are too preliminary to estimate the median approval time.

Figure 2. Median Time to Application Approval for All Filed NDAs and BLAs (Months)

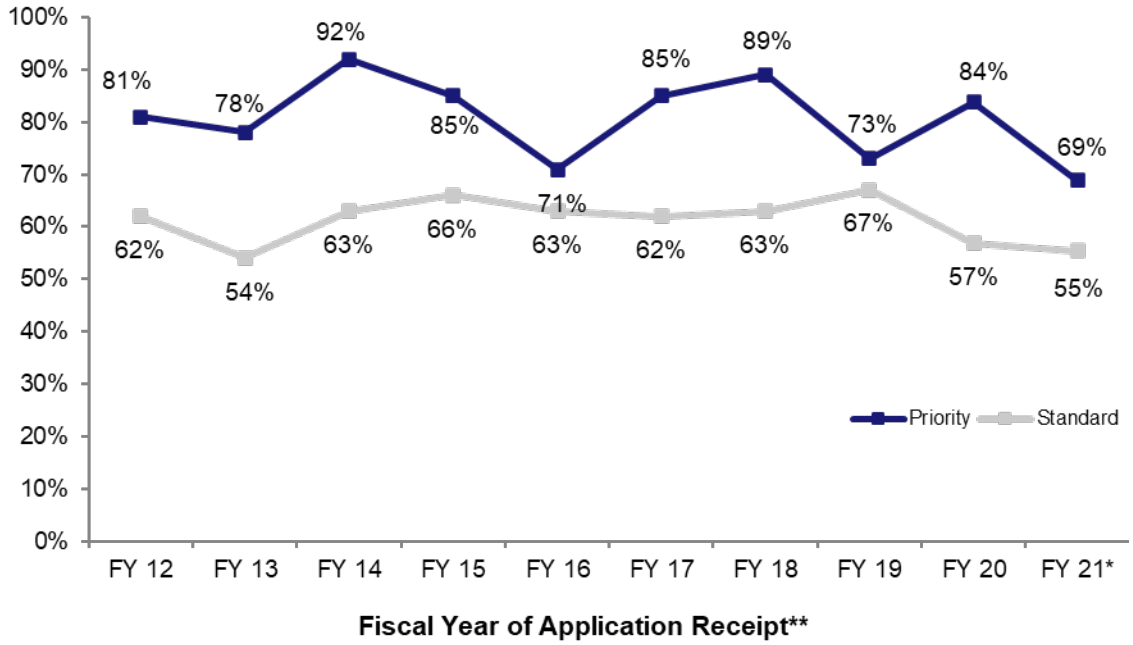


* The median approval times for the 3 most recent years are estimated.
The data represented in this graph are based on the approvals reported in Appendix A.

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

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 2012 to FY 2021. These percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals decreased in FY 2021. For the FY 2021 cohort, which is still preliminary, 55 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications decreased in FY 2021, with 69 percent of approved priority applications being approved on the first cycle. The FY 2022 data are too preliminary to estimate the percent of first-cycle approvals.

Figure 3. Percent of NDAs and BLAs Approved on the First Cycle



* First-cycle approvals are still possible for FY 2021 priority and standard applications, so the data are preliminary. The data were changed to reflect updates to the data presented in the FY 2021 PDUFA Performance Report.
** The data represented in this graph are based on the approvals reported in Appendix A.

V. 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:[5]

- 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 2021 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 2022 PDUFA VI Financial Report. Each accomplishment includes a reference to a specific section of the Commitment Letter. External references are also provided to published guidance documents, 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.

[5] http://www.fda.gov/media/99140/download.

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

Table 31. Section I.I's FY 2022 Commitments and Accomplishments

Commitment Title	FY 2022 Accomplishments
I.I.1 Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• In FY 2022, there were no commitments due.
I.I.2 Ensuring Sustained Success of Breakthrough Therapy Program	• In FY 2022, there were no commitments due.
I.I.3 Early Consultation on the Use of New Surrogate Endpoints	• In FY 2022, there were no commitments due.
I.I.4 Advancing Drug Development of Drugs for Rare Diseases	**OVERALL** • In FY 2022, CDER's Rare Diseases Team (RDT) engaged in critical rare disease drug development enhancement activities. In May 2022, CDER launched the Accelerating Rare disease Cures Program. This program was designed to accelerate and promote the development of effective and safe treatment options that address the unmet needs of patients with rare diseases. It is managed by the RDT and governed by leadership in policy, review, and engagement from CDER's Office of the Center Director, Office of New Drugs (OND), and Office of Translational Sciences (OTS). **EXPERTISE IN REVIEW** • In FY 2022, the RDT continued to consult on or contribute to the approval of rare disease drug applications across the review divisions in OND regarding the design of trials, the assessment • CBER ensured that its review offices considered flexible and feasible approaches in the review of biologics for rare diseases through the sharing of expert review practices and case study presentations during CBER Rare Disease Coordinating Committee meetings. • CDER's Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), in conjunction with the RDT, continued to facilitate CDER's Rare Disease Drug Development Council meetings. Members of CDER's Division of Rare Diseases and Medical Genetics (DRDMG) and RDT serve on the council. The council meetings are a forum (1) to discuss cross-cutting rare disease issues with leaders in rare disease drug development across OND and OTS and (2) to solicit input from OND and OTS on rare disease applications.

	• The RDT worked closely with other offices within CDER to continue to provide expertise for the rare disease pediatric voucher program. • The RDT is the CDER program lead for the development and implementation of the PDUFA VII Rare Disease Endpoint Advancement Pilot Program. This joint CDER/CBER pilot program will support novel efficacy endpoint development for rare disease treatments. **EDUCATION AND TRAINING** • In FY 2022, the RDT and CBER continued to train CDER and CBER review staff, as well as other FDA staff, in areas of rare disease drug development. • In September 2022, the RDT held a 2-day annual reviewer training event titled "Use of RWD/RWE in Rare Disease Medical Product Development." This training focused on collaborations across FDA's Centers and Offices (i.e., the Office of the Commissioner (OC), CDER, and CBER), which have impacted the development of medical products for rare diseases. Approximately 500 staff attended the program. • The RDT holds a quarterly rare diseases seminar series. During these quarterly seminars, which are for FDA staff, topics pertaining to rare diseases are presented, including Bayesian statistical approaches, clinical outcome assessments as endpoints, transformative therapeutic clinical trial platforms (which was presented by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) and use of CRISPR/CAS9 technology (in conjunction with CBER staff and Nobel Laureate Jennifer Doudna). CBER staff were integral contributors of topic ideas to this series. • In September 2022, the RDT collaborated with CDER's Office of the Center Director and Office of Biostatistics to plan and conduct a Complex Innovative Design (CID) Seminar Series continuing education lecture titled "Small Sample SMART Design and Bayesian Methods to Determine the Effectiveness of a Drug." A University of Michigan expert presented research on rare disease clinical trial design that is being investigated under a Broad Agency Announcement contract with FDA. • CDER's DRDMG and ORPURM distributed, in conjunction with the RDT, a bimonthly internal FDA rare disease newsletter, *Zebragram*. The newsletter to FDA staff provided not only news relating to rare disease science, regulations, and policies within OND, across the Agency, and with key stakeholder, but also information about rare disease drug and biological product applications from across CDER and CBER. CBER routinely contributed content to this newsletter on

	CBER rare disease activities and ensured a wide distribution of it within its Center. **EXTERNAL OUTREACH** • In FY 2022, the RDT, in collaboration with CBER, continued its outreach activities with external stakeholders to advance rare disease drug development. • The RDT—along with others in CDER, CBER, the Center for Devices and Radiological Health (CDRH), and OC—participated in the October 2021 National Organization for Rare Disorders (NORD) Summit by coordinating an FDA plenary session on FDA's patient engagement activities. The RDT also facilitated FDA participation in other sessions and presented posters at the summit. • In May 2022, the RDT, along with others in CDER and the Division of Rare Diseases Research Innovation at NIH's NCATS co-sponsored a 2-day workshop on regulatory fitness in rare disease clinical trials (see https://www.fda.gov/drugs/news-events-human-drugs/fda-cder-nih-ncats-regulatory-fitness-rare-disease-clinical-trials-workshop-05162022). This workshop targeted academic investigators, patient groups, and small or emerging pharmaceutical or biotechnology companies that are often the sponsors for rare disease drug development but may lack regulatory experience. The workshop featured CDER's rare disease experts as speakers and case studies from the NCATS division's grantees. • In July 2022, the RDT was a panelist in a NORD webinar titled "Drug Development for Rare Disease: A Community Conversation." • The RDT led and facilitated the International Rare Diseases Cluster for FDA. In addition to including FDA, this cluster includes two other regulatory agencies—namely, the European Medicines Agency and Health Canada. In FY2022, Health Canada transitioned from being a participant to being a co-chair. CBER staff gave presentations at three of the fourteen Cluster meetings held with the European Medicines Agency and Health Canada. • The RDT and CBER became members of the International Rare Diseases Research Consortium's new Regulatory Science Committee, which includes representation from regulatory bodies, patient groups, the biotech and pharmaceutical industries, public and not-for-profit organizations, clinicians, and scientists. The goal of the committee is to promote multi-stakeholder interaction to identify pathways for regulatory harmonization in consideration of global regulatory challenges surrounding therapeutic innovation in rare disease drug development.

	• The Duke-Margolis Center for Health Policy and the RDT, in conjunction with others at CDER, hosted a rare disease public workshop titled "Endpoint Considerations to Facilitate Drug Development for Niemann-Pick Type C (NPC)" in January 2022 (see https://www.fda.gov/drugs/news-events-human-drugs/endpoint-considerations-facilitate-drug-development-niemann-pick-type-c-npc-public-workshop-01242022). Presenters discussed clinical endpoints relevant to NPC clinical trials and innovative strategies to support therapeutic development for patients with NPC. In August 2022, Duke-Margolis and the RDT hosted a follow-up webinar that provided key themes and shared future directions from the January 2022 workshop (see https://www.fda.gov/drugs/news-events-human-drugs/endpoint-considerations-facilitate-drug-development-niemann-pick-type-c-npc-key-themes-and-future). • The RDT and CBER staff interacted with FDA's Office of Orphan Products Development, such as through contributing to the office's bimonthly meetings for planning and participating in the FDA Rare Disease Day 2022, a public meeting held on March 4, 2022 . • DRDMG, the RDT, and CBER ensured the relevance of three draft guidance documents for industry for rare diseases. Two of these draft guidances provided recommendations for real-world data and-real world evidence—one titled *Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products* (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-registries-support-regulatory-decision-making-drug-and-biological-products) and one titled *Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products* (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-real-world-data-and-real-world-evidence-support-regulatory-decision-making-drug). The third draft guidance document, titled *Benefit-Risk Assessment for New Drug and Biological Products* (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-assessment-new-drug-and-biological-products), specifically included recommendations for rare diseases. • ORPURM, DRDMG, and the RDT made over 30 presentations on various rare disease topics. • CDER staff and reviewers in DRDMG published an FDA approval summary for a drug treatment, Nexviazyme for the rare late-onset Pompe disease.

	• In FY 2022, CBER staff participated in a minimum of 138 outreach activities intended to support the development of biological products for rare diseases. These activities included presentations (55%), publications (26%), and posters/abstracts (19%). • The RDT and CBER staff attended multiple Patient-Focused Drug Development (PFDD) and Patient Listening Sessions for rare diseases. The PFDD meetings, some of which were hosted by patient organizations, provided a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation. The Patient Listening Sessions enabled FDA medical product centers to engage with patients and caregivers, which allowed the patient community to share with the Agency their experiences living with a disease/condition or other health-related matter. • On November 16, 2021, and March 6, 2022, CBER held public RegenMedEd webinars on regenerative medicine. The goal of these webinars was to (1) bring together patients, caregivers, patient advocates, and FDA staff to discuss foundational information about regenerative medicine therapies, such as gene therapy and cell therapy, and (2) explore opportunities for stakeholders to engage with FDA to help advance drug development on November 16, 2021, and March 6, 2022. • On May 24, 2022, CBER hosted a public workshop titled "Annual Patient Engagement & Regenerative Medicine Meeting 2022: An FDA CBER Workshop for Patient Advocates," which focused on the importance of natural history studies. • On October 27, 2021, FDA CBER, NIH, and 10 pharmaceutical companies and five non-profit organizations established The Bespoke Gene Therapy Consortium, which was a partnership to accelerate the development of gene therapies with the goal of (1) leveraging and streamlining the gene therapy development process to help fill the unmet medical needs of people with rare diseases and (2) exploring methods to streamline regulatory requirements and processes for FDA's approval of safe and effective gene therapies.
I.I.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• In developing staff capacity for combination products, the Office of Combination Products (OCP) has hired several staff members over the last 5 years to support project management, policy development, scientific reviews, and IT initiatives. These additional hires have enabled OCP to continue to support all three medical product Centers in premarket review and postmarket regulations of combination products. • Work on the final guidance document regarding bridging studies, including the bridging of data from combination

	products, has been delayed due to competing priorities with various public health emergencies. • FDA published the patient-oriented labeling final guidance document *Instructions for Use – Patient Labeling for Human Prescription Drug and Biological Products – Content and Format*, in July 2022 (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/instructions-use-patient-labeling-human-prescription-drug-and-biological-products-content-and-format).
I.I.6 Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making	• In FY 2022, there were no commitments due.

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

Table 32. Section I.J's FY 2022 Commitments and Accomplishments

Commitment Title	FY 2022 Accomplishments
I.J.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	• In June 2022, FDA published the draft guidance document *Patient-Focused Drug Development: Selecting, Developing or Modifying Fit-For-Purpose Clinical Outcomes Assessments* (PFDD Guidance 3) (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome), thereby meeting this commitment. The public comment period for the guidance closed on September 28, 2022. The comments will be reviewed and considered as part of the process to finalize this guidance document. • In September 2022, FDA conducted a public webinar to provide an overview of the PFDD Guidance 3 and to answer stakeholder questions. • In February 2022, FDA finalized the guidance document *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients* (PFDD Guidance 2) (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients). • FDA continued to strengthen its staff capacity to facilitate the development and use of patient-focused methods to inform drug development and regulatory decisions. This strengthened staff were integrated across review divisions, frequently interacted with patient stakeholders. and provided

	consultations to sponsors developing clinical outcome assessments that were to be used to collect patient and caregiver input. These interactions included participating in at least 10 Patient Listening Sessions and 19 externally led PFDD meetings. Staff also continued to support the Clinical Outcome Assessment qualification program. • FDA continued the Standard Core Clinical Outcomes and Endpoints Grant Program that (1) funds the development of core outcome sets in a variety of clinical divisions and (2) increases the familiarity and understanding of the development of Clinical Outcome Assessments within review divisions and other areas. • FDA maintained and enhanced its repository of publicly available tools and resources for stakeholders and, in August 2022, modified the repository to better meet the needs of stakeholders. • FDA continued to hold monthly cross-disciplinary meetings to discuss reviews, guidance documents, and process changes. Staff provided presentations at several internal meetings and public meetings with a high attendance by FDA staff. In addition, FDA staff and reviewers participated in multiple internal trainings to increase their familiarity and understanding of the role of patient preference studies in drug development. • In June 2022, FDA conducted a public meeting titled "Using Methods from PFDD Guidance 1 and Guidance 2 as Tools for Including Patient Experience Data in Clinical Trials: Who to Ask and How to Ask," which focused on the PFDD guidance series." In July 022, FDA conducted a public meeting titled "Using Methods from PFDD Guidance 1 and Guidance 2 as Tools for Including Patient Experience Data in Clinical Trials: Lessons Learned about Data Collection and Analysis," which provided an overview of the PFDD guidance documents and allowed FDA to hear from stakeholders about how they had utilized the guidance documents in their drug development programs.
I.J.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• FDA completed a third-party evaluation of the implementation of the benefit-risk framework in the human drug review program. • FDA began work to develop a final guidance document on the benefit-risk assessment for new drugs and biologics at the close of the public comment period for the draft guidance. • FDA continued to conduct trainings with review staff on the benefit-risk framework and related topics. FDA continued to apply this framework in the review of new drugs and biologics and, in select cases, apply additional benefit-risk approaches to inform this framework. FDA staff presented at conferences on

	topics relevant to benefit-risk assessment and continued participating in multi-stakeholder workgroups seeking to advance best practices in the benefit-risk assessment for drug development.
I.J.3 Advancing Model-Informed Drug Development	• FY 2022 model-informed drug development (MIDD) quarterly selections and meetings: o OCP granted 13 MIDD submissions and conducted 11 industry meetings (eight initial and three follow-up) from October 2021 to September 2022. o CBER granted one submission and conducted two industry meetings (one initial and one follow-up) from October 2021 to September 2022. • Held the MIDD public workshop on disease progression model development titled, "Best Practices for Development and Application of Disease Progression Models" on November 19, 2021. There were 1,052 attendees. • Held the MIDD public workshop on immunogenicity and correlates of protection titled, "Model Informed Drug Development Approaches for Immunogenicity Assessments" on June 9, 2021, and reported in FY 2021. • The publication of summary topics discussed in MIDD public workshop on disease progression model development is expected by December 2022. • Published the summary topics discussed in MIDD public workshop on immunogenicity and correlates of protection in March 2022 in the *Clinical Pharmacology and Therapeutics* journal.
I.J.4 Enhancing Capacity to Review Complex Innovative Designs	• CID Pilot Program FY 2022 quarterly meetings: o FDA completed a paired meeting series for one proposed CID. o FDA denied three CID meeting requests. o FDA presented 14 CID-related presentations at professional meetings.
I.J.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• FDA presented at external meetings sponsored by standards developing organizations.
I.J.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• FDA is currently working on a draft guidance document on the evidentiary framework for biomarker qualification and will continue to evaluate the potential need for a supplemental focused guidance document on evidentiary standards once the evidentiary framework guidance is published.

C. Section I.K: Enhancement and Modernization of FDA's Drug Safety System

Table 33. Section I.K's FY 2022 Commitments and Accomplishments

Commitment Title	FY 2022 Accomplishments
I.K.1 Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System, and Integration into FDA Pharmacovigilance Activities	• FDA updated the Sentinel Common Data Model to version 8.0.0 and began implementation of version 8.1.0 (which was released to public Git6 on April 15, 2022). This update allowed for increased data capture, improved data precision, and the opening of this data model to international and broader use of real-world data. • FDA initiated a project funded by the Assistant Secretary for Planning and Evaluation to add Transformed Medicaid Statistical Information System data to Sentinel. • FDA developed new analytic capabilities in Active Risk Identification and Analysis (ARIA)-distributed tools to enable verification that the Cox proportional hazards assumption was not violated using statistical tests adding the Cox Proportional Hazard Assumption Test and the Kaplan Meier curve estimation for Inverse Probability of Treatment Weighting, which is an analytic method that can reduce confounding bias in observational studies of medical treatments. • FDA completed the TriNetX characterization to improve understanding of this electronic health record-based data sources. • In FY 2022, the Innovation Center continued seven projects and initiated five new ones to advance a strategic goal of developing a new electronic health record-based distributed data network. • FDA continued to post every analytic package and query result on the Sentinel website. • FDA continued to notify sponsors about Sentinel analyses and results according to the policies and processes outlined in the Manual of Policies and Procedures 6701.4 (see www.fda.gov/media/141216/download). • FDA made upgrades to distributed and local reporting tools used for ARIA analyses, including analytic programming code and comprehensive documentation, publicly available on the Sentinel website.

[6] https://dev.sentinelsystem.org/repos?visibility=public.

	• FDA conducted a public training on April 29, 2022, on Inverse Probability of Treatment Weighting. • On January 19, 2022, the Sentinel Community Building and Outreach Center hosted a webinar on how health advocates can use publicly available resources on the Sentinel website. • On September 14, Sentinel's Community Building and Outreach Center developed a webinar titled "An Overview of Sentinel's Publicly Available Analytics Tools" to increase stakeholder awareness and engagement with the Sentinel System. • The Innovation in Medical Evidence Development and Surveillance is a program run by the Reagan-Udall Foundation for FDA that provides the private sector with access to a subset of FDA's Sentinel Network to conduct assessments of medical product safety and effectiveness. This program benefits from Sentinel's curated data and routine analytic toolset. From initiation through FY 2022, the Sentinel Operations Center supported seven program queries. • FDA provided enhancements to the Sentinel website, which serves as a central hub for communications related to Sentinel. These enhancements included adding pages on pregnancy, pediatrics, and COVID-19. • FDA continued to post a public quarterly newsletter to inform the Sentinel community of the work being done by Sentinel, upcoming events, and new publications. • FDA created a new data visualization dashboard called Sentinel Views, a web-based data visualization platform, designed to increase access to study results from the Sentinel System. Sentinel Views was released to the public in April 2022. It can help internal and external users to visualize both descriptive and inferential results for eligible queries. • Hosted the Sentinel annual public workshop on November 8, 2021, and November 9, 2021. • FDA continued to notify sponsors on the sufficiency of FDA's ARIA system to evaluate serious safety concerns in the approval letter for original and supplemental drug and biological product applications. • FDA developed and updated internal templates used in the ARIA process to improve the consistency of implementation. • FDA continued a module-based online training program to provide FDA staff with a working knowledge of Sentinel and to enable staff to consistently use Sentinel to evaluate safety issues and address other regulatory questions.

	• As part of the Sentinel website redesign, FDA created a downloadable table of drug assessments that provides a single view of analytic packages, results, and regulatory impacts of Sentinel analyses (see https://sentinelinitiative.org/assessments/drugs). • FDA made updates to 12 drug assessments pages on the Sentinel website, which describe ongoing queries, completed queries, and regulatory impacts. • FDA made ongoing updates to the "Assessing the ARIA System's Ability to Evaluate a Safety Concern" web page, which contains ARIA sufficiency memos (see https://sentinelinitiative.org/assessments/drugs/assessing-arias-ability-evaluate-safety-concern). • FDA conducted an assessment of the Sentinel system that included analyzing and reporting on the impact of the Sentinel expansion and integration on FDA's use of Sentinel for regulatory purposes (e.g., in the contexts of labeling changes, post-marketing requirements, or post-marketing commitments). Assessment report available at: Assessment in Support of the Sentinel System (fda.gov) (see https://www.fda.gov/media/161944/download).
I.K.2 Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs	• FDA contracted with a third party to assess how data systems and processes, as described in Manuals of Policies and Procedures and Standard Operating Policies and Procedures, support the review, oversight, and communication of postmarketing drug safety issues" in CDER and CBER. Results from this assessment were presented to an internal FDA audience in FY 2022, and a public summary outlining these results is being developed. Several recommendations from the assessment are being actively addressed by FDA.

D. Section II: Enhancing the Management of User Fee Resources

Table 34. Section II's FY 2022 Commitments and Accomplishments

Commitment Title	FY 2022 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• In FY 2022, there were no commitments due.
II.B Financial Transparency and Efficiency	• The FY 2022 annual update to the 5-year financial plan was published on March 30, 2022 (see https://www.fda.gov/media/157297/download). • The FY 2022 financial public meeting was held June 7, 2022 (see https://www.fda.gov/drugs/news-events-human-drugs/2022-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act#:~:text=This%20year%27s%20public%20meeting%20will,10%3A50%20AM%20Eastern%20Time).

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

Table 35. Section III's FY 2022 Commitments and Accomplishments

Commitment Title	FY 2022 Accomplishments
III.A Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity	• In FY 2022, there were no commitments due.
III.B Augmentation of Hiring Staff Capacity and Capability	• In FY 2022, there were no commitments due.
III.C Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Program	• In FY 2022, there were no commitments due.
III.D Set Clear Goals for Human Drug Review Program Hiring	• FDA's FY 2022 hiring goal was for nine full-time equivalents (FTEs), and five FTEs were onboarded (which is 56 percent of the FY 2022 hiring goal). • FDA's hiring progress against this goal and the goals from previous years were posted on FDA's website (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data).

Commitment Title	FY 2022 Accomplishments
III.E Comprehensive and Continuous Assessment of Hiring and Retention	• The "FDA Final Hiring and Retention Assessment" report was completed on December 10, 2021 (see https://www.fda.gov/media/154873/download). • A public meeting on the PDUFA hiring and retention final assessment was held on March 15, 2022 (see https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-pdufa-hiring-and-retention-final-assessment-public-meeting-03152022).

F. Section IV: Information Technology Goals

Table 36. Section IV's FY 2022 Commitments and Accomplishments

Goal	FY 2022 Accomplishments
IV.B Improve the Predictability and Consistency of PDUFA Electronic Submission Processes	• In FY 2022, there were no commitments due.
IV.C Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities	• Four quarterly meetings with industry were held that focused on various topics including the Electronic Submissions Gateway, the electronic Common Technical Document, the identification of medicinal products, pharmaceutical quality data standards, IND safety reporting, and the technical rejection of study data. • In early 2022, via a *Federal Register* notice, the FY 2022 annual public meeting for the IT strategic plan was announced. The meeting was held on April 12, 2022. • The Electronics Submission Gateway staff continues to collect and report submission statistics which can be found at: https://www.fda.gov/industry/electronic-submissions-gateway. • The Office of Digital Technology has attended FDA-industry quarterly meetings to discuss both the data and technology modernization action plans. • The Data Standards Action Plan, which is aligned with the CBER-CDER Data Standards Strategy document, continues to be updated and published quarterly.

G. Additional PDUFA VI Review Program Reporting

1. Hiring and Placement of New PDUFA VI Staff at FDA

The 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.[7] FDA reports its progress in hiring new staff to support new initiatives in the annual PDUFA Financial Report, as per the PDUFA VI Commitment Letter.

[7] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data.

VI. 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) of 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 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 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.

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

FDA committed to hiring 230 FTEs from FY 2018 to FY 2022 as agreed upon in the PDUFA VI Commitment Letter. FDA has successfully hired 223 FTEs of the 230 FTEs (97 percent) as of September 30, 2022. The data in the following table show the total number of FTEs hired towards the FY 2021 and FY 2022 hiring targets as agreed upon in the PDUFA VI Commitment Letter and the change in the number of FTE hires from FY 2021 to FY 2022.

The hiring of FTEs decreased from FY 2021 to FY 2022 due to the hiring goal targets decreasing from 18 FTEs in FY 2021 to 9 FTEs in FY 2022. FDA has successfully fulfilled 100 percent of its hiring target for FY 2021 and 56 percent of its hiring target for FY 2022 as of September 30, 2022. With a total of 7 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.

Table 37. Number of FTEs Hired as Agreed Upon in the PDUFA VI Commitment Letter

Center	FY 2021 Hires*	FY 2022 Hires*	Change in Number of FTEs Hired
CDER	17	5	-12
CBER	1	0	-1
ORA	0	0	0
OC	0	0	0

* 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.

2. Changes in the 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 2021 to FY 2022 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 2,080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2022 and the previous fiscal year, FY 2021, 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 2021 are those FTEs as of September 30, 2021. The number of FTEs funded by budget authority for FY 2022 are those FTEs as of September 30, 2022.

FDA reported an overall decrease in budget authority-funded FTEs in FY 2022 compared to FY 2021.

Table 38. Number of FTEs Funded by Budget Authority

Center and Office	Number of PDUFA Program FTEs Funded by Budget Authority*		Change in Number of PDUFA Program FTEs Funded by Budget Authority
	FY 2021	FY 2022	
CDER			
Office of Communications	3.1	7.3	4.2
Office of Compliance	21.3	17.3	-4.0
Office of the Center Director	0.8	7.3	6.5
Office of Executive Programs	7.5	1.8	-5.7
Office of Generic Drugs	4.5	4.4	-0.1
Office of Management	1.6	11.5	9.9
Office of Medical Policy	5.1	15.0	9.9
Office of New Drugs	137.6	66.3	-71.3
Office of Pharmaceutical Quality	73.4	46.9	-26.5
Office of Regulatory Policy	9.5	18.3	8.8
Office of Surveillance and Epidemiology	20.9	36.2	15.3
Office of Strategic Programs	4.8	14.4	9.6
Office of Information Management and Technology	0.1	0.0	-0.1
Office of Translational Sciences	33.7	21.2	-12.5
Other Offices	3.4	0.3	-3.1
Working Capital Fund (WCF)	55.5	51.7	-5.3
CDRH			
Office of Product Evaluation and Quality	7.1	2.1	-5.0
Office of Management	1.2	0.0	-1.2
Office of Science and Engineering Laboratories	0.6	0.3	-0.3
Office of Communication and Education	1.1	0.0	-1.1
Office of Policy	0.3	0.0	-0.3

Center and Office	Number of PDUFA Program FTEs Funded by Budget Authority*		Change in Number of PDUFA Program FTEs Funded by Budget Authority
	FY 2021	FY 2022	
Office of Strategic Partnership and Technology Innovation	0.1	0.1	0.0
Office of the Center Director	0.1	0.0	-0.1
Office of Information Management and Technology	0.1	0.1	0.0
WCF	0.9	0.8	-0.1
CBER			
Office of Biostatistics and Epidemiology	13.7	6.2	-7.5
Office of Blood Research and Review	4.9	5.3	0.4
Office of Compliance and Biologics Quality	22.8	22.0	-0.8
Office of Tissues and Advanced Therapies	59.5	57.4	-2.1
Office of Vaccines Research and Review	96.4	96.3	-0.1
Office of Communication Outreach and Development	11.9	9.7	-2.2
Office of the Center Director	20.3	14.0	-6.3
Office of Management	17.5	21.5	4.0
Office of Information Management and Technology	0.0	1.8	1.8
Office of Biostatistics and Pharmacovigilance	NA	7.5	7.5
Office of Regulatory Operations‡	NA	5.4	5.4
Other Offices	2.0	0.0	-2.0
WCF	34.0	33.4	-0.6
OC			
OC Immediate Office	2.3	2.7	0.4
Office of the Chief Counsel	6.4	7.2	0.8
Office of the Chief Scientist	4.6	4.6	0.0
Office of Clinical Policy and Programs	9.9	11.6	1.7

Center and Office	Number of PDUFA Program FTEs Funded by Budget Authority*		Change in Number of PDUFA Program FTEs Funded by Budget Authority
	FY 2021	FY 2022	
Office of External Affairs	2.6	3.2	0.6
Office of International Programs	0.0	0.0	0.0
Office of Operations	8.7	10.9	2.2
Office of Policy, Legislation, and International Affairs	4.6	6.5	1.9
Office of Special Medical Programs	0.0	0.0	0.0
WCF	13.0	12.7	-0.3
ORA			
Office of Pharmaceutical Quality Operations	91.0	99.1	8.1
Office of Global Partnerships and Strategy	0.7	0.4	-0.3
WCF	8.4	8.7	0.3

* This table includes PDUFA program FTE calculated through WCF assessments for certain centrally administered services provided to CDER, CDRH, 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.

†A reorganization in CBER created this new office, which was previously a part of the Office of Biostatistics and Epidemiology.
‡A reorganization in CBER created this new office, which was previously a part of the Office of the Center Director.

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 2021 and FY 2022, as well as the changes in these amounts from FY 2021 to FY 2022. 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* represent FDA's total expenditure on the PDUFA program.
- Numbers are provided for both the most recent fiscal year (FY 2022) and the prior fiscal year (FY 2021). Although FDARA does not explicitly require this data, they do provide relevant context necessary to interpret the required information.

In FY 2022, FDA had net collections of $1.159 billion in prescription drug user fees, spent $1.13 billion in user fees for the human drug review process, and carried a cumulative balance of $288 million forward. Detailed financial information for the PDUFA user fee program can be found in the FY 2022 PDUFA Financial Report.[8]

The process for setting the annual target revenue is set forth in the statute. For FY 2022, the base revenue amount is $1,098,077,960. The FY 2022 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 planning 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 FY 2022 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs yielding a total adjusted fee revenue amount of $1,200,129,000 (rounded to the nearest thousand dollars), which funds PDUFA VI initiatives.

In FY 2022, PDUFA review process costs decreased slightly from FY 2021.

Table 39. Changes in the Fee Revenue Amounts and Review Process Costs

Fiscal Year	FY 2021	FY 2022	Change from FY 2021 to FY 2022
Net Fiscal Year Collections	$1,152,538,861	$1,159,139,951	+0.5%
Review Process Cost	$1,499,064,056	$1,480,601,875	-1.2%

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, 2022.

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

[8] See https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports.

Table 40. Time Reporting Requirement for FY 2022

Center	FTEs for Which Time Reporting Is Required	FTEs for Which Time Reporting Is Not Required
CDER	5,430	12
CBER	1,232	5
ORA	4,422	280
OC	55	2,632

Appendix A: List of Approved Applications

This appendix includes detailed review histories of the NDA and BLA submissions approved under PDUFA VI in FY 2022. 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 2022 can be found in the appendices of the earlier PDUFA performance reports.[9]

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 for the average year length, which considers leap years, to calculate review time in months. Prior to FY 2022, FDA did not consider leap years in its calculations, which may have caused a submission to appear overdue even though it was approved on the goal date.

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[10]

[9] http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

[10] 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.

Table A-1. FY 2022 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 2022							
midazolam	RAFA LABORATORIES Ltd.	N	First	4.4	AP	4.4	Y
IMBRUVICA (ibrutinib)	PHARMACYCLICS LLC	N	First	5.9	AP	5.9	Y
RADICAVA ORS (edaravone)	MITSUBISHI TANABE PHARMA Corp.	N	First	5.9	AP	5.9	Y
VIJOICE (alpelisib)	NOVARTIS PHARMACEUTICALS Corp.	N	First	5.9	AP	5.9	Y
ELUCIREM (gadopiclenol)	GUERBET, LLC	Y	First	8.0	AP	8.0	Y♦
LYTGOBI (futibatinib)	TAIHO ONCOLOGY Inc.	Y	First	8.0	AP	8.0	Y♦
XENPOZYME (olipudase alfa-rpcp)	GENZYME CORPORATION	Y	First	9.9	AP	9.9	Y#♦
SKYSONA (elivaldogene autotemcel)	bluebird bio Inc.	Y	First	10.9	AP	10.9	Y#♦
RELYVRIO (sodium phenylbutyrate and taursodiol)	AMYLYX PHARMACEUTICALS Inc.	Y	First	11.0	AP	11.0	Y#♦
SPEVIGO (spesolimab-sbzo)	BOEHRINGER INGELHEIM PHARMACEUTICALS, Inc.	Y	First	11.0	AP	11.0	Y#♦
Submitted in FY 2021							
SCEMBLIX (asciminib)	NOVARTIS PHARMACEUTICALS Corp.	Y	First	4.2	AP	4.2	Y♦
APRETUDE (cabotegravir)	VIIV HEALTHCARE Co.	N	First	4.9	AP	4.9	Y
SPIKEVAX (COVID-19 Vaccine, mRNA)	ModernaTX, Inc.	Y	First	5.2	AP	5.2	Y♦
OXBRYTA (voxelotor)	GLOBAL BLOOD THERAPEUTICS Inc.	N	First	5.7	AP	5.7	Y
FYARRO (sirolimus protein-bound particles for injectable suspension (albumin-bound)	AADI BIOSCIENCE Inc.	N	First	5.8	AP	5.8	Y
naloxone	KALEO Inc.	N	First	5.9	AP	5.9	Y
TRIUMEQ PD (abacavir, dolutegravir, and lamivudine)	VIIV HEALTHCARE Co.	N	First	5.9	AP	5.9	Y
XARELTO (rivaroxaban)	JANSSEN PHARMACEUTICALS Inc.	N	First	5.9	AP	5.9	Y
SUSVIMO (ranibizumab)	GENENTECH, Inc.	N	First	6.0	AP	6.0	Y
XACIATO (clindamycin phosphate)	DARE BIOSCIENCE Inc.	N	First	6.0	AP	6.0	Y

KIMMTRAK (tebentafusp-tebn)	IMMUNOCORE LIMITED	Y	First	7.1	AP	7.1	Y♦
TEZSPIRE (tezepelumab-ekko)	ASTRAZENECA AB	Y	First	7.4	AP	7.4	Y♦
PLUVICTO (lutetium (177lu) vipivotide tetraxetan)	ADVANCED ACCELERATOR APPLICATIONS USA Inc.	Y	First	7.8	AP	7.8	Y♦
MOUNJARO (tirzepatide)	ELI LILLY AND Co.	Y	First	7.9	AP	7.9	Y♦
ZTALMY (ganaxolone)	MARINUS PHARMACEUTICALS Inc.	Y	First	7.9	AP	7.9	Y♦
LIVTENCITY (maribavir)	TAKEDA PHARMACEUTICALS USA Inc.	Y	First	8.0	AP	8.0	Y♦
OPDUALAG (nivolumab and relatlimab-rmbw)	BRISTOL-MYERS SQUIBB COMPANY	Y	First	8.0	AP	8.0	Y♦
PYRUKYND (mitapivat)	AGIOS PHARMACEUTICALS Inc.	Y	First	8.0	AP	8.0	Y♦
VABYSMO (faricimab-svoa)	GENENTECH, Inc.	Y	First	8.0	AP	8.0	Y♦
VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin, co-packaged)	PHATHOM PHARMACEUTICALS Inc.	Y	First	8.0	AP	8.0	Y♦
VOQUEZNA DUAL PAK (vonoprazan; amoxicillin co-packaged)	PHATHOM PHARMACEUTICALS Inc.	N[11]	First	8.0	AP	8.0	Y
NEPHROSCAN (technetium tc99m succimer)	THERAGNOSTICS Inc.	N	First	9.0	AP	9.0	Y#
SKYRIZI (risankizumab-rzaa)	ABBVIE Inc.	N	First	9.0	AP	9.0	Y#
TARPEYO (budesonide)	CALLIDITAS THERAPEUTICS AB	N	First	9.0	AP	9.0	Y#
ZYNTEGLO (betibeglogene autotemcel)	bluebird bio Inc.	Y	First	10.9	AP	10.9	Y#♦
CARVYKTI (ciltacabtagene autoleucel)	Janssen Biotech, Inc.	Y	First	11.0	AP	11.0	Y#♦
CYTALUX (pafolacianine sodium)	ON TARGET LABORATORIES Inc.	Y	First	11.0	AP	11.0	Y#♦
VIVJOA (oteseconazole)	MYCOVIA PHARMACEUTICALS Inc.	Y	First	11.0	AP	11.0	Y#♦
VONJO (pacritinib)	CTI BIOPHARMA Corp.	Y	First	11.0	AP	11.0	Y#♦
TYVASO DPI (treprostinil)	UNITED THERAPEUTICS Corp.	N	First	6.0	CR	6.0	Y
			Sponsor	2.3		8.3	

[11] The applicant submitted two NDAs for the same new moiety (vonoprazan), but one of the NDAs is in combination with two currently marketed drugs (amoxicillin and clarithromycin). The other NDA is in combination with only one currently marketed drug (amoxicillin). Only one NDA retains the NME designation upon approval; in this case, the NDA for the vonoprazan along with amoxicillin and clarithromycin retained the NME designation.

			Second	5.0	AP	13.3	Y#▲
AUVELITY (dextromethorphan hydrobromide and bupropion hydrochloride)	AXSOME THERAPEUTICS Inc.	N	First	17.8	AP	17.8	N
Submitted in FY 2020							
VOXZOGO (vosoritide)[12]	BIOMARIN PHARMACEUTICAL Inc.	Y	First	15.0	AP	15.0	Y#♦
CIBINQO (abrocitinib)	PFIZER Inc.	Y	First	16.7	AP	16.7	N#♦
ENJAYMO (sutimlimab-jome)	BIOVERATIV USA, Inc.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	8.7		16.7	
			Second	6.0	AP	22.7	Y△

Table A-2. FY 2022 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 2022							
IHEEZO (chloroprocaine hydrochloride)	SINTETICA SA	N	First	9.4	AP	9.4	Y
norepinephrine bitartrate	INFORLIFE SA	N	First	9.9	AP	9.9	Y
APONVIE (aprepitant)	HERON THERAPEUTICS Inc.	N	First	10.0	AP	10.0	Y
CALQUENCE (acalabrutinib maleate)	ASTRAZENECA UK Ltd.	N	First	10.0	AP	10.0	Y
Submitted in FY 2021							
LOCAMETZ (gallium (68ga) gozetotide)	ADVANCED ACCELERATOR APPLICATIONS USA Inc. A NOVARTIS Co.	N	First	7.8	AP	7.8	Y
VUITY (pilocarpine hydrochloride)	ABBVIE Inc.	N	First	8.1	AP	8.1	Y
paclitaxel	TEVA PHARMACEUTICALS Inc.	N	First	9.5	TA	9.5	Y
atropine sulfate	BAUSCH AND LOMB Inc.	N	First	9.6	AP	9.6	Y
DARTISLA ODT (glycopyrrolate)	EDENBRIDGE PHARMACEUTICALS LLC	N	First	9.6	AP	9.6	Y
ENTADFI (finasteride and tadalafil)	VERU Inc.	N	First	9.7	AP	9.7	Y
ACUVUE THERAVISION WITH KETOTIFEN (etafilcon a lens with ketotifen)	JOHNSON AND JOHNSON VISION CARE Inc.	N	First	9.9	AP	9.9	Y
BLUDIGO (indigotindisulfonate sodium)	PROVEPHARM SAS	N	First	9.9	AP	9.9	Y
CUVRIOR (trientine tetrahydrochloride)	ORPHALAN SA	N	First	9.9	AP	9.9	Y
diltiazem hydrochloride	EXELA PHARMA SCIENCES LLC	N	First	9.9	AP	9.9	Y
dolutegravir, lamivudine and tenofovir alafenamide	CIPLA Ltd.	N	First	9.9	TA	9.9	Y◊
TYRVAYA (varenicline solution)	OYSTER POINT PHARMA Inc.	N	First	9.9	AP	9.9	Y
ASPRUZYO (ranolazine)	SUN PHARMA INDUSTRIES Ltd.	N	First	10.0	AP	10.0	Y
bendamustine hydrochloride	APOTEX Inc.	N	First	10.0	TA	10.0	Y
bendamustine hydrochloride	DR REDDYS LABORATORIES Ltd.	N	First	10.0	TA	10.0	Y
bendamustine hydrochloride	CELERITY PHARMACEUTICALS LLC	N	First	10.0	TA	10.0	Y
bortezomib	MAIA PHARMACEUTICALS Inc.	N	First	10.0	AP	10.0	Y

CELMITY (citalopram)	ALMATICA PHARMA Inc.	N	First	10.0	AP	10.0	Y
dolutegravir, lamivudine and tenofovir alafenamide	LAURUS LABS Ltd.	N	First	10.0	TA	10.0	Y◊
drospirenone	EXELTIS USA Inc.	N	First	10.0	AP	10.0	Y
ERMEZA (levothyroxine sodium)	MYLAN PHARMACEUTICALS Inc. A VIATRIS Co.	N	First	10.0	AP	10.0	Y
FLEQSUVY (baclofen)	AZURITY PHARMACEUTICALS Inc.	N	First	10.0	AP	10.0	Y
glycopyrrolate	FRESENIUS KABI USA LLC	N	First	10.0	AP	10.0	Y
LYVISPAH (baclofen)	AMNEAL PHARMACEUTICALS LLC	N	First	10.0	AP	10.0	Y
midazolam	EXELA PHARMA SCIENCES LLC	N	First	10.0	AP	10.0	Y
NASONEX 24HR ALLERGY (mometasone furoate)	PERRIGO PHARMA INTERNATIONAL DAC	N	First	10.0	AP	10.0	Y
RECORLEV (levoketoconazole)	STRONGBRIDGE DUBLIN Ltd.	N	First	10.0	AP	10.0	Y
RELEXXII (methylphenidate hydrochloride)	OSMOTICA PHARMACEUTICAL US LLC	N	First	10.0	AP	10.0	Y
roflumilast	ARCUTIS BIOTHERAPEUTICS Inc.	N	First	10.0	AP	10.0	Y
sertraline hydrochloride capsules	ALMATICA PHARMA LLC	N	First	10.0	AP	10.0	Y
testosterone cypionate	SLAYBACK PHARMA LLC	N	First	10.0	AP	10.0	Y
venlafaxine extended-release tablets	ALMATICA PHARMA LLC	N	First	10.0	AP	10.0	Y
PHEBURANE (sodium phenylbutyrate)	MEDUNIK CANADA Inc.	N	First	10.1	AP	10.1	N
VTAMA (tapinarof)	DERMAVANT SCIENCES Inc.	Y	First	11.9	AP	11.9	Y♦
PREHEVBRIO (Hepatitis B Vaccine (Recombinant))	VBI Vaccines (Delaware), Inc.	Y	First	12.0	AP	12.0	Y♦
PRIORIX (Measles, Mumps and Rubella Virus Vaccine Live)	GlaxoSmithKline Biologicals	Y	First	12.0	AP	12.0	Y♦
QUVIVIQ (daridorexant)	IDORSIA PHARMACEUTICALS Ltd.	Y	First	12.0	AP	12.0	Y♦
SOTYKTU (deucravacitinib)	BRISTOL MYERS SQUIBB Co.	Y	First	12.0	AP	12.0	Y♦
VYVGART (efgartigimod alfa-fcab)	ARGENX BV	Y	First	12.0	AP	12.0	Y♦
TASCENSO ODT (fingolimod)	HANDA NEUROSCIENCE LLC	N	First	10.0	TA	10.0	Y
			Sponsor	0.3		10.3	
			Second	1.9	AP	12.2	Y▲
TPOXX (tecovirimat)	SIGA TECHNOLOGIES Inc.	N	First	12.6	AP	12.6	Y#
lanreotide acetate	INVAGEN PHARMACEUTICALS Inc.	N	First	12.7	AP	12.7	N

DHIVY (carbidopa and levodopa)	AVION PHARMACEUTICALS LLC	N	First	12.9	AP	12.9	Y#
XELSTRYM (dextroamphetamine)	NOVEN PHARMACEUTICALS Inc.	N	First	12.9	AP	12.9	Y#
EPRONTIA (topiramate)	AZURITY PHARMACEUTICALS Inc.	N	First	13.0	AP	13.0	Y#
IGALMI (dexmedetomidine)	BIOXCEL THERAPEUTICS Inc.	N	First	13.0	AP	13.0	Y#
AMVUTTRA (vutrisiran)	ALNYLAM PHARMACEUTICALS Inc.	Y	First	14.0	AP	14.0	Y#♦
CAMZYOS (mavacamten)	MYOKARDIA Inc.	Y	First	14.9	AP	14.9	Y#♦
KYZATREX (testosterone undecanoate)	MARIUS PHARMACEUTICALS LLC	N	First	9.7	CR	9.7	Y
			Sponsor	3.2		12.9	
			Second	5.9	AP	18.8	Y△

Second	5.8AP	21.1Y△

SEGLENTIS (celecoxib and tramadol hydrochloride)	KOWA PHARMACEUTICALS AMERICA Inc.	N	First	13.0	CR	13.0	Y#
			Sponsor	10.0		23.0	
			Second	6.0	AP	29.0	Y △

pemetrexed	HOSPIRA Inc.	N	First	9.8	CR	9.8	Y
			Sponsor	36.0		45.8	
			Second	6.0	TA	51.8	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 2022 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.

Table B-1. Original Applications Filed in FY 2022 by Review Division/Office

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CDER Review Divisions					
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	2	0	0	1
Division of Anti-Infectives	2	2	0	0	1
Division of Antivirals	1	3	2	0	0
Division of Cardiology and Nephrology	1	6	0	0	1
Division of Dermatology and Dentistry	0	2	1	0	2
Division of Diabetes, Lipid Disorders, and Obesity	0	1	0	0	0
Division of Gastroenterology	0	3	0	1	0
Division of General Endocrinology	1	0	0	0	1
Division of Hematologic Malignancies I	1	4	0	0	1
Division of Hematologic Malignancies II	1	4	4	0	0
Division of Hepatology and Nutrition	0	1	0	0	0
Division of Imaging and Radiation Medicine	1	3	0	0	2
Division of Neurology I	5	5	2	0	2
Division of Neurology II	2	2	0	0	0
Division of Non-Malignant Hematology	0	5	0	0	2
Division of Non-Prescription Drugs I	0	0	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Oncology I	1	2	1	2	1
Division of Oncology II	1	2	1	1	2
Division of Oncology III	1	0	2	0	0
Division of Ophthalmology	1	5	0	1	1
Division of Psychiatry	0	4	0	0	1
Division of Pulmonology, Allergy, and Critical Care	2	1	0	0	0
Division of Rare Diseases and Medical Genetics	0	0	2	0	0
Division of Rheumatology and Transplant Medicine	0	1	0	0	0
Division of Urology, Obstetrics, and Gynecology	1	1	0	1	0
CDER Totals	*22*	*59*	*15*	*6*	*18*
CBER Review Offices					
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	0	0	7	2	0
Office of Vaccines Research and Review	0	0	0	5	0
CBER Totals	*0*	*0*	*7*	*7*	*0*
FDA Totals	**22**	**59**	**22**	**13**	**18**

Table B-2. Efficacy Supplements Filed in FY 2022 by Review Division/Office

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Review Divisions			
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	2	1
Division of Anti-Infectives	2	3	0
Division of Antivirals	8	4	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Cardiology and Nephrology	0	5	1
Division of Dermatology and Dentistry	5	3	1
Division of Diabetes, Lipid Disorders, and Obesity	2	4	3
Division of Gastroenterology	1	3	0
Division of General Endocrinology	0	7	0
Division of Hematologic Malignancies I	6	6	0
Division of Hematologic Malignancies II	5	6	0
Division of Hepatology and Nutrition	0	0	1
Division of Imaging and Radiation Medicine	3	3	0
Division of Neurology I	3	4	0
Division of Neurology II	0	9	0
Division of Non-Malignant Hematology	3	3	0
Division of Non-Prescription Drugs I	0	3	0
Division of Non-Prescription Drugs II	0	2	0
Division of Oncology I	8	29	2
Division of Oncology II	7	11	0
Division of Oncology III	7	6	4
Division of Ophthalmology	1	4	0
Division of Psychiatry	1	5	0
Division of Pulmonology, Allergy, and Critical Care	2	7	0
Division of Rare Diseases and Medical Genetics	0	1	0
Division of Rheumatology and Transplant Medicine	3	2	2
Division of Urology, Obstetrics, and Gynecology	0	7	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Totals	*67*	*139*	*15*
CBER Review Offices			
Office of Blood Research and Review	0	0	0
Office of Tissues and Advanced Therapies	1	2	0
Office of Vaccines Research and Review	1	18	0
CBER Totals	*2*	*20*	*0*
FDA Totals	**69**	**159**	**15**

Table B-3. Submissions with Special Designations Filed in FY 2022 by Review Division/Office

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
CDER Review Divisions				
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	0	0	1
Division of Anti-Infectives	0	3	1	1
Division of Antivirals	1	3	1	0
Division of Cardiology and Nephrology	1	1	2	3
Division of Dermatology and Dentistry	0	1	1	1
Division of Diabetes, Lipid Disorders, and Obesity	0	0	0	0
Division of Gastroenterology	0	0	1	0
Division of General Endocrinology	0	1	2	0
Division of Hematologic Malignancies I	0	1	5	0
Division of Hematologic Malignancies II	3	1	6	1
Division of Hepatology and Nutrition	0	0	0	0
Division of Imaging and Radiation Medicine	0	0	0	0
Division of Neurology I	2	6	11	2

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*
Division of Neurology II	0	1	1	0
Division of Non-Malignant Hematology	0	0	5	0
Division of Non-Prescription Drugs I	0	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0
Division of Oncology I	1	4	1	2
Division of Oncology II	1	2	5	9
Division of Oncology III	1	2	3	1
Division of Ophthalmology	0	1	0	0
Division of Psychiatry	0	0	0	0
Division of Pulmonology, Allergy, and Critical Care	0	1	1	1
Division of Rare Diseases and Medical Genetics	0	2	2	1
Division of Rheumatology and Transplant Medicine	0	0	0	0
Division of Urology, Obstetrics, and Gynecology	0	0	0	0
CDER Totals	*10*	*30*	*48*	*23*
CBER Review Offices				
Office of Blood Research and Review	0	0	0	0
Office of Tissues and Advanced Therapies	0	2	7	3
Office of Vaccines Research and Review	0	3	3	3
CBER Totals	*0*	*5*	*10*	*6*
FDA Totals	**10**	**35**	**58**	**29**

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2022. BT designation is granted based on indication, and therefore, one submission may have more than one BT designation granted.

Appendix C: Analysis of Use of Funds

On August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to, among other things, revise and extend the user fee programs for prescription drugs, 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 2022. Data represent all the original NDA and BLA approvals that occurred during FY 2022, 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 first cycle approvals, multiple cycle approvals, and tentative approvals. However, performance is calculated based 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, would not affect the performance metric regardless of the fiscal year of the first 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 2022.

Table C-1. FY 2022 Original Application Approval Cycle Summary

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	27	26	1	**96%**
First Cycle Standard NMEs & BLAs	10 months of filing date	9	9	0	**100%**
First Cycle Priority Non-NME NDAs	6 months	15	14	1	**93%**
First Cycle Standard Non-NME NDAs	10 months	52	48	4	**92%**
Class 1 Resubmissions	2 months	1	1	0	**100%**
Class 2 Resubmissions	6 months	34	30	4	**88%**
Total		**138**	**128**	**10**	**--**[*]

[*] 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.[14]

For 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.

The table below represents FDA's FY 2021 updated performance.

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

Table C-2. FY 2021 Performance Enhancement Goals (Updated)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
FY 2021 PDUFA Quarterly Hiring Web Posting (Quarter 4)	10/14/2021	N	10/21/2021	This target goal date is an internal goal set by FDA. The Commitment Letter does not specify a timeline for posting. 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 2022 performance.

Table C-3. FY 2022 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
CY 2021 FDA Data Standards Action Plan Quarterly Updates (Quarter 4)	12/31/2021	Y	10/26/2021	Data Standards Program Strategic Plan and Board (see https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board)
Final Assessment for Hiring and Retention	12/31/2021	Y	12/10/2021	FDA Final Hiring and Retention Assessment Final Report (see https://www.fda.gov/media/154873/download)
FY 2022 PDUFA Quarterly Hiring Web Posting (Quarter 1)	1/14/2022	Y	1/13/2022	FDARA hiring data (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
CY 2022 FDA Data Standards Action Plan Quarterly Updates (Quarter 1)	3/30/2022	Y	2/9/2022	Data Standards Program Strategic Plan and Board (see https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board)
Public Meeting for Final Assessment for Hiring and Retention	3/30/2022	Y	3/15/2022	FDA PDUFA Hiring and Retention Final Assessment Public Meeting (see https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-pdufa-hiring-and-retention-final-assessment-public-meeting-03152022)
FY 2022 Annual Update to 5-Year Financial Plan	3/31/2022	Y	3/30/2022	User Fee Five-Year Financial Plans (see https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans)
FY 2022 PDUFA Quarterly Hiring Web Posting (Quarter 2)	4/14/2022	Y	4/12/2022	FDARA hiring data (see https://www.fda.gov/industry/prescription

				-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
CY 2022 FDA Data Standards Action Plan Quarterly Updates (Quarter 2)	6/20/2022	Y	5/5/2022	Data Standards Program Strategic Plan and Board (see https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board)
FY 2022 Financial Public Meeting	6/30/2022	Y	6/7/2022	2022 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic User Fee Amendments (see https://www.fda.gov/drugs/news-events-human-drugs/2022-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act)
FY 2022 PDUFA Quarterly Hiring Web Posting (Quarter 3)	7/14/2022	N	7/26/2022	This target goal date is an internal goal set by FDA. The Commitment Letter does not specify a timeline for posting. FDARA hiring data (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
Analyze and Report on the Impact of the Sentinel Expansion and Integration on FDA's Use of Sentinel for Regulatory Purposes	9/30/2022	Y	6/25/2019	FDA's Sentinel Initiative (see https://www.fda.gov/safety/fdas-sentinel-initiative#:~:text=Sentinel%20is%20the%20FDA's%20national,FDA%20launched%20the%20Sentinel%20Initiative and click on the "Sentinel Initiative" link) Also, FDA published a report titled *Assessment in Support of Sentinel System* (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-commitment-assessment-support-sentinel-system)
FY 2022 Annual ESG and Standard Metrics - Submission Statistics	9/30/2022	Y	9/15/2021	Submission Statistics (see https://www.fda.gov/industry/about-esg/submission-statistics)
FY 2022 Annual Public Meeting for IT Strategic Plan	9/30/2022	Y	4/12/2022	PDUFA VI Information Technology Goals and Progress (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress)
Assessment of Postmarket Safety Systems and Processes	9/30/2022	Y	7/29/2022	
Evaluation of the Implementation of the Benefit-Risk Framework in the Human Drug Review Program	9/30/2022	Y	9/2/2022	

CY 2022 FDA Data Standards Action Plan Quarterly Updates (Quarter 3)	9/30/2022	Y	8/10/2022	Data Standards Program Strategic Plan and Board (see https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board)
Final Guidance on Bridging Studies, Including the Bridging of Data from Combination Products	9/30/2022	N	N/A	A draft guidance document on this topic was published in December 2019 (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bridging-drug-device-and-biologic-device-combination-products), and the final guidance document is in progress.
FY 2022 Annual Discussion of IT Strategic Plan	9/30/2022	Y	8/6/2021	
FY 2022 E-subs and Data Standards Quarterly Meetings (Quarter 1)	9/30/2022	Y	11/9/2021	
FY 2022 E-subs and Data Standards Quarterly Meetings (Quarter 2)	9/30/2022	Y	2/22/2022	
FY 2022 E-subs and Data Standards Quarterly Meetings (Quarter 3)	9/30/2022	Y	6/14/2022	
FY 2022 E-subs and Data Standards Quarterly Meetings (Quarter 4)	9/30/2022	Y	9/12/2022	
FY 2022 MIDD Quarterly Selections and Meetings (Quarter 1)	9/30/2022	Y	10/8/2021	
FY 2022 MIDD Quarterly Selections and Meetings (Quarter 2)	9/30/2022	Y	1/12/2022	
FY 2022 MIDD Quarterly Selections and Meetings (Quarter 3)	9/30/2022	Y	4/8/2022	
FY 2022 MIDD Quarterly Selections and Meetings (Quarter 4)	9/30/2022	Y	7/8/2022	
Final Guidance on Patient-Oriented Labeling	9/30/2022	Y	7/15/2022	Instructions for Use – Patient Labeling for Human Prescription Drug and Biological Products – Content and Format (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/instructions-use-patient-labeling-human-prescription-drug-and-biological-products-content-and-format)
FY 2022 CID Pilot Program Quarterly Meetings (Quarter 1)	9/30/2022	Y	12/12/2021	
FY 2022 CID Pilot Program Quarterly Meetings (Quarter 2)	9/30/2022	Y	1/28/2022	

FY 2022 CID Pilot Program Quarterly Meetings (Quarter 3)	9/30/2022	Y	4/29/2022	
FY 2022 CID Pilot Program Quarterly Meetings (Quarter 4)	9/30/2022	Y	7/29/2022	
FY 2022 PDUFA Hiring Goals	9/30/2022	N	N/A	FDA's FY 2022 hiring goal was for nine FTEs, and five FTEs were onboarded (56% of the FY 2022 hiring goal). FDARA hiring data (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data)
Hold MIDD Public Workshop on Disease Progression Model Development	N/A	Y	11/19/2021	Best Practices for Development and Application of Disease Progression Models (see https://www.fda.gov/drugs/news-events-human-drugs/best-practices-development-and-application-disease-progression-models-11192021)
Publish Summary Topics Discussed in MIDD Public Workshop on Disease Progression Model Development	N/A	N	N/A	The summary is currently in progress.
Hold MIDD Public Workshop on Immunogenicity and Correlates of Protection	N/A	Y	6/9/2021	Model Informed Drug Development Approaches for Immunogenicity Assessments (see https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/model-informed-drug-development-approaches-immunogenicity-assessments-06092021-06092021)
Publish Summary Topics Discussed in MIDD Public Workshop on Immunogenicity and Correlates of Protection	N/A	Y	3/6/2022	Summary of a Public FDA Workshop: Model Informed Drug Development Approaches for Immunogenicity Assessments (see https://doi.org/10.1002/cpt.2572)
Focused Guidance on Specific Biomarkers Uses and Contexts to Supplement Draft Guidance on General Evidentiary Standards	N/A	N	N/A	After the guidance document on evidentiary framework for biomarker qualification is published, FDA will continue to evaluate the potential need for a supplemental focused guidance and publish such guidance accordingly.

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.

Table C-4. FY 2022 Performance Results

Cause or Trend	Impact on FDA's Commitments
Public Health Emergencies	• The continuing COVID-19 health pandemic and the emergence of monkeypox required FDA to shift resources towards addressing these health emergencies, which impacted the goals that were eventually missed. The increased workload, including Emergency Use Authorizations and meeting requests, continue to constrain FDA's resources.* • Required in-person inspections may not have been able to be conducted within normal time frames due to restrictions set forth by other national entities and travel restrictions in place to protect the safety and well-being of staff.
Specialty Candidates	• The federal hiring process (e.g., security and ethics clearances) delayed the onboarding process. In addition to last minute declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.
High Volume of Meeting Requests and Hiring Challenges	• In FY 2022, FDA continued to receive an increased volume of meeting requests as compared to the pre-pandemic levels. Challenges in hiring led to net increased staffing that still did not meet the high demand of the review and formal meeting workload.

* Additional information on FDA's COVID-19 pandemic-related activities may be found on the Coronavirus Treatment Acceleration Program (CTAP) website (see https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap) and the Emergency Use Authorization web page (see https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

Appendix D: FY 2022 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.

A. Executive Summary

Table D-1 below represents FDA's FY 2021 updated performance results for goal types that the Agency was not able to fully report in last year's report. If a goal type is not listed in this table for FY 2021, then the Agency fully reported on it in last year's report.[15]

Table D-1. FY 2021 Review Goal Performance Results (Updated)

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Procedural and Process Goals	• Major Dispute Resolutions ○ In FY 2021, FDA received 14 requests for formal dispute resolution, many accompanied by a request for a Type A meeting. ○ Dispute resolution typically involves complex regulatory, policy, and legal issues, necessitating coordination across multiple offices as well as participation of leadership at the Center, Super Office, Office, and Review Division level. ○ The management of disputes increases the workload for numerous staff already experiencing a heavy load of other regulatory, review, policy, and legal work.	• Major Dispute Resolutions ○ FDA continues to assess ways to more effectively handle the large volume of requests for formal dispute resolution received each year in addition to completing other regulatory and review work.

Table D-2. FY 2022 Review Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Procedural and Processing Goals	• Meeting Management Goals: ○ There were 4,384 meeting requests in FY 2022. The volume of formal PDUFA meeting requests continued to be high compared to pre-pandemic levels. ○ In addition to regular workloads, the workload continued to increase due to the ongoing COVID-19 pandemic and the emergence of monkeypox. ○ An increased workload, including for Emergency Use Authorizations and meeting requests, continue to constrain FDA's resources.	• Meeting Management Goals: ○ FDA continues to assess ways to more effectively handle the large volume of formal meeting requests received each year in addition to completing other regulatory and review work.
	• Human Factors Protocol Submissions:	• Human Factors Protocol Submissions Goals:

[15] https://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
	○ In FY 2022, FDA received 59 human factors protocol submissions that were subject to PDUFA goal dates. ○ Staffing levels for work related to these submissions is inadequate due to the volume of workload, loss of staff, and continued prioritization of work related to the COVID-19 pandemic. ○ Due to the technical and specialized nature of the work, staff with appropriate training and background are needed, and the use of non-specialized staff to support the work requires a larger learning curve before such staff can achieve the same capacity and efficiency as an experienced employee.	○ FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the high workload of the human factors program. ○ FDA will continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring. Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work.
	• Major Dispute Resolutions ○ In FY 2022, FDA received 13 requests for formal dispute resolution, many accompanied by a request for a Type A meeting. ○ Dispute resolution typically involves complex regulatory, policy, and legal issues, necessitating coordination across multiple offices as well as participation of leadership at the Center, Super Office, Office, and Review Division level. ○ The management of disputes increases the workload for numerous staff already experiencing a heavy load of other regulatory, review, policy, and legal work.	• Major Dispute Resolution ○ FDA continues to assess ways to more effectively handle the large volume of requests for formal dispute resolution received each year in addition to completing other regulatory and review work.
	• Proprietary Name Submitted During IND Phase ○ In FY 2022, FDA received 191 proprietary name submissions during the IND phase that were subject to PDUFA goal dates. ○ An increasing proprietary name submission workload, combined with staffing shortages stemming from the COVID-19 response and other factors, impacted performance on proprietary name submission procedural goals during the IND phase.	• Proprietary Name Submitted During IND Phase ○ FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the proprietary name program. ○ FDA will continue to use hiring authority to advance hiring. ○ FDA will continue to strive to meet PDUFA goals related to proprietary name submissions.

Table D-3. FY 2022 Performance Enhancement Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Guidance Documents	• Final guidance document on bridging studies: ○ In FY 2022, staffing levels for work on this guidance document were reduced for extensive periods of time due to the loss of experienced employees who left the Agency or took on different roles and due to the continued prioritization of work related to the COVID-19 pandemic.	• Final guidance document on bridging studies: ○ Once adequate resources/personnel are available, FDA will resume its work on finalizing this guidance document.
Human Capital/Hiring	• CDER's FY 2022 PDUFA hiring goals were not met; however, constant recruitment efforts and sourcing strategies were used on all vacancies throughout the year consistent with the corrective actions outlined in the FY 2021 report to Congress. For the four remaining vacancies, one candidate is pending a final offer, and one candidate accepted the position but later declined to onboard. In addition to last-minute declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.	○ CDER plans to continue to advance the corrective actions outlined in the FY 2021 report to Congress and pursue new strategies to support hiring. In addition, CDER plans to partner with the Office of Talent Solutions to expand its outreach capacity and recruitment strategies to mitigate the challenges faced with finding candidates with unique specialties in FY 2022.

B. 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 2022, 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 2022.

I. FY 2021 Updated Review Goal Performance Results

A. Summary of Performance:

FDA missed the following procedural and processing goal: Major Dispute Resolution.

B. Justification:

In FY 2021, FDA received 14 requests for formal dispute resolution, many accompanied by request for a Type A meeting. Dispute resolution typically involves complex regulatory, policy, and legal issues, necessitating coordination across multiple offices as well as participation of leadership at the Center, Super Office, Office, and Review Division level. The management of disputes increases the workload for numerous staff already experiencing a heavy load of other regulatory, review, policy, and legal work.

C. FY 2022 Corrective Actions:

FDA continues to assess ways to more effectively handle the large volume of requests for formal dispute resolution received each year in addition to completing other regulatory and review work.

II. FY 2022 Review and Procedural and Processing Performance Results

A. Summary of Performance:

FDA missed the following procedural and processing goals:

- Meeting request for Type A, B, 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)
- Human Factors Protocol Submission
- Major Dispute Resolution
- Proprietary Name Submitted During IND Phase

B. Justification:

Meeting Management Goals

In FY 2022, in addition to FDA's application review workload, FDA held or provided written responses to over 4,100 formal PDUFA meetings. Prior to the public health emergency, formal meetings were steadily increasing each year at a rate that ranged between 2 percent and 8 percent. While the number of FY 2022 formal meetings held or written responses issued decreased slightly (-4%) when compared to FY 2021, the FY 2022 formal meetings still represented a 16 percent increase in meetings when compared to pre-pandemic numbers. Although the Agency was able to hire additional staff, difficulties related to the hiring process resulted in net gains that were not sufficient to handle this increased meeting workload.

Human Factors Protocol Submissions

In FY 2022, FDA received 59 human factors protocol submissions that were subject to PDUFA goal dates. The continued high workload, insufficient staffing, and difficulty hiring new staff with the background and experience to conduct this specialized work resulted in difficulty achieving the human factors protocol submission goal.

Major Dispute Resolution

FDA continues to assess ways to more effectively handle the large volume of requests for formal dispute resolution received each year in addition to completing other regulatory and review work.

Proprietary Name Submitted During IND Phase

In FY 2022, FDA received 191 proprietary name submissions during the IND phase that were subject to PDUFA goal dates. An increasing proprietary name submission workload, combined with staffing shortages stemming from the COVID-19 response and other factors, impacted performance on proprietary name submission procedural goals during the IND phase.

C. FY 2023 Corrective Actions:

Review and Meeting Management Goals

FDA continues to assess ways to more effectively handle the marketing applications, meeting requests, and other regulatory submissions received each year. In addition, FDA continues to work on improving hiring.

Human Factors Protocol Submissions

FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the high workload in the human factors program.

FDA will also continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring. Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work.

Major Dispute Resolution

FDA continues to assess ways to more effectively handle the large volume of requests for formal dispute resolution received each year in addition to completing other regulatory and review work.

Proprietary Name Submitted During IND Phase

FDA will re-evaluate its resource allocation to ensure that adequate resources are allotted to support the proprietary name program and will continue to use its hiring authority to advance hiring.

C. 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 2023 Corrective Actions").

This section presents non-review performance goals cited in the PDUFA VI Commitment Letter with required completion dates in FY 2022. For 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 2023 will be covered in subsequent corrective action reports.

III. Guidances

A. Summary of Performance:

The PDUFA goal date for the following guidance documents were missed:

- Final guidance document on bridging studies, including the bridging of data from combination products that employ different device components for the same drug or biologic and the same device component across different drugs and biologics.

B. Justification:

In FY 2022, staffing levels for this work were reduced for extensive periods of time due to the loss of experienced employees who left the Agency or took on different roles and due to the continued prioritization of work related to the COVID-19 pandemic.

C. FY 2023 Corrective Actions:

Once adequate resources/personnel are available, FDA will resume work on finalizing this guidance.

IV. Human Capital/Hiring

A. Summary of Performance:

FDA missed the PDUFA goal for hiring in FY 2022. Specifically, five out of nine employees (56 percent) were hired.

B. Justification:

CDER's FY 2022 PDUFA hiring goals were not met; however, constant recruitment efforts and sourcing strategies were used on all vacancies throughout the year consistent with the corrective actions outlined in the FY 2021 report to Congress. For the four remaining vacancies, one candidate is pending a final offer, and one candidate accepted the position but later declined to onboard. In addition to last-minute declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.

C. FY 2023 Corrective Actions:

CDER plans to continue to advance the corrective actions outlined in the FY 2021 report to Congress and pursue new strategies to support hiring. In addition, CDER plans to partner with the Office of Talent Solutions to expand its outreach capacity and recruitment strategies to mitigate the challenges faced with finding candidates with unique specialties in FY 2022.

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,[16] 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

[16] https://www.fda.gov/media/132157/download.

FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

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

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

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 http://www.fda.gov/media/71236/download.

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Office of Planning, Evaluation, and Risk Management
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: (301) 796-4850
Email: OPERM_ADMIN_Team@fda.hhs.gov

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