Performance Report to Congress

Prescription Drug User Fee Act

FY 2024

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. With respect to products covered by PDUFA, the FDA committed to certain review performance goals, procedural and processing goals, and other commitments.

PDUFA has been reauthorized by Congress every 5 years. The sixth reauthorization (known as PDUFA VII) occurred on September 30, 2022, when the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Public Law No. 117-180, of which Division F is titled the FDA User Fee Reauthorization Act of 2022 (FUFRA). FUFRA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize the PDUFA program for an additional 5 years and is effective from fiscal year (FY) 2023 through FY 2027.

As directed by Congress, FDA developed proposed enhancements for PDUFA VII in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. These discussions led to the current set of performance goals for the FY 2023 to FY 2027 period, detailed in a document commonly known as the PDUFA VII Commitment Letter.[1]

This report summarizes FDA's performance results in meeting PDUFA goals and commitments for FY 2023 and FY 2024. Specifically, this report updates performance data for submissions received in FY 2023 (initially reported in the FY 2023 PDUFA performance report)[2] and presents preliminary data on FDA's progress in meeting FY 2024 goals. Updates on FDA's accomplishments related to additional PDUFA VII commitments for FY 2024 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 2024, 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 5 of this report.

The estimated[3] median approval times for priority NDAs and BLAs received in FY 2023 are lower compared to the estimated median approval times for priority NDAs and BLAs received in FY 2022. The preliminary data show that the percentage of priority and

[1] https://www.fda.gov/media/151712/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.

standard applications filed in FY 2023 and approved during the first review cycle were 77 percent and 56 percent, respectively.

A. Achievements in FY 2024

In FY 2024, FDA met or exceeded 10 of the 10 review performance goals. For example, current performance is at 100 percent for Original Priority New Molecular Entities (NMEs) and BLAs, Original Standard NMEs and BLAs, Original Priority Non-NME NDAs, Original Standard Non-NME NDAs, Priority NDA and BLA Efficacy Supplements, and Resubmitted Class 1 and Class 2 Efficacy Supplements.

B. Review Performance Results

The FY 2023 cohort had a workload of 3,494 goal closing actions. FDA met or exceeded the 90-percent performance level for eight of the 10 review performance goals for FY 2023.

For the FY 2024 cohort, FDA had completed 1,979 actions as of September 30, 2024. FDA is currently meeting or exceeding 10 of the 10 review performance goals for FY 2024. With 1,690 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 10 of the 10 review performance goals for FY 2024.

C. Procedural and Processing Performance Results

For the FY 2023 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 11,101 actions. FDA met or exceeded the performance level for 17 of the 30 procedural and processing goals for FY 2023.

For the FY 2024 cohort, FDA is currently meeting or exceeding 23 of the 32[4] procedural and processing goals. With 1,399 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 24 of the 30 applicable procedural and processing goal commitments for FY 2024. There are 32 procedural and processing goals, but calculating the highest potential performance is not applicable for the two Post Marketing Requirement (PMR)-related goals. The PMR-related goals apply to submissions approved with PMRs, and it is not possible to accurately predict the number of pending submissions that will be approved with PMRs.

[4] Beginning in FY 2024, FDA began reporting on two new procedural and processing goals. FDA committed to establish timelines for reviewing Use-Related Risk Analysis submissions and Risk Evaluation Mitigation Strategy Assessment Methods and Protocols.

D. Additional PDUFA VII Commitments

To highlight just a few achievements, there were several important PDUFA commitments completed in FY 2024, including:

- Two guidances,
- Four public meetings or workshops,
- Six public reports or documents, and
- Seven demonstration projects.

Table of Contents

List of Tables and Figures

Acronym List

ARC Program	Accelerating Rare Disease Cures Program
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
CPA	Capacity Planning Adjustment
DHT	Digital Health Technology
DRDMG	Division of Rare Diseases and Medical Genetics
EOP	End of Phase
ETASU	Elements to Assure Safe Use
ESG	Electronic Submissions Gateway
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDARA	FDA Reauthorization Act of 2017
FTE	Full-Time Equivalent
FUFRA	FDA User Fee Reauthorization Act of 2022
FY	Fiscal Year (October 1 to September 30)
IND	Investigational New Drug
IT	Information Technology
MAPP	Manual of Policies and Procedures
NDA	New Drug Application
NME	New Molecular Entity
OC	Office of the Commissioner
OND	Office of New Drugs

ORA	Office of Regulatory Affairs
PDUFA	Prescription Drug User Fee Act
PFDD	Patient Focused Drug Development
PMR	Postmarketing Requirement
RDT	Rare Diseases Team
REMS	Risk Evaluation and Mitigation Strategy
RFI	Request for Information
URRA	Use-Related Risk Analysis
WCF	Working Capital Fund

I. Introduction

On September 30, 2022, the President signed the FDA Reauthorization Act of 2022 (FUFRA) into law, which included the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal year (FY) 2023 through FY 2027, known as PDUFA VII. PDUFA VII continues 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

[1] A history of PDUFA and past performance reports are available at http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

submissions received during the current fiscal year. This report presents the final performance results for the FY 2023 cohort of submissions based on actions completed in FY 2023 and FY 2024. In addition, this report includes the preliminary performance results for the FY 2024 cohort of submissions that had actions completed or due for completion in FY 2024. Final performance for the FY 2024 cohort will be presented in the FY 2025 PDUFA performance report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2024.

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 (e.g., an approval, a tentative approval, a complete response) or withdrawal of the submission by the sponsor for any of the above.

- Under PDUFA VII, 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 only applications that are sufficiently complete to permit a substantive review. The Agency makes a filing decision within 60 days of an original

[2] See the BsUFA performance reports at http://www.fda.gov/about-fda/user-fee-performance-reports/bsufa-performance-reports.

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 VII 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 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 2023 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 2024 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2024, 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.[4] The highest possible percent of reviews that may be completed on time (i.e., the highest possible performance results) if

[3] See the PDUFA VII Commitment Letter at https://www.fda.gov/media/151712/download.
[4] There are two processing and procedural performance goals with performance thresholds at 50 percent, four goals at 60 percent, and two goals at 70 percent. Therefore, a current performance result at these rates or higher will be shown as currently meeting the goal.

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. Data include applications or supplements that were administratively split to allow the Agency to take different actions with respect to different aspects of the submission.

- FY 2024 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, 2024.

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

Submission Types Included in This Report

- **NDA** – An NDA is an application that contains data and information about a new drug product for review, including chemistry & manufacturing processes, pharmacology, clinical, and statistical, among others. 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. 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.

Additional definitions are included in Appendix E of this report.

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

II. PDUFA Review Goals

A. Review Workload: FY 2019 to FY 2024

In the table below, preliminary workload numbers from FY 2024 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. The workload over the past 5 years has remained generally consistent.

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 Table 1.

Table 1. Workload for Applications and Submissions.

Submission Type	FY 19	FY 20	FY 21	FY 22	FY 23*	FY 24	FY 19 to FY 23 5-Year Average	FY 24 Compared to 5-Year Average
Original Priority NMEs and BLAs	44	54	52	43	38	44†	46	-4%‡
Original Standard NMEs and BLAs	35	29	29	33	27	31	31	0%
Original Priority Non-NME NDAs	16	14	22	11	18	13†	16	-19%‡
Original Standard Non-NME NDAs	68	59	72	44	72	40	63	-37%
Class 1 Resubmitted NDAs and BLAs	8	5	5	8	10	6	7	-14%
Class 2 Resubmitted NDAs and BLAs	41	57	51	59	66	48	55	-13%
Priority NDA and BLA Efficacy Supplements	81	112	100	77	67	99†	87	14%‡
Standard NDA and BLA Efficacy Supplements	197	195	173	171	178	182	183	-1%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	4	3	3	1	2	2	3	-33%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	2	20	10	11	4	7	9	-22%

Submission Type	FY 19	FY 20	FY 21	FY 22	FY 23*	FY 24	FY 19 to FY 23 5-Year Average	FY 24 Compared to 5-Year Average
NDA and BLA Manufacturing Supplements Requiring Prior Approval	973	1,168	1,243	1,155	1,275	1,506	1,163	29%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,450	1,717	1,779	1,518	1,738	1,691	1,640	3%

* FY 2023 numbers were changed to reflect updates to the data presented in the FY 2023 PDUFA performance report.

† Some applications have not yet received a review priority designation. There were five undesignated NMEs and BLAs counted as Priority NMEs and BLAs, six undesignated Non-NME NDAs counted as Priority Non-NME NDAs, and 17 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 2025 PDUFA performance report.

‡ The percentage difference may be inflated due to the inclusion of undesignated submissions.

B. Final FY 2023 Review Goal Performance Results

The final FY 2023 review goal performance results are presented in Table 2. 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 8 of 10 review performance goals in FY 2023. The two goals for which FDA did not meet the 90-percent performance level, Original Priority Non-NME NDAs and Class 1 and 2 Resubmitted NDA and BLA efficacy supplements, reflected a small number of submissions, 18 and six respectively. For these two categories, missing the goal date for one or two submissions brought performance below the 90-percent target.

Table 2. FY 2023 Final Review Goal Performance Results.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2023 Performance
Original Priority NMEs and BLAs	6 months of filing date	35 of 38 on time	**92%**
Original Standard NMEs and BLAs	10 months of filing date	27 of 27 on time	**100%**
Original Priority Non-NME NDAs	6 months	16 of 18 on time	89%
Original Standard Non-NME NDAs	10 months	68 of 71 on time	**96%**
Class 1 Resubmitted NDAs and BLAs	2 months	10 of 10 on time	**93%**
Class 2 Resubmitted NDAs and BLAs	6 months	61 of 66 on time	
Priority NDA and BLA Efficacy Supplements	6 months	64 of 67 on time	**96%**
Standard NDA and BLA Efficacy Supplements	10 months	171 of 178 on time	**96%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	1 of 2 on time	83%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	4 of 4 on time	
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	1,224 of 1,275 on time	**96%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,691 of 1,738 on time	**97%**

C. Final FY 2023 Review Goal Performance Details

Tables 3 to 7 detail the final performance data for the FY 2023 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 2023 PDUFA performance report.

Table 3. FY 2023 Original Applications.

Original Application Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority NMEs & BLAs	6 months of filing date	38	35	3	92%
Standard NMEs & BLAs	10 months of filing date	27	27	0	100%
Priority Non-NME NDAs	6 months	18	16	2	89%
Standard Non-NME NDAs	10 months	72	68	3	96%*

* One standard Non-NME NDA is pending within goal as of September 30, 2024. Regardless of the action, the final performance result will remain above 90 percent.

Table 4. FY 2023 Resubmitted Original Applications.

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	10	10	0	93%
Class 2	6 months	66	61	5	

Table 5. FY 2023 Efficacy Supplements.

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	67	64	3	96%
Standard	10 months	178	171	7	96%

Table 6. FY 2023 Resubmitted Efficacy Supplements.

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	2	1	1	83%
Class 2	6 months	4	4	0	

Table 7. FY 2023 Manufacturing Supplements.

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	1,275	1,224	51	96%
Prior Approval Not Required	6 months	1,738	1,691	47	97%

D. Preliminary FY 2024 Review Goal Performance Results

The preliminary FY 2024 review goal performance results are presented in Table 8.

- 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. *FY 2024 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, 2024, are shown in bold text. FDA is currently meeting or exceeding the 90-percent performance level for all 10 performance goals.

- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance results presented in the Highest Possible Final Performance

column. FDA has the potential to meet or exceed the 90-percent performance level for all 10 review performance goals.

Table 8. FY 2024 Preliminary Review Goal Performance Results.

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2024 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	14 of 39 complete	6 months of filing date	**100%**	100%
Original Standard NMEs and BLAs	2 of 31 complete	10 months of filing date	**100%**	100%
Original Priority Non-NME NDAs	3 of 7 complete	6 months	**100%**	100%
Original Standard Non-NME NDAs	1 of 40 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	4 of 6 complete	2 months	**96%**	98%
Class 2 Resubmitted NDAs and BLAs	20 of 48 complete	6 months		
Priority NDA and BLA Efficacy Supplements	54 of 82 complete	6 months	**100%**	100%
Standard NDA and BLA Efficacy Supplements	55 of 182 complete	10 months	**95%**	98%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 of 2 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 of 7 complete	6 months		
NDA and BLA Manufacturing Supplements Requiring Prior Approval	914 of 1,506 complete	4 months	**96%**	98%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	904 of 1,691 complete	6 months	**99%**	99%

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

E. Preliminary FY 2024 Review Goal Performance Details

The following detailed performance information for the FY 2024 cohort submissions includes the number of submissions *Filed* or *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 9. FY 2024 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	39	14	0	25	100%	100%
Standard NMEs & BLAs	10 months of filing date	31	2	0	29	100%	100%
Priority Non-NME NDAs	6 months	7	3	0	4	100%	100%
Standard Non-NME NDAs	10 months	40	1	0	39	100%	100%
Review Priority Undesignated*	N/A	11	--	--	--	--	--
Total	N/A	128	20	0	97	--†	--†

* These applications have not yet received a review priority designation.
† Performance is not calculated on combined goals.

Table 10. FY 2024 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	6	3	1	2	96%	98%
Class 2	6 months	48	20	0	28		

Table 11. FY 2024 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	82	54	0	28	100%	100%
Standard	10 months	182	52	3	127	95%	98%
Review Priority Undesignated*	N/A	17	--	--	--	--	--

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

Table 12. FY 2024 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	2	2	0	0	100%	100%
Class 2	6 months	7	6	0	1		

Table 13. FY 2024 Manufacturing Supplements.

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Prior Approval Required	4 months	1,506	878	36	592	96%	98%
Prior Approval Not Required	6 months	1,691	895	9	787	99%	99%
Review Priority Undesignated*	N/A	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 2019 to FY 2024

The FY 2024 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 Table 14. The upward trend of meeting management workload continued into FY 2024. Additionally, FDA saw an increase between FY 2023 and FY 2024 in the number of Proprietary Names Submitted During IND Phase.

New meeting types, specifically Type D meeting and Type INTERACT meeting, were created under PDUFA VII. These new categories included new meeting metrics for Type D and Type INTERACT meetings: Requests, Scheduled, Written Response, and Preliminary Response. Meeting type definitions and other terms can be found in Appendix E. Additionally, FDA committed to establish timelines for reviewing Use-Related Risk Analysis submissions and Risk Evaluation and Mitigation Strategy (REMS) Assessment Methods and Protocols beginning in FY 2024. The table shows updated final FY 2023 performance and presents new reporting required under PDUFA VII.

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

Submission/ Request Type	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023*	FY 2024	FY 2019 to FY 2023 5-Year Average	FY 2024 Compared to 5-Year Average
Meeting Management								
Type A Meeting Requests‡	153	182	178	211	176	295†	180	64%§
Type B Meeting Requests‡	1,725	2,438	2,332	2,174	1,940	1,900	2,122	-10%
Type B(EOP) Meeting Requests‡	343	350	347	304	301	320	329	-3%
Type C Meeting Requests‡	1,550	1,716	1,706	1,699	1,510	1,476	1,636	-10%
Type D Meeting Requests‡	--	--	--	--	390	756	--	--

Submission/ Request Type	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023*	FY 2024	FY 2019 to FY 2023 5-Year Average	FY 2024 Compared to 5-Year Average
Type INTERACT Requests‡	--	--	--	--	115	180	--	--
Type A Meetings Scheduled	130	147	143	157	140	261†	143	83%§
Type B Meetings Scheduled	936	869	741	714	626	818	777	5%
Type B(EOP) Meetings Scheduled	325	322	282	259	260	294	290	1%
Type C Meetings Scheduled	732	699	648	619	575	656	655	0%
Type D Meetings Scheduled¶	--	--	--	--	90	196	--	--
Type INTERACT Meetings Scheduled¶	--	--	--	--	28	63	--	--
Type A Written Response	6	13	11	19	12	10	12	-17%
Type B Written Response	719	1,430	1,451	1,341	1,214	1,005	1,231	-18%
Type B(EOP) Written Response	11	23	49	38	30	23	30	-23%
Type C Written Response	728	905	918	974	839	766	873	-12%
Type D Meeting Written Response¶	--	--	--	--	276	500	--	--
Type INTERACT Written Response¶	--	--	--	--	31	65	--	--
Preliminary Response for Type B(EOP) Meetings	305	309	271	246	254	270	277	-3%
Preliminary Response for Type D Meetings¶	--	--	--	--	90	187	--	--
Preliminary Response for Type INTERACT Meetings¶	--	--	--	--	28	52	--	--

Submission/ Request Type	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023*	FY 2024	FY 2019 to FY 2023 5-Year Average	FY 2024 Compared to 5-Year Average
Meeting Minutes	1,638	1,515	1,363	1,281	1,251	1,510	1,410	7%
Procedural Notifications and Responses								
Responses to Clinical Holds	197	261	275	344	282	280	272	3%
Major Dispute Resolutions	28	35	14	12	19	16	22	-27%
Special Protocol Assessments	158	148	150	167	139	107	152	-30%
Review of Proprietary Names Submitted During IND Phase	212	224	211	188	154	174	198	-12%
Review of Proprietary Names Submitted During NDA/BLA Phase	230	255	223	206	239	236	231	2%
Human Factors Validation Protocol Submissions to NDAs, BLAs, or INDs#	70	79	79	59	--	--	--	--
Human Factors Validation Protocol Submissions to INDs¶#	--	--	--	--	64	61	--	--
Use-Related Risk Analysis Submissions¶	--	--	--	--	--	23	--	--
REMS Assessment Methods and Protocols¶	--	--	--	--	--	126	--	--

* FY 2023 numbers were changed to reflect updates to the data presented in the FY 2023 PDUFA performance report.

† Some meeting requests and the subsequent scheduling of meetings are for requests for which the type cannot be initially determined. There were 116 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 2025 PDUFA performance report.

‡ Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

§ The percentage difference may be inflated due to the inclusion of undesignated meetings.

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

Under PDUFA VII, the Performance Goal related to Human Factors Validation Protocol Submissions was updated to apply only to INDs.

B. Final FY 2023 Procedural and Processing Performance Results

Table 15 presents the final performance results for FY 2023 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 17 of the 30 procedural and processing goals in FY 2023.

Table 15. FY 2023 Final Procedural and Processing Performance Results.

Submission/Request Type	Goal: 90 Percent	Total	FY 2023 Performance
Type A Meeting Requests*	Respond within 14 days	166 of 176 on time	**94%**
Type B Meeting Requests*	Respond within 21 days	1,793 of 1,940 on time	**92%**
Type B(EOP) Meeting Requests*	Respond within 14 days	262 of 301 on time	87%
Type C Meeting Requests*	Respond within 21 days	1,425 of 1,510 on time	**94%**
Type D Meeting Requests*	Respond within 14 days	345 of 390 on time	88%
Type INTERACT Meeting Requests*	Respond within 21 days	109 of 115 on time	**95%**
Type A Meetings Scheduled	Schedule within 30 days	103 of 140 on time	74%
Type B Meetings Scheduled	Schedule within 60 days	499 of 626 on time	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	209 of 260 on time	80%
Type C Meetings Scheduled	Schedule within 75 days	483 of 575 on time	84%
Type A Written Response	Send within 30 days	10 of 12 on time	83%
Type B Written Response	Send within 60 days	908 of 1,214 on time	75%
Type B(EOP) Written Response	Send within 70 days	27 of 30 on time	**90%**
Type C Written Response	Send within 75 days	704 of 839 on time	84%

Submission/Request Type	Goal: 90 Percent	Total	FY 2023 Performance
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	230 of 254 on time	**91%**
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	79 of 90 on time	88%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	24 of 28 on time	86%
Meeting Minutes	Issue within 30 days after meeting date	1,166 of 1,251 on time	**93%**
Responses to Clinical Holds	Respond within 30 days	250 of 282 on time	89%
Major Dispute Resolutions	Respond within 30 days	18 of 19 on time	**95%**
Special Protocol Assessments	Complete and return within 45 days	130 of 139 on time	**94%**
Proprietary Name Submitted During IND Phase	Review and notify of tentative acceptance or non-acceptance within 180 days	144 of 154 on time	**94%**
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	221 of 239 on time	**92%**
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	18 of 64 on time	28%

* Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Submission/Request Type	Goal: 50 Percent	Total	FY 2023 Performance
Type D Meetings Scheduled	Schedule within 50 days	76 of 90 on time	**84%**
Type INTERACT Scheduled	Schedule within 75 days	26 of 28 on time	**93%**

Submission/Request Type	Goal: 50 Percent	Total	FY 2023 Performance
Type D Meeting Written Response	Send within 50 days	240 of 276 on time	**87%**
Type INTERACT Written Response	Send within 75 days	29 of 31 on time	**94%**

Application Type	Goal: 60 Percent	Total	FY 2023 Performance
Priority NME NDAs and Original BLAs Approved with PMRs*	Communicate anticipated PMRs 6 weeks prior to action goal date	18 of 23 on time	**78%**
Standard NME NDAs and Original BLAs Approved with PMRs*	Communicate anticipated PMRs 8 weeks prior to action goal date	8 of 12 on time	**67%**

* Data reflect the communication of anticipated PMRs for NME NDAs and Original BLAs that were received in FY 2023 and approved with PMRs, regardless of approval date.

C. Final FY 2023 Procedural and Processing Performance Details

Tables 16 to 23 detail the final performance data for the FY 2023 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 2023 PDUFA performance report.

Table 16. FY 2023 Meeting Management.

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests†	Respond within 14 days	176	166	10	94%
Type B Meeting Requests†	Respond within 21 days	1,940	1,793	147	92%
Type B(EOP) Meeting Requests†	Respond within 14 days	301	262	39	87%
Type C Meeting Requests†	Respond within 21 days	1,510	1,425	85	94%
Type D Meeting Requests†	Respond within 14 days	390	345	45	88%
Type INTERACT Meeting Requests†	Respond within 21 days	115	109	6	95%
Type A Meetings Scheduled	Schedule within 30 days	140	103	37	74%
Type B Meetings Scheduled	Schedule within 60 days	626	499	127	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	260	209	51	80%
Type C Meetings Scheduled	Schedule within 75 days	575	483	92	84%
Type A Written Response	Send within 30 days	12	10	2	83%
Type B Written Response	Send within 60 days	1,214	908	306	75%
Type B(EOP) Written Response	Send within 70 days	30	27	3	90%
Type C Written Response	Send within 75 days	839	704	135	84%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	254	230	24	91%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	90	79	11	88%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days	28	24	4	86%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
	prior to meeting date				
Meeting Minutes	Issue within 30 days after meeting date	1,251	1,166	85	**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.
† Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Type	Goal: 50 Percent	Received*	On Time	Overdue	Percent on Time
Type D Meetings Scheduled	Schedule within 50 days	90	76	14	84%
Type INTERACT Scheduled	Schedule within 75 days	28	26	2	93%
Type D Meeting Written Response	Send within 50 days	276	240	36	87%
Type INTERACT Written Response	Send within 75 days	31	29	2	94%

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

Table 17. FY 2023 Responses to Clinical Holds.

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	282	250	32	89%

Table 18. FY 2023 Major Dispute Resolutions.

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	19	18	1	95%

* 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 2023 Special Protocol Assessments.

Goal	Received	On Time	Overdue	Percent on Time
Complete and return 90 percent within 45 days	139	130	9	94%

Table 20. FY 2023 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
24	22	2	0	0	26

Table 21. FY 2023 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 notify of tentative acceptance or non-acceptance within 180 days	154	144	10	94%
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	239	221	18	92%

Table 22. FY 2023 Human Factors Validation Protocol Submissions.

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	64	18	46	28%

Table 23. FY 2023 Communication of Anticipated Post Marketing Requirements (PMRs).

Application Type	Goal: 60 Percent	Approved Applications with PMRs	On Time*	Overdue†	Percent on Time
Priority NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 6 weeks prior to action goal date	23	18	5	78%
Standard NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 8 weeks prior to action goal date	12	8	4	67%

* *On Time* refers to the number of approved applications with PMRs where the PMRs required at approval were communicated by the 6- or 8-week goal date.
† *Overdue* refers to the number of approved applications with PMRs where the PMRs required at approval were not communicated by the 6- or 8-week goal date.
‡ Data reflect the communication of anticipated PMRs for NME NDAs and Original BLAs that were received in FY 2023 and approved with PMRs, regardless of approval date.

D. Preliminary FY 2024 Procedural and Processing Performance Results

Table 24 presents preliminary performance results for FY 2024 submissions in achieving goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA VII.

- 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, 2024, are shown in bold text. FDA is currently meeting or exceeding the performance level for 23 of the 32 applicable procedural and processing goals (e.g., 90 percent or more reviews were completed by the goal date). If all pending submissions are reviewed on time,

FDA has the potential to meet 24 of the 30 applicable goals, as seen in the Highest Possible Final Performance column.[5]

Table 24. FY 2024 Preliminary Procedural and Processing Performance Results.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Type A Meeting Requests*†	183 of 295 complete	Respond within 14 days	89%	93%
Type B Meeting Requests*	1,866 of 1,900 complete	Respond within 21 days	**96%**	96%
Type B(EOP) Meeting Requests*	313 of 320 complete	Respond within 14 days	**91%**	92%
Type C Meeting Requests*	1,463 of 1,476 complete	Respond within 21 days	**95%**	95%
Type D Meeting Requests*	748 of 756 complete	Respond within 14 days	**93%**	93%
Type INTERACT Requests*	175 of 180 complete	Respond within 21 days	**90%**	90%
Type A Meetings Scheduled†	140 of 261 complete	Schedule within 30 days	76%	87%
Type B Meetings Scheduled	745 of 818 complete	Schedule within 60 days	78%	80%
Type B(EOP) Meetings Scheduled	278 of 294 complete	Schedule within 70 days	82%	83%
Type C Meetings Scheduled	627 of 656 complete	Schedule within 75 days	86%	87%
Type A Written Response	9 of 10 complete	Send within 30 days	56%	60%

[5] The highest potential performance is not calculated for the two PMR goals as is it not possible to accurately predict the number of pending submissions that will be approved with PMRs.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Type B Written Response	853 of 1,005 complete	Send within 60 days	88%	90%
Type B(EOP) Written Response	16 of 23 complete	Send within 70 days	**100%**	100%
Type C Written Response	649 of 766 complete	Send within 75 days	89%	91%
Preliminary Response for Type B(EOP) Meetings	229 of 270 complete	Issue no later than 5 days prior to meeting date	**90%**	92%
Preliminary Response for Type D Meetings	174 of 187 complete	Issue no later than 5 days prior to meeting date	**93%**	94%
Preliminary Response for Type INTERACT Meetings	48 of 52 complete	Issue no later than 5 days prior to meeting date	**90%**	90%
Meeting Minutes	1,132 of 1,510 complete	Issue within 30 days after meeting date	**94%**	96%
Responses to Clinical Holds	258 of 280 complete	Respond within 30 days	**93%**	93%
Major Dispute Resolutions	14 of 16 complete	Respond within 30 days	**93%**	94%
Special Protocol Assessments	93 of 107 complete	Complete and return within 45 days	**95%**	95%
Proprietary Name Submitted During IND Phase	99 of 174 complete	Review and notify of tentative acceptance or non-acceptance within 180 days	**97%**	98%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Proprietary Name Submitted During NDA/BLA Phase	198 of 236 complete	Review and notify of tentative acceptance or non-acceptance within 90 days	**98%**	98%
Human Factors Validation Protocol Submissions to INDs	54 of 61 complete	Review and provide comments within 60 days	72%	75%

* Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

† Some meeting requests and subsequent scheduling of meetings are for requests for which the type cannot be initially determined. There were 116 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 2025 PDUFA performance report.

Submission/Request Type	Progress	Goal: 50 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Use-Related Risk Analysis Submissions	22 of 23 complete	Review and respond within 60 days	**91%**	91%
REMS Assessment Methods and Protocols	104 of 126 complete	Review and respond within 90 days	**70%**	75%

Submission/Request Type	Progress	Goal: 60 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Type D Meetings Scheduled	185 of 196 complete	Schedule within 50 days	**85%**	86%

Submission/Request Type	Progress	Goal: 60 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Type INTERACT Scheduled	52 of 63 complete	Schedule within 75 days	**96%**	97%
Type D Meeting Written Response	446 of 500 complete	Send within 50 days	**91%**	92%
Type INTERACT Written Response	54 of 65 complete	Send within 75 days	**96%**	97%

Application Type	Progress	Goal: 70 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Priority NME NDAs and Original BLAs Approved with PMRs*	9 of 9 complete	Communicate anticipated PMRs 6 weeks prior to action goal date	**78%**	N/A†
Standard NME NDAs and Original BLAs Approved with PMRs*	2 of 2 complete	Communicate anticipated PMRs 8 weeks prior to action goal date	**100%**	N/A†

* Data reflect the communication of anticipated PMRs for NME NDAs and Original BLAs that were received in FY 2024 and approved with PMRs, regardless of approval date.

† The highest possible final performance is not calculated for the two PMR goals as it is not possible to accurately predict the number of pending submissions that will be approved with PMRs.

E. Preliminary FY 2024 Procedural and Processing Performance Details

The following detailed performance information for FY 2024 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 25. FY 2024 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	295	163	20	112	89%	93%
Type B Meeting Requests‡	Respond within 21 days	1,900	1,789	77	34	96%	96%
Type B(EOP) Meeting Requests‡	Respond within 14 days	320	286	27	7	91%	92%
Type C Meeting Requests‡	Respond within 21 days	1,476	1,390	73	13	95%	95%
Type D Meeting Requests‡	Respond within 14 days	756	693	55	8	93%	93%
Type INTERACT Meeting Requests‡	Respond within 21 days	180	157	18	5	90%	90%
Type A Meetings Scheduled†	Schedule within 30 days	261	106	34	121	76%	87%
Type B Meetings Scheduled	Schedule within 60 days	818	579	166	73	78%	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	294	228	50	16	82%	83%
Type C Meetings Scheduled	Schedule within 75 days	656	539	88	29	86%	87%
Type A Written Response	Send within 30 days	10	5	4	1	56%	60%
Type B Written Response	Send within 60 days	1,005	751	102	152	88%	90%
Type B(EOP) Written Response	Send within 70 days	23	16	0	7	100%	100%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type C Written Response	Send within 75 days	766	580	69	117	89%	91%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	270	207	22	41	90%	92%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	187	162	12	13	93%	94%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	52	43	5	4	90%	90%
Meeting Minutes	Issue within 30 days after meeting date	1,510	1,066	66	378	94%	96%

* 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 for which the type cannot be initially determined. There were 116 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 2025 PDUFA performance report.

‡ Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Type	Goal: 60 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type D Meetings Scheduled	Schedule within 50 days	196	158	27	11	85%	86%
Type INTERACT Scheduled	Schedule within 75 days	63	50	2	11	96%	97%

Type	Goal: 60 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type D Written Response	Send within 50 days	500	407	39	54	91%	92%
Type INTERACT Written Response	Send within 75 days	65	52	2	11	96%	97%

* 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 26. FY 2024 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	280	239	19	22	93%	93%

Table 27. FY 2024 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	16	13	1	2	93%	94%

* 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 28. FY 2024 Special Protocol Assessments.

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Complete and return 90 percent within 45 days	107	88	5	14	95%	95%

Table 29. FY 2024 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
19	16	3	0	0	22

Table 30. FY 2024 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 notify of tentative acceptance or non-acceptance within 180 days	174	96	3	75	97%	98%
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	236	194	4	38	98%	98%

Table 31. FY 2024 Human Factors Validation 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 Validation Protocol Submissions to INDs	Review and provide comments within 60 days	61	39	15	7	72%	75%

Table 32. FY 2024 Use-Related Risk Analysis Submissions.

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Use-Related Risk Analysis Submissions	Review and respond within 60 days	23	20	2	1	91%	91%

Table 33. FY 2024 REMS Assessment Methods and Protocols.

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
REMS Assessment Methods and Protocols	Review and respond within 90 days	126	73	31	22	70%	75%

Table 34. FY 2024 Communication of Anticipated Post Marketing Requirements (PMRs).

Application Type	Goal: 70 Percent	Approved Applications with PMRs	On Time*	Overdue†	Current Percent on Time
Priority NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 6 weeks prior to action goal date	9	7	2	78%
Standard NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 8 weeks prior to action goal date	2	2	0	100%

* *On time* refers to the number of approved applications with PMRs where the PMRs required at approval were communicated by the 6- or 8-week goal date.

† *Overdue* refers to the number of approved applications with PMRs where the PMRs required at approval were not communicated by the 6- or 8-week goal date.

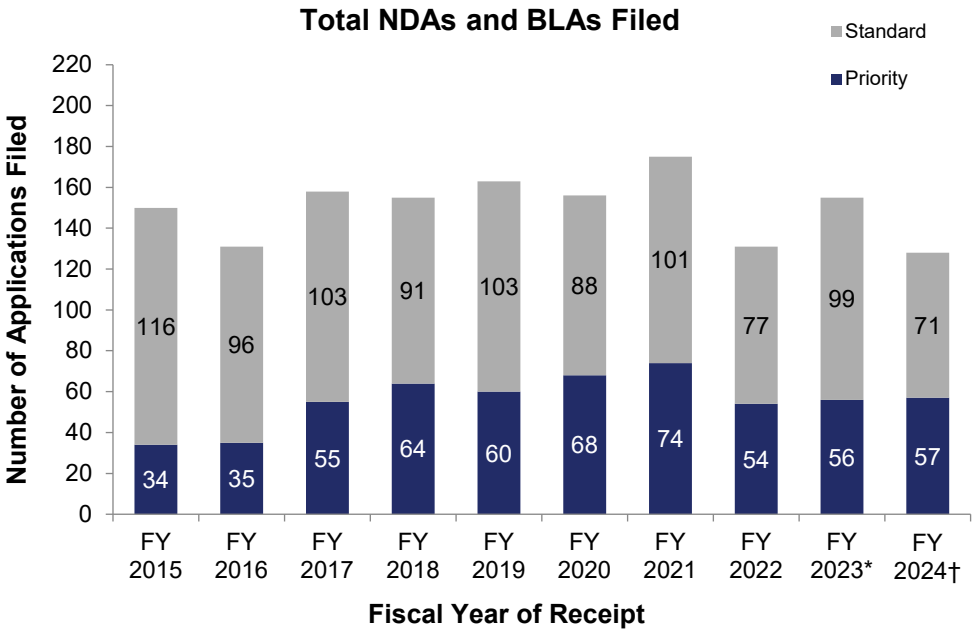
‡ Data reflect the communication of anticipated PMRs for NME NDAs and Original BLAs that were received in FY 2024 and approved with PMRs, regardless of approval date.

IV. PDUFA Trend Graphs

A. Total NDAs and BLAs Filed

The number of NDAs and BLAs filed from FY 2015 to FY 2024 is presented in Figure 1. The total number of all original applications (NDAs and BLAs) filed in FY 2024 decreased from the number filed in FY 2023.

Figure 1. Total NDAs and BLAs Filed.



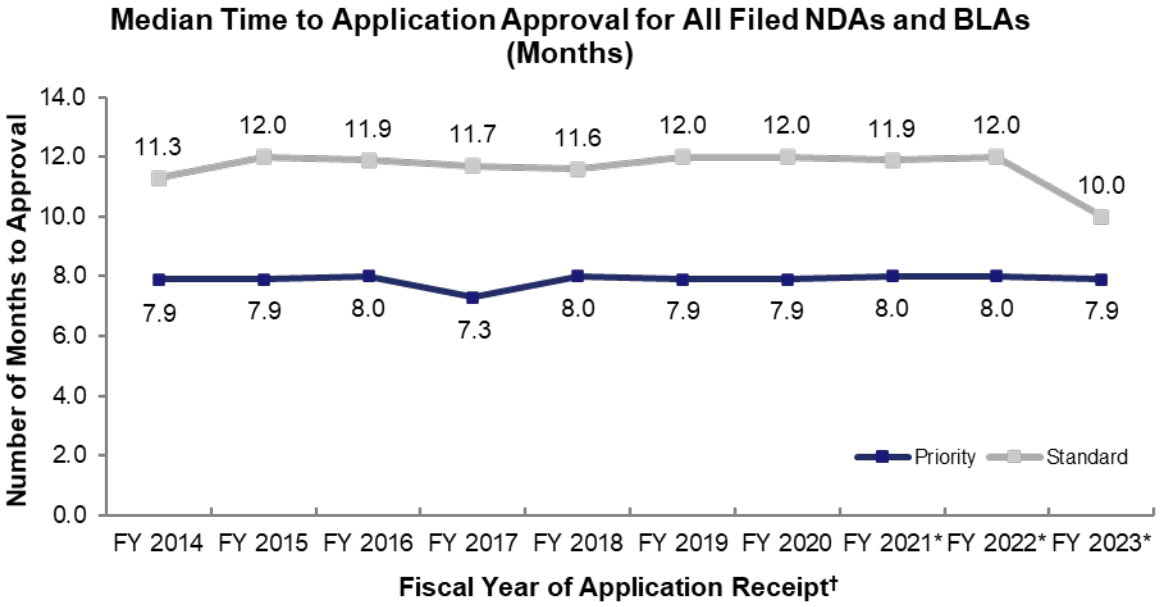
* FY 2023 numbers were changed to reflect updates to the data presented in the FY 2023 PDUFA performance report.

† Some applications filed in FY 2023 have not yet received a review priority designation. The undesignated NDAs and BLAs are counted as Priority NDAs and BLAs. Designation may change and the table will then be updated accordingly, as appropriate, in the FY 2025 PDUFA performance report.

B. Median Total Times to Approval

The median total times to approval for priority and standard applications received from FY 2014 through FY 2023 are presented in the graph below.[6] The data represented in Figure 2 are updated based on the approvals reported in Appendix A. FY 2024 data are too preliminary to estimate the median approval time.

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



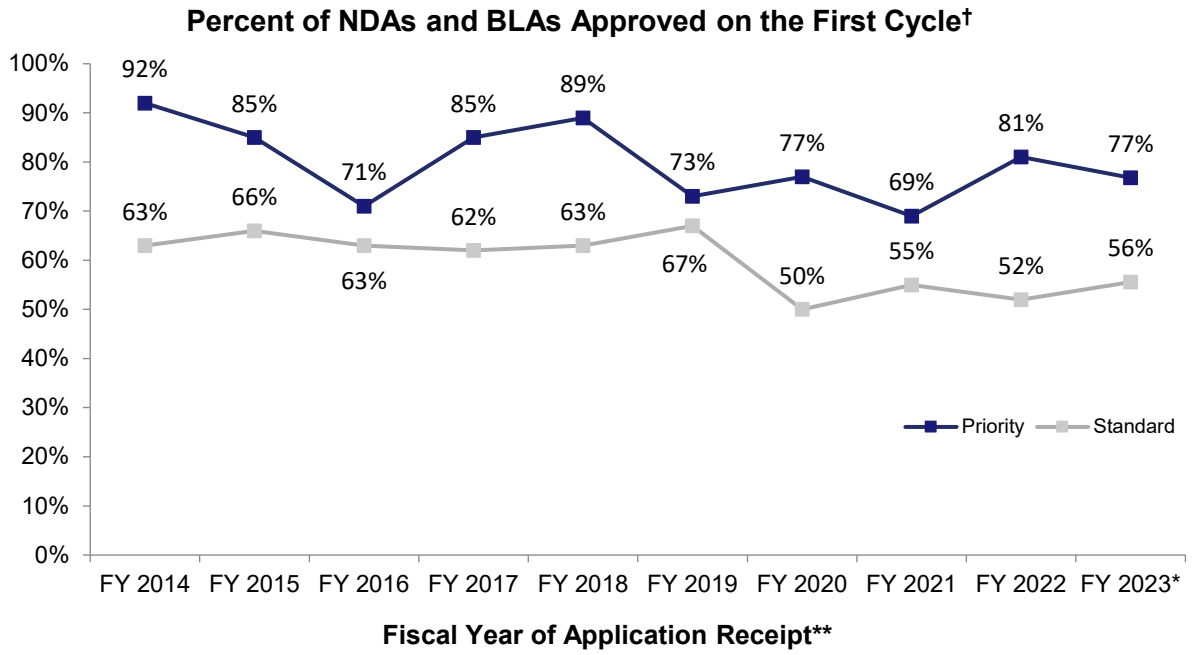
* The median approval times for the 3 most recent years are estimated.
† The data represented in this figure are based on the approvals reported in Appendix A.

[6] 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.

C. Percent of NDAs and BLAs Approved on the First Cycle

Figure 3 depicts the percentages of priority and standard NDAs and BLAs approved in the first review cycle for the receipt cohorts from FY 2014 to FY 2023. These percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals increased in FY 2023. For the FY 2023 cohort, which is still preliminary, 56 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications decreased in FY 2023, with 77percent of approved priority applications being approved on the first cycle. The FY 2024 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 2023 standard applications, so the data are preliminary.
† The data were changed to reflect updates to the data presented in the FY 2023 PDUFA performance report.
‡ The data represented in this graph are based on the approvals reported in Appendix A.

V. Additional PDUFA VII Commitments

Under Section VI ("Progress reporting for PDUFA VII and Continuing PDUFA VI initiatives") of the PDUFA VII Commitment Letter, FDA committed to report its progress on the specific commitments identified in the following sections of the Commitment Letter:[7]

- Section I.A: Review Performance Goals
- Section I.B: Program for Review Transparency and Communication for NME NDAs and Original BLAs
- Section I.C: New Molecular Entity (NME) Milestones and Postmarketing Requirements (PMRs)
- Section I.D: Split Real Time Application Review (STAR) Pilot Program
- Section I.E: Expedited Reviews
- Section I.F: Review of Proprietary Names to Reduce Medication Errors
- Section I.G: Major Dispute Resolutions
- Section I.H: Clinical Holds
- Section I.I: Special Protocol Assessment and Agreement
- Section I.J: Meeting Management Goals
- Section I.K: Enhancing Regulatory Science and Expediting Drug Development
- Section I.L: Enhancing Regulatory Decision Tools to Support Drug Development and Review
- Section I.M: Enhancement and Modernization of the FDA Drug Safety System

[7] See the PDUFA VII Commitment Letter at https://www.fda.gov/media/151712/download.

- Section I.N: Enhancing Related to Product Quality Reviews, Chemistry, Manufacturing, and Control Approaches, and Advancing the Utilization of Innovative Manufacturing Technologies

- Section I.O: Enhancing CBER's Capacity to Support Development, Review, and Approval of Cell and Gene Therapy Products

- Section I.P: Supporting Review of New Allergenic Extract Products

- Section II: Continued Enhancement of User Fee Resource Management

- Section III: Improving FDA Hiring and Retention of Review Staff

- Section IV: Information Technology and Bioinformatics Goals

Further, section 736B(a) of the FD&C Act, as amended by section 103 of the FDA Reauthorization Act of 2017 (FDARA), requires FDA to report on the Agency's performance under PDUFA VII.

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 2024 with updates on commitments in respective sections of the Commitment Letter cited above in the list. Each accomplishment includes a reference to a specific section of the Commitment Letter. External references are also provided to published guidances, meeting summaries, and other pertinent public information.

FDA is dedicated to the goals outlined in these sections of the Commitment Letter. When applicable, for each section, additional information is included on other activities FDA has conducted that are not specifically committed but further the goals outlined in the Commitment Letter.

A. Section I.A – I.J: Human Drug Review Program and Meeting Management

Table 35. Section I.A - I.J's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.A Review Performance Goals	• There were no commitments due.
I.B Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs	• There were no commitments due.
I.C New Molecular Entity (NME) Milestones and Postmarketing Requirements (PMRs)	• There were no commitments due.

I.D Split Real Time Application Review (STAR) Pilot Program	Education and Training:
	• Internal:
	  ○ Provided training for FDA staff (June 2024)
	• External:
	  ○ Provided an overview of the STAR Pilot Program for a webinar sponsored by PhRMA and the Biotechnology Innovation Organization (February 2024)
	  ○ Presentation on the STAR Pilot at the Regulatory Affairs Professionals Society Convergence (September 2024)

I.E Expedited Reviews	• There were no commitments due.
I.F Review of Proprietary Names to Reduce Medication Errors	• There were no commitments due.
I.G Major Dispute Resolution	• There were no commitments due.
I.H Clinical Holds	• There were no commitments due.
I.I Special Protocol Assessment and Agreement	• There were no commitments due.

I.J Meeting Management Goals	• There were no commitments due.

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

Table 36. Section I.K's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.K.1 Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• On July 22, 2024, CDER and CBER held a public workshop, *Best Practices for Meeting Management under PDUFA VII*,[8] to discuss the current state of and best practices for meeting management at FDA. During the workshop, FDA presented an overview of FDA's performance on a variety of PDUFA meeting management metrics. This overview was followed by panel discussions between FDA and industry representatives to seek and provide feedback on the current best practices for meeting management and potential areas of improvement. • Topics discussed during the panel included meeting purpose and objectives, meeting requests and background packages, meeting minutes and follow up opportunities, in-person and virtual face-to-face meetings, and INTERACT and Type D meetings.
I.K.2 Ensuring Sustained Success of Breakthrough Therapy Program	• There were no commitments due.
I.K.3 Early Consultation on the Use of New Surrogate Endpoints	• There were no commitments due.
I.K.4 Advancing Drug Development of Drugs for Rare Diseases	**OVERALL**

[8] https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-best-practices-meeting-management-under-pdufa-vii-07222024.

	• Advancing drug development for rare diseases is a intra-Agency collaborative effort. In FY 2024, CDER's Rare Diseases Team (RDT), CBER and others engaged in critical rare disease drug development enhancement activities. • In FY 2024, the CDER Accelerating Rare disease Cures Program[9] (CDER ARC Program), managed by CDER's RDT, continued work to accelerate and promote the development of effective and safe treatment options that address the unmet needs of patients with rare diseases. The CDER ARC Program is governed by senior leadership in policy, review, and engagement from CDER's Office of the Center Director, Office of New Drugs (OND) and Office of Translational Sciences. A recent summary of ARC's work can be found in FDA's 2024 annual report.[10] • In July 2024, the Rare Disease Innovation Hub (the Hub), a joint CDER-CBER initiative, was launched to facilitate development of rare disease treatments. The Hub will leverage the activities of the CDER ARC Program and the CBER Rare Disease Program and will enhance existing cross-Center collaborations. The Hub will enhance CDER-CBER policy coordination and provide external parties with a single cross-Center point of contact, which will further ensure CDER and CBER coordination and reduce silos on cross-cutting rare disease issues related to product development. **EXPERTISE IN REVIEW** • In FY 2024, the RDT continued to consult on and contribute to the review of rare disease drug applications across the review divisions both through the CDER ARC Program's workstreams such as CDER's Translational Science Team and Rare Disease Drug Development Design[11] and through working directly with review divisions in OND regarding the design of trials, the assessment of

[9] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program.
[10] https://www.fda.gov/media/182662/download.
[11] https://www.fda.gov/media/182662/download.

	substantial evidence of effectiveness, the use of confirmatory evidence, the selection of endpoints, and the labeling of rare disease products. • CBER continued to ensure that its review offices considered flexible and feasible approaches and endpoint development issues in the review of biologics for rare diseases through sharing of expert review practices and case study presentations during CBER Rare Disease Coordinating Committee meetings. CBER's Office of Therapeutic Products clinical division meetings serve as a forum for discussing such approaches and issues concerning gene therapy products intended for rare diseases. • CDER's Rare Disease Team and CBER's Rare Disease Program co-lead the development and implementation of the PDUFA Rare Disease Endpoint Advancement Pilot Program. This joint CDER/CBER pilot program supports novel efficacy endpoint development for rare disease treatments. • The RDT continues to collaborate with other offices within CDER to provide expertise for the rare pediatric disease priority review voucher program. • The Division of Rare Diseases and Medical Genetics (DRDMG) and CBER's Office of Therapeutic Products continue to hold an informal forum for quarterly internal reviewer discussion of rare disease products and indications. This informal forum serves as an opportunity for CBER's and CDER's medical officers to interact and work more closely together on rare disease specific issues that are relevant to both Centers. **EDUCATION AND TRAINING** • In FY 2024, 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 2024, CDER's RDT—in collaboration with CBER, the Center for Devices and Radiological Health (CDRH), and other FDA offices—held a 2-day annual reviewer training event titled *Digital Health*

	Technology in Rare Disease Product Development. This training focused on presentations, discussion, and rare disease case examples of challenges encountered when reviewing applications with digital health technologies, as well as a presentation on the December 2023 final guidance titled *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations*. Over 700 staff attended the training. • CDER's RDT hosts a rare diseases seminar series. During these seminars, which host internal and external speakers for all FDA staff, timely and innovative topics pertaining to rare diseases are presented, such as challenges encountered in drug development programs for rare diseases and approaches used to resolve those challenges. CBER staff were integral contributors of topic ideas to this series. • The CDER RDT distributes the CDER ARC Program's internal FDA rare disease newsletter, Zebragram. In 2024, this newsletter for FDA staff provided news relating to rare disease science, regulations, and policies from across the Agency and provided information about rare disease drug and biological product applications from across CDER and CBER. CBER Rare Disease Program staff routinely contributed content to this newsletter on CBER rare disease activities and ensured a wide distribution of the newsletter within the Center. **EXTERNAL OUTREACH** • In FY 2024, the RDT, in collaboration with CBER, continued its outreach activities with external stakeholders to advance rare disease drug development by engaging and presenting at multiple meetings, poster presentations, and speaking engagements and by publishing on regulatory rare disease topics. • In FY 2024, CDER, in conjunction with its RDT, further enhanced the CDER ARC Program website[12] with rare disease information and resources to create

[12] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program.

	a “one-stop site” for external stakeholders and FDA staff. CDER also continued to distribute its quarterly CDER ARC Program newsletter to provide external stakeholders and FDA staff with highlights of rare disease drug development news. • The RDT meets monthly with the Division of Rare Diseases Research Innovation in the National Center for Advancing Translational Sciences at the National Institutes of Health and continues to build on successful collaborative efforts such as the cosponsored Reagan-Udall Foundation for the FDA May 2024 workshop entitled *Natural History Studies and Registries in the Development of Rare Disease Treatments*. • The RDT and CBER Rare Disease Program staff interacted with FDA’s Office of Orphan Products Development on rare disease activities, such as bimonthly planning meetings for and participation in the FDA Rare Disease Day 2024, a public meeting held on March 1, 2024, titled Dedicated to Patients and Providers. The RDT and CBER staff also contributed to the review of extramural grants on natural history studies for that office’s Natural History Study Grants Program. • In February 2024, CBER, in collaboration with the Reagan-Udall Foundation for the FDA, hosted a public workshop to explore primary disease activity biomarkers in rare genetic diseases through exploration of case studies (*heparan sulfate in neuronopathic lysosomal storage diseases)* and a dialogue on the challenges in qualifying biomarkers to support rare disease approvals. • CDER ARC Program’s Learning and Education to Advance and Empower Rare Disease Drug Developers is RDT’s initiative focused on developing and disseminating educational materials for the rare disease community. FDA and rare disease community input on materials was gathered and resulted in a February 2024 publication of a public report entitled *LEADER 3D: Learning and Education to Advance and Empower Rare Disease Drug*

	Developers.[13] This report is being used to inform the development and dissemination of educational materials of high priority to the community. Case studies have been developed and posted for internal FDA staff for learning purposes. In addition, a video on clinical trial design,[14] as well as links to guidance documents for rare disease drug development[15] and funding opportunities[16] can be found at the LEADER 3D Webpage.[17] • The RDT coordinates FDA's Critical Path for Lysosomal Storage Diseases Consortium, working closely with scientific advisors in DRDMG. This consortium unites a diverse community of stakeholders to work collaboratively on generating actionable solutions to accelerate drug development in neuronopathic lysosomal storage diseases to develop novel tools such as Clinical Outcome Assessments and biomarkers to support neuronopathic lysosomal storage diseases drug development. • The RDT leads and facilitates the International Rare Disease Cluster for FDA. In addition to including CDER and CBER, this cluster includes the European Medicines Agency and Health Canada. Cluster meetings include an exchange of information related to the development and scientific evaluation of medicines for rare diseases for protocol assistance, marketing applications, and informational topics. In FY 2024, there were six cluster meetings discussing 13 topics spanning both CDER and CBER. • CDER's RDT and CBER Rare Disease Program staff continued to participate on the International Rare Diseases Research Consortium's Regulatory Science Committee, which includes representation from regulatory bodies, patient groups, the biotech and pharmaceutical industries, public and not-for-profit

[13] https://www.fda.gov/media/176557/download?attachment.
[14] https://www.youtube.com/watch?v=KKm2hG7foQw&t=7s.
[15] https://www.fda.gov/drugs/guidances-drugs/guidance-documents-rare-disease-drug-development.
[16] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/funding-opportunities-rare-diseases-fda.
[17] https://www.fda.gov/about-fda/accelerating-rare-disease-cures-arc-program/learning-and-education-advance-and-empower-rare-disease-drug-developers-leader-3d.

	organizations, clinicians, and scientists. The committee works to identify pathways for regulatory harmonization in consideration of global regulatory challenges surrounding therapeutic innovation in rare disease drug development. • CDER and CBER rare disease experts issued guidance documents for industry to facilitate rare disease drug development. CDER and CBER published the final guidance—*Rare Diseases: Considerations for the Development of Drugs and Biological Products*.[18] In January 2024, CBER published two final guidances—*Human Gene Therapy Products Incorporating Human Genome Editing*[19] and *Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products*[20]—which provide regulatory advice on product, manufacturing, pre-clinical and clinical development of these biological products, most of which are intended for the treatment of rare diseases. • The RDT continues to provide quarterly updates to CDER's Drugs and Biologics Dashboard on FDA-TRACK,[21] the Agency-wide performance management program that reports on performance measures and key projects for various FDA Centers and programs. Using FDA-TRACK, visitors can toggle-view the history of CDER's cumulative drug approvals from FY2016 to view those that were approved by type of approval, such as accelerated approval, breakthrough therapy approval, and fast track approval. Rare disease approval information is currently available for approvals from September 1, 2022, to June 30, 2024. • Between the staff of the CDER ARC Program, Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, DRDMG and RDT staff,

[18] https://www.fda.gov/media/119757/download.
[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-gene-therapy-products-incorporating-human-genome-editing.
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-development-chimeric-antigen-receptor-car-t-cell-products.
[21] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-drug-evaluation-and-research-pre-approval-safety-review-drugs-and-biologics.

	collectively over 70 presentations were made to support rare disease drug development. • In FY 2024, CBER staff participated in a minimum of 157 outreach activities intended to support the development of biological products for rare diseases. These stakeholder engagement activities included presentations (103), publications (26), and posters/abstracts (28). • The RDT and CBER staff attended multiple Patient-Focused Drug Development (PFDD) meetings 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 were captured and meaningfully incorporated into drug development and evaluation. The listening sessions enabled FDA medical product Centers to engage informally with patients and caregivers, including those belonging to under-represented communities, allowing them to share with the Agency their experiences living with a disease/condition. Similar to PFDD meetings, the listening sessions help the Agency inform medical product development, clinical trial design, patient preferences, and regulatory thinking. • CDER's RDT, CBER, and PFDD staff participated on the organizing committee for the *Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement*[22] public meeting held in December 2023. In collaboration with the Duke Margolis Institute for Health Policy, this public meeting was convened to discuss approaches and opportunities for engaging patients, patient groups, rare disease or condition experts, and experts on small population studies during the drug development process for rare diseases. The meeting focused on how to best understand patients' experiences living with a rare disease and how to incorporate those experiences and priorities throughout the drug development process.

[22] https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-advancing-development-therapeutics-through-rare-disease-patient-community-engagement.

	• In FY 2024, CBER held the following rare disease-relevant workshops and webinars on cell and gene therapy topics for industry and patient stakeholders, including: ○ CBER Patient Listening Meeting: Patient and Care Partner Perspectives on Safety Considerations for Approved Gene Therapy Treatments for Rare Diseases, September 20, 2024[23] ○ CBER Webinar: Considerations for the Development of CAR-T Cell Products, March 7, 2024[24] ○ CBER Webinar: Human Gene Therapy Products Incorporating Human Genome Editing, February 29, 2024[25] ○ Reagan-Udall Foundation for the FDA Announces Hybrid Public Meeting on Qualifying Biomarkers to Support Rare Disease Regulatory Pathways, February 24, 2024[26] ○ Warrior Families: Advancing Regenerative Medicine Through Science, October 5, 2023[27] • CBER keeps its web page CBER Rare Disease Program[28] current and relevant, including providing highlights of the CBER Rare Disease Program activities, including collaborative efforts with partners at FDA and beyond. The web page also provides annual listings of CBER's recent orphan approvals starting from 2022 and currently to the end of FY 2024, as well as CBER Rare Disease Program Frequently Asked Questions | FDA.[29]

[23] https://www.fda.gov/news-events/2024-cber-patient-and-care-partner-listening-meetings.
[24] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/fda-cber-webinar-considerations-development-car-t-cell-products-03072024.
[25] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/fda-cber-webinar-human-gene-therapy-products-incorporating-human-genome-editing-02292024.
[26] https://reaganudall.org/news-and-events/announcements/reagan-udall-foundation-fda-announces-hybrid-public-meeting.
[27] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/warrior-families-advancing-regenerative-medicine-through-science-10052023.
[28] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program.
[29] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program-frequently-asked-questions.

I.K.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• FDA updated its Use-Related Risk Analysis (URRA) review templates and best practice documents to facilitate the review of URRAs. ○ FDA published the following draft guidance for industry and FDA staff describing considerations related to drug-device and biologic-device combination products: *Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products* (July 2024).[30]
I.K.6 Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making	• FDA completed the first three submission cycles of the Advancing Real-World Evidence Program. • FDA published the Real-World Evidence Submissions to CBER and CDER[31] report for FY 2023.

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

Table 37. Section I.L's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.L.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	• FDA continued to strengthen its capacity to facilitate the development and use of patient-focused methods to inform drug development and regulatory decisions. FDA expanded internal staff training and external outreach to industry sponsors and other involved stakeholders with an emphasis on PFDD methods and tools-related guidance to achieve broad acceptance and integration into regulatory decision-making across review divisions and industry development programs. ○ FDA continued to provide ongoing just-in-time in-service trainings on patient-focused

[30] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products.
[31] https://www.fda.gov/science-research/real-world-evidence/real-world-evidence-submissions-center-biologics-evaluation-and-research-center-drug-evaluation-and.

	methodologies to review divisions throughout the fiscal year. ○ FDA conducted targeted outreach to industry and methodological consulting organizations to provide a variety of presentations, sessions, and resources. Selected examples include participation in multiple FDA public webinars, as well as participating as moderators, presenters, and panelists in meetings hosted by the Professional Society for Health Economics and Outcomes Research, the Drug Information Association Annual Global Meeting, the Biotechnology Innovation Organization International Convention, the Critical Path Patient-Reported Outcome Consortium, and the American College of Medical Genetics Annual Clinical Genetics Meeting. FDA also participated in a PhRMA roundtable to discuss patient experience data. FDA engaged an external expert through the Intergovernmental Personnel Act to support the review of patient experience data, including the provision of internal staff training. • Methodological Issues: ○ In December 2023, FDA published a summary (*Methodological Challenges Related to Patient Experience Data; Summary of Received Comments)*[32] of the comments received for a notice on methodological challenges related to patient experience data (*Methodological Challenges Related to Patient Experience Data; Request for Information and Comments)*.[33] ○ FDA held the first public workshop on the methodological issues identified on December 13, 2024 (*Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data*).[34]

[32] https://www.federalregister.gov/documents/2023/12/13/2023-27312/methodological-challenges-related-to-patient-experience-data-summary-of-received-comments.
[33] https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments.
[34] https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-discuss-methodologic-and-other-challenges-related-patient.

	• FDA continued the Standard Core Clinical Endpoints and 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 staff members continued to interact with stakeholders to systematically obtain the patient's perspective on specific diseases and their treatments. These interactions included participating in 10 Patient Listening Sessions and 17 externally led PFDD meetings. FDA staff across review divisions were also active participants at many patient-led meetings such as the National Organization for Rare Disorders Annual Summit, Patients as Partners, the Global Heart Hub, and many others. • Guidance Documents: ○ In November 2023, FDA published the technical specifications guidance document *Submitting Patient-Reported Outcome Data in Cancer Clinical Trials*.[35] ○ In November 2023, FDA published the technical specifications guidance document *Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments Using Item Response Theory*.[36] ○ Through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, FDA and other stakeholders began the development of the international guideline *General Considerations for Patient Preference Studies* and have published a final Concept Paper.[37]
I.L.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• There were no commitments due.

[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submitting-patient-reported-outcome-data-cancer-clinical-trials.
[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submitting-clinical-trial-datasets-and-documentation-clinical-outcome-assessments-using-item.
[37] https://database.ich.org/sites/default/files/ICH_E22_ConceptPaper_2024_0602.pdf.

I.L.3 Advancing Model-Informed Drug Development	• FDA issued the request for information (RFI) *Identifying Priority Focus Areas for Future Guidance Development and Engagement With Interested Parties in Model-Informed Drug Development; Request for Information*[38] on September 3, 2024. • Under PDUFA VII, FDA has granted 20 meeting requests as part of the MIDD Paired Meeting Program to date.
I.L.4 Enhancing Capacity to Review Complex Innovative Designs	• FDA satisfied the commitment to complete a public workshop to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs by March 31, 2024. ○ FDA hosted the hybrid public workshop Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice[39] on March 5, 2024. ○ The workshop focused on case studies that illustrated various aspects of complex innovative designs and their implementation, accompanied by panel discussions inspired by the case studies.
I.L.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• There were no commitments due.
I.L.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• There were no commitments due.

D. Section I.M: Enhancement and Modernization of FDA's Drug Safety System

[38] https://www.federalregister.gov/documents/2024/09/03/2024-19712/identifying-priority-focus-areas-for-future-guidance-development-and-engagement-with-interested.
[39] https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024.

Table 38. Section I.M's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.M.1 Modernization and Improvement of REMS Assessments	• To meet the commitment to issue new or update existing policies and procedures for reviewing methodological approaches and study protocols for REMS: ○ On March 25, 2024, FDA published a Manual of Policies and Procedures (MAPP) titled *Review of Proposed Methodological Approaches to Assess a Risk Evaluation and Mitigation Strategy (REMS)*.[40] ○ FDA developed and cleared review templates to support the REMS assessment methodological review process. ○ FDA provided training to staff on the MAPP. ○ FDA developed job aids to assist staff in implementing the MAPP. • To meet the commitment to update relevant REMS guidances to incorporate REMS assessment planning into the design of REMS, on May 7, 2024, FDA published the draft guidance for industry titled *REMS Logic Model: A Framework to Link Program Design With Assessment*.[41] • To meet the commitment to issue new or update existing policies and procedures to systematically determine if modifications are needed: ○ On March 25, 2024, FDA published a MAPP titled *Review of Risk Evaluation and Mitigation Strategy (REMS) Reports*.[42] ○ FDA developed and cleared new letter and review templates to support the REMS assessment report review process.

[40] https://www.fda.gov/media/177310/download.
[41] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-logic-model-framework-link-program-design-assessment.
[42] https://www.fda.gov/media/133675/download.

	○ FDA provided training to staff on the MAPP.
I.M.2 Optimization of the Sentinel Initiative	• CBER and CDER reported on $10.0M in expenditures related to updated PDUFA VI commitments for the PDUFA VII Sentinel Initiative. These funds supported the Agency's performance of key safety surveillance activities and related work in five core areas: data infrastructure; analytical capabilities; safety issue analyses; dissemination of relevant product and safety information; and Sentinel system development. This information was provided in February 2024. • Methods development projects on negative controls: ○ CDER initiated a methods development project on negative controls on March 31, 2024. This methods development project focuses on the development of empirical methods to automate the negative control identification process in Sentinel and integrate it into the Sentinel System tools. ○ CBER initiated a methods development project on July 17, 2024. This methods development project focuses on using a double negative control approach to adjust for the impact of unmeasured confounding in studying vaccine effectiveness. • FDA made information available on the *FDA Demonstration Projects to Inform Development of a Pregnancy Safety Study Framework*[43] website. ○ CDER and CBER initiated the Pregnancy Safety Demonstration Projects described in the PDUFA VII Commitment Letter with kick-off meetings on May 8, 2024. As of September 2024, protocols for all five projects were under active development. • In coordination with the Duke Margolis Institute for Health Policy, FDA published the following report on

[43] https://www.fda.gov/safety/fdas-sentinel-initiative/fda-demonstration-projects-inform-development-pregnancy-safety-study-framework.

	the public workshop held on post market pregnancy data: *Optimizing the Use of Postapproval Pregnancy Safety Studies.*[44]

E. Section I.N: Enhancements Related to Product Quality Reviews, Chemistry, Manufacturing, and Control Approaches, and Advancing the Utilization of Innovative Manufacturing Technologies

Table 39. Section I.N's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I. N.1 Enhancing Communication Between FDA and Sponsors During Application Review	• There were no commitments due.
I. N.2 Enhancing Inspection Communication for Applications, not Including Supplements	• There were no commitments due.
I.N.3 Alternative Tools to Assess Manufacturing Facilities Named in Pending Applications	• There were no commitments due.
I.N.4 Facilitating Chemistry, Manufacturing, and Controls Readiness for Products with Accelerated Clinical Development	• There were no commitments due.
I.N.5 Advancing Utilization and Implementation of Innovative Manufacturing	• FDA published the *Draft Strategy Document on Innovative Manufacturing Technologies*[45] on September 12, 2024.

[44] https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies.
[45] https://www.federalregister.gov/documents/2024/09/12/2024-20665/the-food-and-drug-administrations-draft-strategy-document-on-innovative-manufacturing-technologies.

F. Section I.O: Enhancing CBER's Capacity to Support Development, Review, and Approval of Cell and Gene Therapy Products

Table 40. Section I.O's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.O.1 Patient-Focused Drug Development	• There were no commitments due.
I.O.2 Novel Approaches to Development of Cell and Gene Therapy	• CBER held a public meeting titled *Methods and Approaches for Capturing Post-Approval Safety and Efficacy Data on Cell and Gene Therapy Products*[46] on April 27, 2023. • FDA developed a draft guidance on frequently asked questions and commonly faced issues titled *Frequently Asked Questions - Developing Potential Cellular and Gene Therapy Products*.[47] The guidance published in November 2024.
I.L.3 Advancing Model-Informed Drug Development	• There were no commitments due.
I.O.4 Leveraging Knowledge	• There were no commitments due.

G. Section I.P: Supporting Review of New Allergenic Extract Products

Table 41. Section I.P's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
I.P.1 Allergenic Extract Products Licensed After October 1, 2022	• There were no commitments due.

[46] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/methods-and-approaches-capturing-post-approval-safety-and-efficacy-data-cell-and-gene-therapy.
[47] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-developing-potential-cellular-and-gene-therapy-products.

I.P.2 Allergenic Extract Products Licensed Before October 1, 2022	• There were no commitments due.

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

Table 42. Section II's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• FDA provided information on use of the capacity planning adjustment (CPA) fee revenue on page 13 of the FY 2023 PDUFA Financial Report.[48] • FDA published an annual update[49] on the Agency's progress relative to activities described in the resource capacity planning and modernized time reporting implementation plan in March 2024.
II.B Financial Transparency and Efficiency	• FDA published the FY 2024 update to the PDUFA Five-Year Financial Plan[50] in April 2024. • FDA conducted the public meeting and opportunity to comment on *Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments* on June 6, 2024.[51] • FDA included information on appropriated user fee funds in the FY 2023 *Financial Report to Congress: Prescription Drug User Fee Act of 1992*.[52]

[48] https://www.fda.gov/media/176045/download?attachment.
[49] https://www.fda.gov/media/177222/download?attachment.
[50] https://www.fda.gov/media/177786/download?attachment.
[51] https://www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act.
[52] https://www.fda.gov/media/176045/download?attachment.

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

Table 43. Section III's FY 2024 Commitments and Accomplishments.

Commitment Title	FY 2024 Accomplishments
III.A Set Clear Goals for Human Drug Review Program Hiring	• CDER was allocated 31 PDUFA VII positions for FY 2024. As of September 30, 2024, 23 were on board, and two received Final Offers and were set to enter on duty in FY 2025. Of the remaining positions, three have candidates identified who are below the Final Offer stage. • CBER was allocated 48 PDUFA VII positions for FY 2024. As of September 30, 2024, 33 were on board, and one received a Final Offer and was set to enter on duty in FY 2025. Of the remaining positions, one has a candidate identified who is below the Final Offer stage. • Quarterly hiring data for PDUFA VII is posted on the public website (PDUFA and BsUFA Quarterly Hiring Updates | FDA)[53] within 2 weeks past the end date of the quarter.
III.B Assessment of Hiring and Retention	• There were no commitments due.

J. Section IV: Information Technology and Bioinformatics Goals

Table 44. Section IV's FY 2024 Commitments and Accomplishments.

Goal	FY 2024 Accomplishments
IV.A Enhancing Transparency and Leveraging Modern Technology	• CDER and CBER participated in the PDUFA VII Annual Meeting and Quarterly Industry Meeting on April 9, 2024. FDA provided answers to key questions that industry had, specifically regarding

[53] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates.

	FDA's IT Strategy and IT Operating Plan, cloud innovation activities, CBER's modernization, FDA's current thinking on AI, and data standards priorities.
	
	• FDA conducted its quarterly meetings with industry on November 7, 2023; February 6, 2024; April 9, 2024; and July 30, 2024, using these meetings as a mechanism to enhance transparency of FDA's IT activities and modernization plans.
	
	  ○ Targeted updates and discussions were held on key initiatives such as Electronic Submissions Gateway (ESG) modernization, CBER's modernization, and cloud demonstration projects such as the Pharmaceutical Quality Knowledge Management cloud demonstration project for which industry is actively engaging and the Information Requests demonstration project.
	
	• FDA published quarterly data standards action plans.
	
	  ○ The Data Standards Operations Subcommittee approved the FY24 Q1 Data Standards Action Plan on February 15, 2024, and it was published on February 20, 2024.
	  ○ The Data Standards Operations Subcommittee approved the FY24 Q2 Data Standards Action Plan on May 1, 2024, and it was published on May 08, 2024.
	  ○ The Data Standards Operations Subcommittee approved the FY24 Q3 Data Standards Action Plan on July 24, 2024, and it was published on August 19, 2024.
	  ○ The FY24 Data Standards Action Plan was published on November 20, 2024.
	
	• The annual update of the FDA Information Technology Strategy for FY 2024 – FY 2027 | FDA[54] was published on September 25, 2024.
	
	  ○ FDA continues to use an iterative and collaborative approach to update the strategy, leveraging input from internal and external stakeholders. FDA reassessed the strategy and

[54] https://www.fda.gov/about-fda/office-digital-transformation/fda-information-technology-strategy-fy-2024-fy-2027.

	determined it continues to reflect the Agency's long-term goals. ○ The Operating Plan provides the "how" FDA will advance and govern the FDA IT Strategy. The IT Operating Plan is being updated to reflect planned improvements to FDA's enterprise IT governance framework and the progress of FDA's strategic initiatives. FDA plans to publish the updated Operating Plan in FY25 Q1. • CBER's Roadmap priorities were updated and shared during FDA's regular meetings with industry on August 23, 2024; version 5 was shared in April 2024. • FDA posted quarterly updates on transaction times for PDUFA submissions via ESG on the following public webpage: Submission Times | FDA.[55] FDA also posted monthly summary statistics about ESG submission volume (e.g., total submissions, acknowledgements, traffic) on the following public webpage: Submission Statistics | FDA.[56] • In collaboration with Eagle Hill, FDA published a summary of an assessment on challenges and barriers to cloud technologies. FDA also published a response to the assessment summary. See *Leverage Cloud Technology to Progress Regulatory Digital Transformation.*[57] • FDA completed its annual assessment of bioinformatics capabilities of the High-performance Integrated Virtual Environment (which is a high-performance computing facility) in September 2024. • FDA initiated pilots with several stakeholders to evaluate the feasibility and effectiveness of using BioCompute Object standard (IEEE 2791-2020) to facilitate analysis and review of bioinformatic information in regulatory submissions.

[55] https://www.fda.gov/industry/about-esg/submission-times.
[56] https://www.fda.gov/industry/about-esg/submission-statistics.
[57] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-information-technology-and-bioinformatics-goals-and-progress.

IV.B Expanding and Enhancing Bioinformatics Support	• There were no commitments due.
IV.C Enhancing Use of Digital Health Technologies to Support Drug Development and Review	• The Digital Health Technology (DHT) Steering Committee engaged with four external stakeholder groups on DHT-related issues in FY 2024. • FDA convened the second of five public workshops[58] with the Foundation for the National Institutes of Health on digital measures on June 24-25, 2024. • FDA initiated two issue-focused demonstration projects in FY 2024. • FDA posted a funding opportunity[59] and awarded an additional issue-focused demonstration project. • In December 2023, FDA published the final guidance *Digital Health Technologies for Remote Acquisition in Clinical Investigation*.[60] • FDA provided staff with training on use of DHTs in clinical investigations in April and September 2024.

K. Additional PDUFA VII Review Program Reporting

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

The hiring and placement of new staff at FDA under PDUFA VII are reported on a quarterly basis and posted on the FDARA hiring performance web page.[61] FDA reports its progress in hiring new staff to support new initiatives in the annual PDUFA financial report, as per the PDUFA VII Commitment Letter.

[58] https://fnih.org/our-programs/digital-measures-workshop/.
[59] https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-24-037.html.
[60] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations.
[61] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates.

VI. Rationale for PDUFA Program Changes

Section 736B(a)(4) of the FD&C Act requires the annual PDUFA performance reporting requirements to include the following:

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 736, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human prescription drug activities, including identifying –

  (i) drivers of such changes; and
  (ii) changes in the total average cost per full-time equivalent in the prescription drug review program

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of human drug applications.

The information below fulfills these reporting requirements.

A. Changes in the Number of Individuals Hired as Agreed in the PDUFA VII Commitment Letter, the Number of Remaining Vacancies, the Number of Full-Time Equivalents (FTEs) Funded by Fees Collected Pursuant to Section 736, and the Number of FTEs Funded by Budget Authority by Division Within CDER, CBER, ORA, and OC

1. Changes in the Number of Individuals Hired as Agreed Upon in the PDUFA VII Commitment Letter and Remaining Vacancies

FDA is committed to hiring 352 FTEs from FY 2023 to FY 2027 as agreed upon in the PDUFA VII Commitment Letter. FDA had successfully hired 251 FTEs of the 352 FTEs (71 percent) as of September 30, 2024. The data in the following table show the total number of FTEs hired towards the FY 2023 and FY 2024 hiring targets as agreed upon in the PDUFA VII Commitment Letter and the change in the number of FTE hires from FY 2023 to FY 2024.

Table 45. Number of Individuals Hired as Agreed Upon in the PDUFA VII Commitment Letter and Remaining Vacancies.

Center	Number Hired in FY 2023	Number Hired in FY 2024	Change in Number Hired	Remaining Vacancies in FY 2023	Remaining Vacancies in FY 2024	Change in Number of Remaining Vacancies
CDER	41	49	8	36	18	-18
CBER	109	51	-58	23	20	-3
OC	0	0	0	0	0	0
ORA	1	0	-1	0	0	0
Total	**151**	**100**	**-51**	**59**	**38**	**-21**

* .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. Change in the Number of FTEs Funded by Budget Authority and Number of FTEs Funded by Fees by Division Within CDER, CBER, ORA, and OC

The data in the table below show the number of User Fee and Budget Authority funded FTEs at FDA by each division within CDER, CBER, ORA and OC. This table reflects the number of FTEs funded by User Fee and Budget Authority for the PDUFA VII program. For this table, "budget authority" refers to FDA's non-user fee annual appropriations. To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," the information in this table is broken down to the office level for the Centers, ORA, and OC. FDA uses a 2080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2024 represent the number of FTEs committed to PDUFA work. The number of FTEs funded by User Fee and budget authority for FY 2024 are those FTEs as of September 30, 2024.

Table 46. Number of FTEs Funded by Budget Authority and Number of FTEs funded by Fees by Division Within CDER, CBER, ORA, and OC.

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
CDER						
Office of Communications	7.51	10.05	2.54	39.38	44.21	4.83
Office of Compliance	14.95	15.16	0.21	77.98	81.43	3.45
Office of the Center Director	2.06	4.67	2.61	36.84	33.23	-3.61
Office of Executive Programs	3.65	3.36	-0.29	65.91	61.95	-3.96
Office of Generic Drugs	3.76	3.66	-0.10	3.40	3.61	0.21
Office of Management	9.00	8.70	-0.30	79.18	80.65	1.47
Office of Medical Policy	7.12	8.22	1.10	107.52	116.27	8.75
Office of New Drugs	132.16	64.03	-68.13	1,162.77	1,269.48	106.71
Office of Pharmaceutical Quality	58.59	51.72	-6.87	387.35	407.85	20.50

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Office of Regulatory Policy	15.49	3.10	-12.39	46.08	59.15	13.07
Office of Surveillance and Epidemiology	13.37	38.59	25.22	213.49	227.30	13.81
Office of Strategic Programs	5.12	9.56	4.44	76.81	81.92	5.11
Office of Information Management and Technology	0.12	0.00	-0.12	4.90	0.00	-4.90
Office of Translational Sciences	34.37	69.36	34.99	518.08	511.80	-6.28
Other Offices	0.66	0.15	-0.51	0.00	3.88	3.88
Working Capital Fund (WCF)	56.62	59.64	3.02	156.41	195.20	38.79
CDRH						
Office of Product Evaluation and Quality	1.06	0.19	-0.87	12.60	12.48	-0.12
Office of Management	0.50	0.08	-0.42	0.58	0.97	0.39
Office of Science and Engineering Laboratories	0.22	0.04	-0.18	0.00	0.06	0.06
Office of Communication, Information Disclosure, Training and Education†	0.36	0.11	-0.25	0.38	0.57	0.19
Office of Policy	0.05	0.02	-0.03	0.15	0.21	0.06
Office of Strategic Partnership and	0.05	0.19	0.14	0.00	0.03	0.03

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Technology Innovation						
Office of the Center Director	0.15	0.01	-0.14	0.09	0.30	0.21
Office of Digital Transformation‡	0.05	0.04	-0.01	0.00	0.00	0.00
WCF	0.59	0.55	-0.04	0.78	1.13	0.35
CBER						
Office of Biostatistics and Pharmacovigilance	25.59	17.12	-8.47	68.37	82.85	14.48
Office of Blood Research and Review	6.83	3.69	-3.14	7.26	6.15	-1.11
Office of Compliance and Biologics Quality	23.04	15.23	-7.81	82.37	87.74	5.37
Office of Therapeutic Products	60.53	50.86	-9.67	187.99	216.18	28.19
Office of Vaccines Research and Review	97.06	69.39	-27.67	126.99	147.29	20.30
Office of Communication Outreach and Development	7.67	4.53	-3.14	38.04	39.04	1.00
Office of the Center Director	8.20	3.86	-4.34	22.46	25.61	3.15
Office of Regulatory Operations	9.18	6.74	-2.44	38.66	44.55	5.89
Office of Management	13.52	11.36	-2.16	62.29	63.05	0.76
Office of Information	1.54	0.92	-0.62	3.91	3.12	-0.79

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Management and Technology						
Working Capital Fund	36.11	34.77	-1.34	49.27	64.63	15.36
OC						
OC Immediate Office	6.09	9.12	3.03	15.08	16.05	0.97
Office of the Chief Counsel	12.94	18.09	5.15	32.07	31.83	-0.24
Office of the Chief Scientist	7.84	11.97	4.13	19.42	21.06	1.64
Office of Clinical Policy and Programs	20.56	25.53	4.97	50.95	44.91	-6.04
Office of Digital Transformation	0.64	1.58	0.94	1.59	2.78	1.19
Office of Enterprise Management Services	3.59	0.00	-3.59	8.89	0.00	-8.89
Office of External Affairs	6.34	9.77	3.43	15.72	17.19	1.47
Office of Global Policy and Strategy	0.40	0.56	0.16	0.99	0.99	0.00
Office of International Programs	0.00	0.00	0.00	0.00	0.00	0.00
Office of Operations	12.66	3.99	-8.67	31.37	7.03	-24.34
Office of Policy, Legislation, and International Affairs	9.67	12.80	3.13	23.97	22.52	-1.45
WCF	6.34	18.29	11.95	18.42	23.53	5.11
ORA						

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Office of Pharmaceutical Quality Operations	106.80	107.90	1.10	45.59	46.72	1.13
WCF	9.53	10.38	0.85	3.01	4.37	1.36

* This table includes PDUFA program FTEs 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.

† CDRH's Office of Communication and Education was reorganized to the Office of Communication, Information Disclosure, Training and Education in FY 2024.

‡ CDRH's Office of Information Management and Technology was reorganized to the Office of Digital Transformation in FY 2024.

B. Changes in the Average Total Cost Per FTE in the Prescription Drug Review Program

Section 736B(a)(4) of the FD&C Act requires FDA to provide data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of prescription drugs, including identifying drivers of such changes and changes in the average total cost per FTE in the prescription drug review program. Accordingly, the table below provides data for the PDUFA fee revenue amounts and process costs for FY 2023 and FY 2024, as well as the changes in these amounts from FY 2023 to FY 2024. As amended by FDORA section 3626, FDA is also required to report on changes in the total average cost per FTE in the PDUFA program. 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 2024) and the prior fiscal year (FY 2023). Although section 736B(a)(4) of the FD&C Act as amended by FDARA does not explicitly require this data, they do provide

relevant context necessary to interpret the required information.

In FY 2024, FDA had net collections of $1,381,243,203 in prescription drug user fees, spent $1,377,172,919 in user fees for the human drug review process, and carried a cumulative balance of $297,371,048 forward for future fiscal years. Detailed financial information for the PDUFA user fee program can be found in the FY 2024 PDUFA financial report.[62]

The process for setting the annual target revenue is set forth in the statute. For FY 2024, the base revenue amount was $1,256,844,387. The FY 2024 base revenue amount is adjusted for inflation to maintain the purchasing power of fee funds. The inflation-adjusted base is increased by the strategic hiring and retention adjustment to cover the costs of hiring and retaining highly qualified scientific and technical staff. The revenue amount is further adjusted using the capacity planning adjustment for the resource capacity needs for the process for the review of human drug applications. An additional dollar amount specified in the statute is then added to provide for additional FTE positions to support PDUFA VII initiatives. The FY 2024 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 $1,422,104,000 (rounded to the nearest thousand dollars).

In FY 2024, PDUFA review process costs increased from FY 2023.

Table 47. Changes in the Average Total Cost Per FTE in the Prescription Drug Review Program.

Revenue/Cost	FY 2023	FY 2024	Change from FY 2023 to FY 2024
Fee Revenue Amounts (Net Collections)	$1,222,888,088	$1,381,243,203	13%
Process Cost (Cost of Activities)	$1,686,733,841	$1,772,198,497	5%
Average Total Cost Per FTE	**$216,474**	**$227,401**	5%

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

C. Number of Employees for Whom Time Reporting Is Required

Section 736B(a)(4) of the FD&C Act requires 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, 2024.

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

Table 48. Time Reporting Requirement for FY 2024.

Center	FTEs for Whom Time Reporting is Required	FTEs for Whom Time Reporting is Not Required
CDER	5,802	0
CBER	1,362	2
CDRH	2,237	5
OC	68	2,771
ORA	4,563	0
Total	**14,032**	**2,778**

D. Changes in the Average FTE Hours Required to Complete the Review of Each Type of Human Drug Application

Section 736B(a)(4) of the FD&C Act, as amended by FDORA section 3626, requires that FDA provide data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of human drug application.

Table 49. Changes in the Average FTE Hours Required to Complete the Review of Each Type of Human Drug Applications.

Application Type	Average FTE Hours Required to Complete Human Drug Application Reviews in FY 2023	Average FTE Hours Required to Complete Human Drug Application Reviews in FY 2024	Change from FY 2023 to FY 2024
PDUFA NME and BLA Applications	7,386	7,718	332
PDUFA Non-NME Applications	2,435	2,869	434
Total	**9,821**	**10,587**	**766**

To calculate the average hours required to complete review of PDUFA applications, FDA compared the 3-year average (sum of hours reported divided by the sum of applications submitted) ending in FY 2023 to the 3-year average ending in FY 2024. As application review activities span multiple fiscal years, this method provides an interpretable benchmark for any shifts in average hours required to complete application reviews over time.

Appendix A: List of Approved Applications

This appendix includes detailed review histories of the NDA and BLA submissions approved under PDUFA VII in FY 2024. 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 2024 can be found in the appendices of the earlier PDUFA performance reports.[1]

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 takes into account leap years, to calculate review time in months. Prior to FY 2022, FDA did not take into account leap years in our 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

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

♯ Major amendment was received, which extended the action goal date by 3 months[2]

Table A-1. FY 2024 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 2024							
PIVYA (pivmecillinam)	UTILITY THERAPEUTICS Ltd.	N	First	6.0	AP	6.0	Y
ZURNAI (nalmefene hydrochloride)	PURDUE PHARMA LP	N	First	6.0	AP	6.0	Y
PREVYMIS (letermovir)	MERCK SHARP AND DOHME LLC	N	First	6.0	AP	6.0	Y
IMDELLTRA (tarlatamab-dlle)	AMGEN Inc.	Y	First	7.1	AP	7.1	Y♦
VORANIGO (vorasidenib)	SERVIER PHARMACEUTICALS LLC	Y	First	7.6	AP	7.6	Y♦
NIKTIMVO (axatilimab-csfr) injection	INCYTE CORPORATION	Y	First	7.6	AP	7.6	Y♦
TECELRA (afamitresgene autoleucel)	Adaptimmune LLC	Y	First	8.0	AP	8.0	Y♦
CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine)	Merck Sharp & Dohme LLC	Y	First	8.0	AP	8.0	Y♦
LIVDELZI (seladelpar)	GILEAD SCIENCES Inc.	Y	First	8.0	AP	8.0	Y♦
IQIRVO (elafibranor)	IPSEN BIOPHARMACEUTICALS Inc.	Y	First	8.0	AP	8.0	Y♦
LAZCLUZE (lazertinib)	JANSSEN BIOTECH Inc.	Y	First	8.0	AP	8.0	Y♦
AQNEURSA (levacetylleucine)	INTRABIO Inc.	Y	First	8.0	AP	8.0	Y♦
NEMLUVIO (nemolizumab-ilto) injection	GALDERMA LABORATORIES, L.P.	Y	First	8.0	AP	8.0	Y♦

[2] Beginning with PDUFA V, a major amendment can be received any time during the review cycle and extend the goal date by 3 months. If the review cycle occurred prior to FY 2013, the major amendment must have been received within 3 months of the action due date to extend the action goal date by 3 months.

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
Submitted in FY 2023							
ROZLYTREK (entrectinib)	GENENTECH Inc.	N	First	5.7	AP	5.7	Y
ZEPBOUND (tirzepatide)	ELI LILLY AND Co.	N	First	6.0	AP	6.0	Y
EDURANT PED (rilpivirine)	JANSSEN PRODUCTS LP	N	First	6.0	AP	6.0	Y
FRUZAQLA (fruquintinib)	TAKEDA PHARMACEUTICALS USA Inc.	Y	First	7.3	AP	7.3	Y♦
LYFGENIA (lovotibeglogene autotemcel)	bluebird bio Inc.	Y	First	7.6	AP	7.6	Y♦
TRUQAP (capivasertib)	ASTRAZENECA PHARMACEUTICALS LP	Y	First	7.7	AP	7.7	Y♦
AUGTYRO (repotrectinib)	BRISTOL MYERS SQUIBB Co.	Y	First	7.7	AP	7.7	Y♦
ADZYNMA (ADAMTS13, recombinant-krhn)	Takeda Pharmaceuticals U.S.A., Inc.	Y	First	7.7	AP	7.7	Y♦
OJEMDA (tovorafenib)	DAY ONE BIOPHARMACEUTICALS Inc.	Y	First	7.8	AP	7.8	Y♦
OJEMDA (tovorafenib)	DAY ONE BIOPHARMACEUTICALS Inc.	N[3]	First	7.8	AP	7.8	Y♦
XOLREMDI (mavorixafor)	X4 PHARMACEUTICALS Inc.	Y	First	7.9	AP	7.9	Y♦
LENMELDY (atidarsagene autotemcel)	Orchard Therapeutics (Europe) Ltd.	Y	First	8.0	AP	8.0	Y♦
EXBLIFEP (cefepime and enmetazobactam)	ALLECRA THERAPEUTICS SAS	Y	First	8.0	AP	8.0	Y♦
rezdiffra	MADRIGAL PHARMACEUTICALS Inc.	Y	First	8.0	AP	8.0	Y♦

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

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
ZEVTERA (ceftobiprole medocaril sodium)	BASILEA PHARMACEUTICA INTERNATIONAL Ltd. ALLSCHWIL	Y	First	8.0	AP	8.0	Y♦
FABHALTA (iptacopan)	NOVARTIS PHARMACEUTICALS Corp.	Y	First	8.0	AP	8.0	Y♦
WINREVAIR (sotatercept-csrk)	MERCK SHARP & DOHME LLC	Y	First	8.0	AP	8.0	Y♦
Casgevy (exagamglogene autotemcel)	Vertex Pharmaceuticals Inc.	Y	First	8.2	AP	8.2	Y♦
MRESVIA (Respiratory Syncytial Virus Vaccine, mRNA (mRNA-1345))	ModernaTX, Inc.	Y	First	8.6	AP	8.6	N♦
IXCHIQ (Chikungunya Vaccine, Live)	Valneva Austria GmbH	Y	First	10.6	AP	10.6	Y♯♦
AMTAGVI (Lifileucel)	Iovance Biotherapeutics, Inc.	Y	First	10.7	AP	10.7	Y♯♦
OGSIVEO (nirogacestat)	SPRINGWORKS THERAPEUTICS Inc.	Y	First	11.0	AP	11.0	Y♯♦
DUVYZAT (givinostat)	ITALFARMACO SPA	Y	First	11.0	AP	11.0	Y♯♦
IWILFIN (eflornithine)	USWM LLC	N	First	12.7	AP	12.7	N
AURLUMYN (iloprost)	EICOS SCIENCES Inc.	N	First	12.8	AP	12.8	N
LUMISIGHT (pegulicianine)	LUMICELL Inc.	Y	First	13.0	AP	13.0	N♦
Submitted in FY 2022							
XROMI (hydroxyurea)	NOVA LABORATORIES Ltd.	N	First	19.1	AP	19.1	N
YORVIPATH (palopegteriparatide)	ASCENDIS PHARMA BONE DISEASES AS	Y	First	7.9	CR	7.9	Y♦
			Sponsor	6.6		14.5	
			Second	8.8	AP	23.3	Y#△
		Y	First	8.0	CR	8.0	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
KISUNLA (donanemab-azbt)	ELI LILLY AND COMPANY		Sponsor	4.8		12.8	
			Second	12.7	AP	25.5	N♯△
Submitted in FY 2021							
LOQTORZI (toripalimab-tpzi)	COHERUS BIOSCIENCES, Inc.	Y	First	7.9	CR	7.9	Y♦
			Sponsor	1.8		9.7	
			Second	16.1	AP	25.8	N△
FILSUVEZ (birch triterpenes)	CHIESI FARMACEUTICI SPA	Y	First	10.9	CR	10.9	Y♯♦
			Sponsor	19.7		30.6	
			Second	2.0	AP	32.6	Y▲
EOHILIA (budesonide oral suspension)	TAKEDA PHARMACEUTICALS USA Inc.	N	First	14.1	CR	14.1	N
			Sponsor	20.1		34.2	
			Second	5.6	AP	39.8	Y△
Submitted in FY 2020							
DEFENCATH (taurolidine and heparin) catheter lock solution	CORMEDIX Inc.	Y	First	7.9	CR	7.9	Y♦
			Sponsor	12		19.9	
			Second	5.3	CR	25.2	Y△
			Sponsor	9.3		34.5	
			Third	6.0	AP	40.5	Y△
MIPLYFFA (arimoclomol)	ZEVRA DENMARK AS	Y	First	11.0	CR	11.0	Y♯♦
			Sponsor	30.1		41.1	
			Second	9.0	AP	50.1	Y♯△
Submitted in FY 2017							
darunavir and ritonavir	MYLAN LABORATORIES Ltd.	N	First	6.0	CR	6.0	Y
			Sponsor	4.9		10.9	
			Second	6.0	CR	16.9	Y△
			Sponsor	1.5		18.4	
			Third	6.0	CR	24.4	Y△
			Sponsor	45.3		69.7	
			Fourth	6.0	TA	75.7	Y△

Table A-2. FY 2024 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 2024							
TECENTRIQ HYBREZA (atezolizumab and hyaluronidase-tqjs)	GENENTECH, Inc.	N	First	9.9	AP	9.9	Y
OCREVUS ZUNOVO (ocrelizumab and hyaluronidase-ocsq) injection	GENENTECH, Inc.	N	First	10.0	AP	10.0	Y
Submitted in FY 2023							
pantoprazole sodium in 0.9% sodium chloride injection	BAXTER HEALTHCARE Corp.	N	First	5.9	AP	5.9	Y
TALZENNA (talazoparib)	PFIZER Inc.	N	First	9.7	AP	9.7	Y
IDOSE TR (travoprost)	GLAUKOS Corp.	N	First	9.7	AP	9.7	Y
QLOSI (pilocarpine hydrochloride)	ORASIS PHARMACEUTICALS Ltd.	N	First	9.8	AP	9.8	Y
FEMLYV (norethindrone acetate and ethinyl estradiol)	MILLICENT PUERTO RICO LLC	N	First	9.8	AP	9.8	Y
CABTREO (clindamycin phosphate, benzoyl peroxide, and adapalene)	BAUSCH HEALTH US LLC	N	First	9.9	AP	9.9	Y
ZITUVIMET XR (sitagliptin and metformin hydrochloride)	ZYDUS LIFESCIENCES GLOBAL FZE	N	First	9.9	AP	9.9	Y
TEPYLUTE (thiotepa)	SHORLA PHARMA Ltd.	N	First	9.9	AP	9.9	Y
ZORYVE (roflumilast)	ARCUTIS BIOTHERAPEUTICS Inc.	N	First	9.9	AP	9.9	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
hydromorphone hydrochloride injection, 2 mg/ml	HIKMA PHARMACEUTICALS USA Inc.	N	First	9.9	AP	9.9	Y
COXANTO (oxaprozin)	SOLUBIOMIX LLC	N	First	9.9	AP	9.9	Y
RETEVMO (selpercatinib)	LOXO ONCOLOGY A WHOLLY OWNED SUB OF ELI LILLY AND Co.	N	First	9.9	AP	9.9	Y
potassium phosphates in 0.9% sodium chloride injection	AMNEAL EU Ltd.	N	First	9.9	AP	9.9	Y
VIJOICE (alpelisib)	NOVARTIS PHARMACEUTICALS Corp.	N	First	9.9	AP	9.9	Y
aprepitant injectable emulsion	AZURITY PHARMACEUTICALS Inc.	N	First	9.9	TA	9.9	Y
ZYMFENTRA (infliximab)	CELLTRION, Inc.	N	First	9.9	AP	9.9	Y
ERZOFRI (paliperidone palmitate)	LUYE INNOMIND PHARMA (SHIJIAZHUANG) Co. Ltd.	N	First	10.0	AP	10.0	Y
ZITUVIMET (sitagliptin and metformin hydrochloride)	ZYDUS LIFESCIENCES GLOBAL FZE	N	First	10.0	AP	10.0	Y
ONYDA XR (clonidine hydrochloride)	TRIS PHARMA Inc.	N	First	10.0	AP	10.0	Y
VIGAFYDE (vigabatrin)	PYROS PHARMACEUTICALS Inc.	N	First	10.0	AP	10.0	Y
TEZRULY (terazosin)	NOVITIUM PHARMA LLC	N	First	10.0	AP	10.0	Y
clobetasol propionate ophthalmic nanosuspension	EYENOVIA Inc.	N	First	10.0	AP	10.0	Y
SEHIPPY (vortioxetine)	SEASONS BIOTECHNOLOGY (TAIZHOU) Co. Ltd.	N	First	10.0	TA	10.0	Y
RINVOQ LQ (upadacitinib)	ABBVIE Inc.	N	First	10.0	AP	10.0	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
INGREZZA SPRINKLE (valbenazine)	NEUROCRINE BIOSCIENCES Inc.	N	First	10.0	AP	10.0	Y
OPSYNVI (macitentan and tadalafil)	ACTELION PHARMACEUTICALS US Inc.	N	First	10.0	AP	10.0	Y
CHEWTADZY (tadalafil)	B BETTER LLC	N	First	10.0	AP	10.0	Y
ZUNVEYL (benzgalantamine)	ALPHA COGNITION Inc.	N	First	10.0	AP	10.0	Y
ENTRESTO SPRINKLE (sacubitril and valsartan)	NOVARTIS PHARMACEUTICALS Corp.	N	First	10.0	AP	10.0	Y
LIBERVANT (diazepam)	AQUESTIVE THERAPEUTICS Inc.	N	First	10.0	AP	10.0	Y
teriparatide injection	ALMAJECT Inc.	N	First	10.0	AP	10.0	Y
COSENTYX (secukinumab)	NOVARTIS PHARMACEUTICALS CORPORATION	N	First	10.0	AP	10.0	Y
OPIPZA (aripiprazole) oral film	XIAMEN LP PHARMACUETICAL Co. Ltd.	N	First	10.1	AP	10.1	N
YIMMUGO (immune globulin intravenous, human-dira)	Biotest AG	Y	First	11.5	AP	11.5	Y♦
lumify preservative free	BAUSCH AND LOMB Inc.	N	First	11.6	AP	11.6	Y♯
RYTELO (imetelstat)	GERON Corp.	Y	First	11.7	AP	11.7	Y♦
BEQVEZ (fidanacogene elaparvovec-dzkt)	Pfizer Inc.	Y	First	11.9	AP	11.9	Y♦
VELSIPITY (etrasimod)	PFIZER Inc.	Y	First	11.9	AP	11.9	Y♦
LEQSELVI (deuruxolitinib phosphate)	SUN PHARMACEUTICAL INDUSTRIES Inc.	Y	First	11.9	AP	11.9	Y♦
PENBRAYA (Meningococcal Groups A, B, C, W and Y Vaccine)	Pfizer Ireland Pharmaceuticals	Y	First	12.0	AP	12.0	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
AGAMREE (vamorolone)	CATALYST PHARMACEUTICALS Inc.	Y	First	12.0	AP	12.0	Y♦
WAINUA (eplontersen)	ASTRAZENECA AB	Y	First	12.0	AP	12.0	Y♦
OHTUVAYRE (ensifentrine)	VERONA PHARMA Inc.	Y	First	12.0	AP	12.0	Y♦
ZELSUVMI (berdazimer)	LNHC Inc.	Y	First	12.0	AP	12.0	Y♦
VOYDEYA (danicopan)	ALEXION PHARMACEUTICALS Inc.	Y	First	12.0	AP	12.0	Y♦
FLYRCADO (flurpiridaz f 18)	GE HEALTHCARE Inc.	Y	First	12.0	AP	12.0	Y♦
COBENFY (xanomeline and trospium chloride)	BRISTOL-MYERS SQUIBB Co.	Y	First	12.0	AP	12.0	Y♦
PIASKY (crovalimab-akkz) injection	GENENTECH, Inc.	Y	First	12.0	AP	12.0	Y♦
vasopressin	LONG GROVE PHARMACEUTICALS LLC	N	First	10.0	TA	10.0	Y
			Sponsor	0.4		10.4	
			Second	1.9	AP	12.3	Y▲
REZENOPY (naloxone hydrochloride)	SUMMIT BIOSCIENCES LLC	N	First	12.9	AP	12.9	N
TRYVIO (aprocitentan)	IDORSIA PHARMACEUTICALS Ltd.	Y	First	15.0	AP	15.0	Y♯♦
Submitted in FY 2022							
ZILBRYSQ (zilucoplan)	UCB Inc.	Y	First	13.5	AP	13.5	Y♯♦
OMVOH (mirikizumab-mrkz)	ELI LILLY AND COMPANY	Y	First	12.0	CR	12.0	Y♦
			Sponsor	1.8		13.8	
			Second	5.1	AP	18.9	Y△
LEGUBETI (acetylcysteine)	GALEPHAR PHARMACEUTICAL RESEARCH Inc.	N	First	9.9	CR	9.9	Y
			Sponsor	3.3		13.2	
			Second	6.0	AP	19.2	Y△
VOQUEZNA (vonoprazan)	PHATHOM PHARMACEUTICALS Inc.	N	First	10.9	CR	10.9	N
			Sponsor	3.3		14.2	
			Second	5.5	AP	19.7	Y△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
NEFFY (epinephrine)	ARS PHARMACEUTICALS OPERATIONS Inc.	N	First	13.0	CR	13.0	Y♯
			Sponsor	6.4		19.4	
			Second	4.2	AP	23.6	Y△
SOFDRA (sofpironium)	BOTANIX SB Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	2.9		14.9	
			Second	5.9	AP	20.8	Y△
PHYRAGO (dasatinib)	NANOCOPOEIA LLC	N	First	9.7	CR	9.7	Y
			Sponsor	0.2		9.9	
			Second	5.8	TA	15.7	Y△
			Sponsor	4.8		20.5	
			Third	1.8	AP	22.3	Y▲
LYMPHIR (denileukin diftitox-cxdl)	CITIUS PHARMACEUTICALS Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	6.6		16.6	
			Second	5.8	AP	22.4	Y△
ANKTIVA (nogapendekin alfa inbakicept-pmln)	ALTOR BIOSCIENCE, LLC, AN INDIRECT WHOLLY-OWNED SUBSIDIARY OF IMMUNITYBIO, Inc.	Y	First	11.5	CR	11.5	Y♦
			Sponsor	5.5		17.0	
			Second	6.0	AP	23.0	Y△
CREXONT (carbidopa and levodopa)	IMPAX LABORATORIES LLC	N	First	10.0	CR	10.0	Y
			Sponsor	7.3		17.3	
			Second	6.0	AP	23.3	Y△
EBGLYSS (lebrikizumab-lbkz)	ELI LILLY AND COMPANY	Y	First	12.0	CR	12.0	Y♦
			Sponsor	5.5		17.5	
			Second	6.0	AP	23.5	Y△
alvaiz	TEVA PHARMACEUTICALS Inc.	N	First	10	TA	10	Y
			Sponsor	11.9		21.9	
			Second	2.0	AP	23.9	Y▲
MYHIBBIN (mycophenolate mofetil)	AZURITY PHARMACEUTICALS Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	9.8		19.8	
			Second	6.0	AP	25.8	Y△
Submitted in FY 2021							
ryzneuta	EVIVE BIOTECHNOLOGY SINGAPORE PTE. Ltd.	Y	First	31.6	AP	31.6	N♦
		N	First	10.0	CR	10.0	Y
			Sponsor	9.6		19.6	

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
COMBOGESIC IV (acetaminophen and ibuprofen)	HIKMA PHARMACEUTICALS USA Inc.		Second	6.0	AP	25.6	Y△
Alyglo (immune globulin intravenous, human-stwk)	GC Biopharma Corp.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	16.7		28.7	
			Second	5.0	AP	33.7	Y△
LETYBO (letibotulinumtoxina-wlbg)	HUGEL Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	6.2		18.2	
			Second	6.2	CR	24.4	N△
			Sponsor	4.6		29.0	
			Third	6.0	AP	35.0	Y△
ZITUVIO (sitagliptin)	ZYDUS LIFESCIENCES GLOBAL FZE	N	First	10.0	TA	10.0	Y
			Sponsor	16.1		26.1	
			Second	1.9	CR	28.0	Y▲
			Sponsor	1.5		29.5	
			Third	6.0	AP	35.5	Y△
TEVIMBRA (tislelizumab-jsgr)	BEIGENE USA, Inc.	Y	First	32.0	AP	32.0	N♦
VAFSEO (vadadustat)	AKEBIA THERAPEUTICS Inc.	Y	First	12.0	CR	12.0	Y♦
			Sponsor	18.0		30.0	
			Second	6.0	AP	36.0	Y△
RISVAN (risperidone)	LABORATORIOS FARMACEUTICOS ROVI SA	N	First	10.0	CR	10.0	Y
			Sponsor	3.8		13.8	
			Second	5.8	CR	19.6	Y△
			Sponsor	6.4		26.0	
			Third	5.9	CR	31.9	Y△
			Sponsor	2.1		34.0	
			Fourth	6.0	AP	40.0	Y△
Submitted in FY 2020							
XPHOZAH (tenapanor hydrochloride)	ARDELYX Inc.	N	First	12.9	CR	12.9	Y♯
			Sponsor	20.6		33.5	
			Second	6.0	AP	39.5	Y△
BIMZELX (bimekizumab)	UCB, Inc.	Y	First	21.9	CR	21.9	N♯♦
			Sponsor	6.3		28.2	
			Second	10.8	AP	39.0	N△
	LAURUS LABS Ltd.	N	First	10.0	TA	10.0	Y◊

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
dolutegravir, emtricitabine, and tenofovir alafenamide			Sponsor	14.7		24.7	
			Second	8.9	CR	33.6	Y♯△
			Sponsor	4.7		38.3	
			Third	6.0	TA	44.3	Y△
efavirenz, emtricitabine and tenofovir alafenamide	MYLAN LABORATORIES Ltd.	N	First	9.7	CR	9.7	Y◊
			Sponsor	34.2		43.9	
			Second	5.6	TA	49.5	Y△
YUTREPIA (treprostinil)	LIQUIDIA TECHNOLOGIES Inc.	N	First	10.0	CR	10.0	Y
			Sponsor	5.4		15.4	
			Second	5.9	TA	21.3	Y△
			Sponsor	20.6		41.9	
			Third	12.8	TA	54.7	N△
Submitted in FY 2019							
dolutegravir, emtricitabine, and tenofovir alafenamide	HETERO LABS Ltd. UNIT III	N	First	9.9	CR	9.9	Y◊
			Sponsor	6.1		16.0	
			Second	5.9	CR	21.9	Y△
			Sponsor	24.0		45.9	
			Third	6.0	TA	51.9	Y△
bortezomib	SHILPA MEDICARE Ltd.	N	First	9.4	CR	9.4	Y
			Sponsor	34.8		44.2	
			Second	5.9	CR	50.1	Y△
			Sponsor	4.6		54.7	
			Third	8.2	AP	62.9	Y#△
BYNFEZIA PEN (octreotide acetate) injection	SUN PHARMACEUTICAL INDUSTRIES Ltd.	N	First	25.7	CR	25.7	N
			Sponsor	34.3		60.0	
			Second	6.0	AP	66.0	Y△
Submitted in FY 2017							
pemetrexed	AVYXA HOLDINGS LLC	N	First	9.9	TA	9.9	Y
			Sponsor	72.0		81.9	
			Second	3.0	AP	84.9	N▲
Submitted in FY 2015							
cabazitaxel	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA	N	First	9.9	TA	9.9	Y
			Sponsor	26.5		36.4	
			Second	2.5	TA	38.9	N▲

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
	PHARMACEUTICALS USA Inc.		Sponsor	68.1		107.0	
			Third	5.7	AP	112.7	Y△
Submitted in FY 2014							
abacavir and lamivudine	NORVIUM BIOSCIENCE LLC	N	First	10	TA	10.0	Y◊
			Sponsor	51.5		61.5	
			Second	5.9	CR	67.4	Y△
			Sponsor	35.3		102.7	
			Third	6.0	CR	108.7	Y△
			Sponsor	5.3		114.0	
			Fourth	6.0	AP	120.0	Y△

Appendix B: Filed Application Numbers by Review Division

The tables below and on the pages that follow show the number of applications filed in FY 2024 for various application types and review designations broken out by review division. This reporting for PDUFA VII is required under section 736B(a) of the FD&C Act.

Table B-1. Original Applications Filed in FY 2024 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	2	2	0	1	1
Division of Anti-Infectives	3	3	0	0	0
Division of Antivirals	2	0	0	0	0
Division of Cardiology and Nephrology	2	12	0	0	1
Division of Dermatology and Dentistry	0	2	2	1	0
Division of Diabetes, Lipid Disorders, and Obesity	1	1	0	0	0
Division of Gastroenterology	0	1	0	0	0
Division of General Endocrinology	2	3	0	0	1
Division of Hematologic Malignancies I	2	3	1	0	0
Division of Hematologic Malignancies II	0	1	1	0	1
Division of Hepatology and Nutrition	2	2	0	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Imaging and Radiation Medicine	0	4	0	0	2
Division of Neurology I	0	1	0	0	1
Division of Neurology II	0	2	0	1	0
Division of Non-Malignant Hematology	0	2	1	2	1
Division of Non-Prescription Drugs I	0	1	0	0	0
Division of Non-Prescription Drugs II	0	1	0	0	0
Division of Oncology I	1	2	0	1	1
Division of Oncology II	4	2	4	2	1
Division of Oncology III	1	2	1	1	1
Division of Ophthalmology	0	2	0	0	0
Division of Psychiatry	2	3	0	0	0
Division of Pulmonology, Allergy, and Critical Care	1	2	0	1	0
Division of Rare Diseases and Medical Genetics	3	1	0	1	0
Division of Rheumatology and Transplant Medicine	0	0	0	0	0
Division of Urology, Obstetrics, and Gynecology	0	2	0	0	0
CDER Totals	*28*	*57*	*10*	*11*	*11*
CBER Review Offices					
Office of Blood Research and Review	0	0	0	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Office of Tissues and Advanced Therapies	0	0	6	1	0
Office of Vaccines Research and Review	0	0	2	2	0
CBER Totals	*0*	*0*	*8*	*3*	*0*
FDA Totals	28	57	18	14	11

Table B-2. Efficacy Supplements Filed in FY 2024 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	5	1	0
Division of Anti-Infectives	1	4	0
Division of Antivirals	8	12	2
Division of Cardiology and Nephrology	3	7	3
Division of Dermatology and Dentistry	1	9	0
Division of Diabetes, Lipid Disorders, and Obesity	6	15	0
Division of Gastroenterology	2	6	0
Division of General Endocrinology	0	7	1
Division of Hematologic Malignancies I	2	1	0
Division of Hematologic Malignancies II	5	9	1

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Hepatology and Nutrition	0	5	0
Division of Imaging and Radiation Medicine	1	4	1
Division of Neurology I	2	7	0
Division of Neurology II	0	4	0
Division of Non-Malignant Hematology	0	3	1
Division of Non-Prescription Drugs I	0	0	0
Division of Non-Prescription Drugs II	0	0	0
Division of Oncology I	13	17	5
Division of Oncology II	10	8	0
Division of Oncology III	5	16	0
Division of Ophthalmology	0	7	1
Division of Psychiatry	4	10	0
Division of Pulmonology, Allergy, and Critical Care	8	1	0
Division of Rare Diseases and Medical Genetics	0	1	1
Division of Rheumatology and Transplant Medicine	0	9	1
Division of Urology, Obstetrics, and Gynecology	0	1	0
CDER Totals	*76*	*164*	*17*
CBER Review Divisions			
Office of Blood Research and Review	0	0	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Office of Tissues and Advanced Therapies	4	4	0
Office of Vaccines Research and Review	2	14	0
CBER Totals	*6*	*18*	*0*
FDA Totals	82	182	17

Table B-3. Submissions with Special Designations Filed in FY 2024 by Review Division/Office.

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
CDER Review Divisions					
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	2	1	3	74
Division of Anti-Infectives	0	2	0	1	23
Division of Antivirals	0	0	1	0	37
Division of Cardiology and Nephrology	1	1	3	4	84
Division of Dermatology and Dentistry	0	1	0	1	75
Division of Diabetes, Lipid Disorders, and Obesity	0	1	1	3	74
Division of Gastroenterology	0	0	1	0	48

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
Division of General Endocrinology	0	2	3	3	14
Division of Hematologic Malignancies I	0	3	1	2	90
Division of Hematologic Malignancies II	1	2	3	3	118
Division of Hepatology and Nutrition	1	0	3	6	20
Division of Imaging and Radiation Medicine	0	2	2	1	87
Division of Neurology I	0	1	2	3	93
Division of Neurology II	0	1	0	2	39
Division of Non-Malignant Hematology	0	2	5	1	40
Division of Non-Prescription Drugs I	0	0	0	0	2
Division of Non-Prescription Drugs II	0	0	0	0	2
Division of Oncology I	0	0	0	4	236
Division of Oncology II	3	4	5	14	192
Division of Oncology III	0	2	1	1	160
Division of Ophthalmology	0	0	0	0	42
Division of Psychiatry	0	1	1	4	125
Division of Pulmonology,	0	3	4	3	57

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
Allergy, and Critical Care					
Division of Rare Diseases and Medical Genetics	0	4	5	0	8
Division of Rheumatology and Transplant Medicine	0	0	0	1	45
Division of Urology, Obstetrics, and Gynecology	0	0	0	1	28
CDER Totals	*6*	*34*	*42*	*61*	*1,813*
CBER Review Divisions					
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	1	1	1	1	1
Office of Vaccines Research and Review	0	0	0	0	0
CBER Totals	*1*	*1*	*1*	*1*	*1*
FDA Totals	7	35	43	62	1,814

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2024. 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 September 30, 2022, FUFRA was signed into law. FUFRA reauthorized the user fee programs for prescription drugs, generic drugs, medical devices, and biosimilar biological products.

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 2024. Data represent all the original NDA and BLA approvals that occurred during FY 2024, regardless of when the application was received. Data are presented by the type of application and performance goal, as well as whether the approval occurred on time or was overdue on the performance goal.

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

Figures provided in the table below are indicated in detail in Appendix A of this report, which provides a detailed review history of the NDAs and BLAs approved under PDUFA during FY 2024.[1]

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

Table C-1. FY 2024 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	30	28	2	**93%**
First Cycle Standard NMEs & BLAs	10 months of filing date	22	20	2	**91%**
First Cycle Priority Non-NME NDAs	6 months	10	7	3	70%
First Cycle Standard Non-NME NDAs	10 months	40	38	2	**95%**
Class 1 Resubmissions	2 months	1	1	0	**100%**
Class 2 Resubmissions	6 months	30	26	4	87%
Total	**--**	**133**	**120**	**13**	**--***

* Performance is not calculated on combined goals.

B. Performance Enhancement Goals

Section 736B(a)(5)(B) of the FD&C Act, which requires FDA to include relevant data to determine whether CDER and CBER have met performance enhancement goals identified in the Commitment Letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022 for the applicable fiscal year. A link to each performance enhancement goal completed under PDUFA VII can be found on FDA's website.[2]

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

The table below represents FDA's FY 2023 updated performance enhancement goals.

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

Table C-2. FY 2023 Performance Enhancement Goals (Updated).

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Hiring PDUFA Human Drug Review Program Staff FY23	9/30/2023	N	N/A	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates

The table below represents FDA's FY 2024 performance enhancement goals.

Table C-3. FY 2024 Performance Enhancement Goals.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Implement URRA Review	10/1/2023	Y	3/8/2023	
ESG Website Update FY23	10/21/2023	Y	10/10/2023	https://www.fda.gov/industry/about-esg/submission-statistics
Quarterly Hiring Reporting Q4 FY23	10/21/2023	Y	10/3/2023	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Issue FR Notice Summarizing PFDD RFI	12/31/2023	Y	12/12/2023	https://www.federalregister.gov/documents/2023/12/13/2023-27312/methodological-challenges-related-to-patient-experience-data-summary-of-received-comments
Publish Data Standards Action Plan Q4 FY23	12/31/2023	Y	11/9/2023	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board

Publish Public Report on Challenges and Barriers to Cloud Technologies	12/31/2023	Y	12/27/2023	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-information-technology-and-bioinformatics-goals-and-progress
Quarterly Hiring Reporting Q1 FY24	1/21/2024	Y	1/11/2024	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Contribute Information on Sentinel to PDUFA Financial Report FY23	1/30/2024	Y	11/30/2023	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports
Include Rare Diseases Information in OND New Drug Report FY23	1/30/2024	Y	12/11/2023	https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs-ond-annual-reports
Provide Rare Diseases Information to PDUFA Annual Report FY23	1/30/2024	Y	9/29/2023	https://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports
Conduct Public Workshop for CID	3/31/2024	Y	3/4/2024	https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024
Issue New or Update Existing Policies and Procedures for Reviewing Methodological Approaches and Study Protocols for REMS	3/31/2024	Y	3/26/2024	https://www.fda.gov/media/177310/download
Issue New or Update Existing Policies and Procedures to Systematically Determine if Modifications are Needed	3/31/2024	Y	3/26/2024	https://www.fda.gov/media/133675/download?attachment
Provide Information on Appropriated User Fee Funds Financial Report FY23	3/31/2024	Y	2/16/2024	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports

Provide Information on CPA Fee Revenues to PDUFA Annual Financial Report FY23	3/31/2024	Y	2/7/2024	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports
Publish Data Standards Action Plan Q1 FY24	3/31/2024	Y	2/20/2024	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board
Publish Financial Plan Updates FY24	3/31/2024	N	4/15/2024	https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans
Publish Implementation Plan Updates FY24	3/31/2024	Y	3/22/2024	https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting
Update Relevant REMS Guidances to incorporate REMS assessment planning into the design of REMS	3/31/2024	N	5/6/2024	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-logic-model-framework-link-program-design-assessment
Quarterly Hiring Reporting Q2 FY24	4/21/2024	Y	4/12/2024	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Conduct Public Meeting Financial Plan FY24	6/30/2024	Y	6/6/2024	https://www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act
Publish Data Standards Action Plan Q2 FY24	6/30/2024	Y	5/8/2024	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board

Report Real-World Evidence Submissions to CDER and CBER - FY24	6/30/2024	Y	6/26/2024	https://www.fda.gov/science-research/real-world-evidence/real-world-evidence-submissions-center-biologics-evaluation-and-research-center-drug-evaluation-and
Quarterly Hiring Reporting Q3 FY24	7/21/2024	Y	7/8/2024	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Hold Public Workshop About Meetings Management	7/30/2024	Y	7/22/2024	https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-best-practices-meeting-management-under-pdufa-vii-07222024
Annual FDA-Industry IT Leadership Meeting 2 FY24	9/30/2024	Y	4/9/2024	
Assess and Share Bioinformatics Capabilities FY24	9/30/2024	Y	9/30/2024	
CBER Roadmap Updates FY24	9/30/2024	Y	8/23/2024	
Conduct PFDD Methodology Workshop 1	9/30/2024	N	12/13/2024	https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-discuss-methodologic-and-other-challenges-related-patient.
Conduct Public Meeting for Post Approval CGT	9/30/2024	Y	4/27/2023	https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/methods-and-approaches-capturing-post-approval-safety-and-efficacy-data-cell-and-gene-therapy
Develop and Update Data and Tech Modernization Strategy FY24	9/30/2024	Y	9/25/2024	https://www.fda.gov/about-fda/office-digital-transformation/fda-

				information-technology-strategy-fy-2024-fy-2027
Hiring PDUFA Human Drug Review Program Staff FY24	9/30/2024	N	--	See corrective actions for more information. https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Initiate Development Project (1) on Negative Controls (CDER)	9/30/2024	Y	6/30/2024	
Initiate Development Project (2) on Negative Controls (CBER)	9/30/2024	Y	7/17/2024	
Initiate Pregnancy Safety Demonstration Project A	9/30/2024	Y	5/8/2024	https://www.fda.gov/safety/fdas-sentinel-initiative/fda-demonstration-projects-inform-development-pregnancy-safety-study-framework
Initiate Pregnancy Safety Demonstration Project B	9/30/2024	Y	5/8/2024	
Initiate Pregnancy Safety Demonstration Project C	9/30/2024	Y	5/8/2024	
Initiate Pregnancy Safety Demonstration Project D	9/30/2024	Y	5/8/2024	
Initiate Pregnancy Safety Demonstration Project E	9/30/2024	Y	5/8/2024	
Issue RFI for MIDD	9/30/2024	Y	9/3/2024	
Publish Combo Products Guidance Related to URRAs	9/30/2024	Y	7/8/2024	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products
Publish Data Standards Action Plan Q3 FY24	9/30/2024	Y	8/19/2024	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-

				program-strategic-plan-and-board
Publish Draft Guidance Q&A CGT	9/30/2024	N	11/19/2024	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-developing-potential-cellular-and-gene-therapy-products See corrective actions for additional information.
Publish Draft Innovative Manufacturing Strategy Document	9/30/2024	Y	9/11/2024	https://www.fda.gov/media/181689/download?attachment
Publish Report on Public Workshop on Post Market Pregnancy Data	9/30/2024	Y	7/11/2024	https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies
Quarterly PDUFA Standing Meetings with Industry FY24	9/30/2024	Y	7/30/2024	
Rare Disease Endpoint Advancement Selection Committee Meetings FY24	9/30/2024	Y	9/1/2024	

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 Commitment Letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2022.

Table C-4. FY 2024 Performance Results.

Cause or Trend	Impact on FDA's Commitments
High Volume of Meeting Requests	In FY 2024, FDA continued to receive an increased volume of meeting requests. Total meeting volume was at a historical high in FY 2024. Notwithstanding the increased volume of meeting requests, FDA generally improved meeting performance in FY 2024 when compared to FY 2023.

Appendix D: FY 2024 Corrective Action Report

Section 736B(c) of the FD&C Act requires FDA to publicly issue a corrective action report that details its progress in meeting the review and performance enhancement goals identified in the PDUFA VII Commitment Letter 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 2023 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 2023, then the Agency fully reported on it in last year's report.[1]

Table D-1. FY 2023 Review and Procedural and Processing Goal Performance Results (Updated).

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Review Goals	Class 1 and Class 2 Resubmitted NDA and BLA Efficacy Supplements were missed in FY 2023, after the 2023 Annual Performance Report was published.	FDA will continue to strive to meet all review goals.

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

	○ In FY 2023, FDA received only six combined Class 1 and Class 2 resubmitted NDA and BLA Efficacy Supplements. Due to the small number of submissions received, missing a single goal date brought performance below the 90-percent target. Unfortunately, with the small number of submissions, the only way to have met this goal would have been to review 100 percent on time, which is inconsistent with the 10-percent margin normally allowed for unexpected circumstances.	
Procedural and Processing Goals	See below for 2024.	See below for 2024.

Table D-2. FY 2024 Review and Procedural and Processing Goal Performance Results.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Procedural and Processing Goals	FDA missed several performance goals related to formal meetings in 2024. It appears this was primarily due to a general trend in overall increase in complexity of meeting-related questions, combined with a sustained high review workload and increased meeting volume. The increased question complexity required involvement from a greater number of disciplines, which led to difficulties finding times to schedule some meetings within the specified goal date.	FDA is continuing to explore ways to improve meeting performance and improve upon the upward performance trend.
	Human Factors Validation Protocol Submissions to INDs ○ In FY 2024, FDA significantly improved performance on Human Factors Validation Protocol Submissions to IND goals, with 72 percent currently on time (75	FDA will continue to strive to iteratively improve just as we did in FY 2024. • FDA continues to assess ways to handle the large volume and increasing complexity of Human

	percent highest possible on time) compared to 28 percent in FY 2023. FY 2024 improvements reflect increased efforts to recruit and hire candidates with the specialized training and background needed for the technical work. The work unit responsible for Human Factors Validation Protocol Submission Review has doubled in size, though training and onboarding continues to occur and is necessary before FDA can realize the full impact of the hiring.	Factors Validation Protocol Submissions to INDs more effectively. • FDA has filled nearly all vacancies in this work unit, and work unit managers have now focused efforts toward the ongoing training of new staff and toward continued improvements to work processes to gain efficiencies and meet FDA's target goal dates.

Table D-3. FY 2024 Performance Enhancement Goal Performance Results.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
REMS	Given that the REMS Logic Model was a new approach and initiative across CDER, clearance from multiple offices and regulatory authorities across FDA were needed for this guidance. This guidance also required clearance from the Department of Health and Human Services and the Office of Management and Budget.	FDA will continue to evaluate and modernize its guidance development processes to streamline the review and clearance process. This was a one-time commitment; this delay will have no downstream impact on other commitments. At this point, no further corrective actions are planned.
Hiring	FDA's FY 2024 PDUFA VII 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 2023 PDUFA report to Congress.	FDA plans to continue to advance the corrective actions outlined in the FY 2023 report to Congress and pursue new strategies to support hiring. FDA will fill the remaining PDUFA VII positions allocated for FY 2024 and continue to track hiring progress until all 79 are on board.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Financial Transparency	Delays occurred because of a heavily manual financial reporting process which hindered performance, resulting in late publication of the PDUFA Five-Year Financial Plan.	FDA has implemented automation for the processes involved in generating the Five-Year Financial Plans. This automation not only reduces the likelihood of future delays but also enhances the overall efficiency and reliability of financial reporting.
Patient-Focused Drug Development	Based on information that was received through the related RFI and information received during a meeting with industry representatives, FDA performed a small internal assessment to better understand specific challenges related to patient experience data. That assessment took several months, and, as such, the scheduling of the public meeting was delayed.	This was a one-time incident and is not anticipated to occur again. FDA plans to conduct the subsequent public meeting that is part of this PDUFA commitment during FY 2025 as expected.
Cell and Gene Therapy	FDA needed to coordinate review of a draft Questions and Answers guidance across multiple offices, while the Agency balanced many policy priorities that became particularly acute in the last half of 2024.	FDA will continue to evaluate and modernize its guidance development processes to streamline the review and clearance process. This was a one-time commitment; this delay will have no downstream impact on other commitments. At this point, no further corrective actions are planned.

B. PDUFA Performance 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 2024, 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 VII goals as they pertain to receipts/filed submissions in FY 2024.

If a goal type is not listed for FY 2023, then the Agency fully reported on it in last year's report.

1. FY 2023 Updated Review and Procedural and Processing Goal Performance Results

Summary of Performance:

FDA missed the following review goal:

- Class 1 and 2 Resubmitted NDA and BLA Efficacy Supplements

FDA missed the following procedural and processing goal:

- Final Written Response for Type A Meeting

Justification:

Class 1 and 2 Resubmitted NDA and BLA Efficacy Supplements

In FY 2023, FDA received only six Class 1 and Class 2 resubmitted NDA and BLA Efficacy Supplements collectively. Due to the small number of submissions received, missing the goal for a single application significantly impacted performance. (FDA met the goal for five of six resubmitted efficacy supplements, resulting in an overall performance of 83 percent on-time.)

Given the small number of submissions, the only way to have met the overall performance goal would have been to review 100 percent on time, which is inconsistent with the 10-percent margin normally allowed for performance.

Final Written Response for Type A Meeting

In FY 2023, a sustained high workload, including marketing applications, Emergency Use Authorizations, and meeting requests, continued to constrain FDA resources.

FY 2024 Corrective Actions:

Class 1 and 2 Resubmitted NDA and BLA Efficacy Supplements

FDA will continue to strive to meet all review goals.

Final Written Response for Type A Meeting

FDA is continuing to explore ways to improve meeting performance and improve upon the upward performance trend.

2. FY 2024 Review and Procedural and Processing Performance Results

Summary of Performance:

FDA did not miss any review goals in FY 2024.

FDA missed the following procedural and processing goals:

- Meeting scheduling for Type A, B, B(EOP), and C
- Final written response for Type A Meeting
- Human Factors Validation Protocol Submissions to INDs

Justification:

In FY 2024, in addition to FDA's application review workload, FDA had to schedule or respond to over 4,650 meeting requests, 12 percent more than in FY 2023. Notwithstanding, FDA made a concerted effort in 2024 to improve performance on formal meetings. That effort yielded clear overall improvement. In 2024, FDA missed fewer formal meetings goals than in 2023. Even for the formal meetings goals that were missed in 2024, the performance on those goals was generally higher than in 2023.

Specifically, in FY 2024, FDA is currently meeting or exceeding 14 of 22 (63 percent) formal meetings goals compared to only 11 of 22 (50 percent) in FY 2023. In 2024,

FDA improved performance on 18 out of 22 (81 percent) formal meeting goals when compared to 2023.

FDA continued to increase hiring for the Human Factors teams in CDER while training a large number of new hires that came on board to the Human Factors teams between FY 2023 and FY 2024, which impacted CDER's ability to meet all Human Factors protocol goal dates for IND submissions. In FY 2024, FDA significantly improved performance on Human Factors Validation Protocol Submissions to IND goal, with 72 percent currently on time (75 percent highest possible on time) compared to 28 percent in FY 2023.

FY 2025 Corrective Actions:

FDA will continue to strive to iteratively improve procedural and process performance just as the Agency did in FY 2024 when compared to FY 2023 PDUFA Performance Goals.

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 2025 Corrective Actions").

This section presents non-review performance goals cited in the PDUFA VII Commitment Letter with required completion dates in FY 2024. For the purposes of this report, *performance enhancement goals* are defined as any non-review performance goal with a specified deadline as named in the PDUFA Commitment Letter. Performance enhancement goals with specified completion dates in FY 2025 will be covered in subsequent corrective action reports.

I. REMS

A. Summary of Performance:

FDA missed the PDUFA goal date to update relevant REMS guidances to incorporate REMS assessment planning into the design of REMS. The

Commitment Letter stated that relevant guidances should be updated or published by March 31, 2024. FDA published a new guidance (*REMS Logic Model: A Framework to Link Program Design With Assessment*) on May 6, 2024, to meet this commitment.

B. Justification:

FDA reviewed the current guidances and decided that it would benefit stakeholders to develop and issue a new draft guidance for industry that incorporates the concepts of a logic model to apply a structured approach and be more intentional about how the development, implementation, and evaluation of a REMS relate to one another, rather than update multiple guidances.

Given that the REMS Logic Model was a new approach and initiative across CDER, clearance from multiple offices and regulatory authorities across FDA were needed for this guidance. This guidance also required clearance from the Department of Health and Human Services and the Office of Management and Budget.

C. FY 2025 Corrective Actions:

FDA will continue to evaluate and modernize its guidance development processes to streamline the review and clearance process.

This was a one-time commitment; this delay will have no downstream impact on other commitments. At this point, no further corrective actions are planned.

II. Hiring

A. Summary of Performance:

FDA missed the PDUFA VII goal for hiring in FY 2024. As of September 30, 2024, 56 of 79 FTEs were hired.

B. Justification:

FDA's FY 2024 PDUFA VII 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 2023 PDUFA report to Congress. As of September 30, 2024, of the remaining vacancies, three candidates were set to enter on duty during FY 2025, and four positions have candidates identified who were pending final offers. In addition to declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed for the position. Despite missing the goal for these specific positions, both CDER and CBER experienced significant net gains in FY 2024, increasing overall review capacity.

C. FY 2025 Corrective Actions:

FDA plans to continue to advance the corrective actions outlined in the FY 2023 report to Congress and pursue new strategies to support hiring. FDA will fill the remaining PDUFA VII positions allocated for FY 2024 and continue to track hiring progress until all 79 are on board.

III. Financial Transparency

A. Summary of Performance:

FDA missed the goal to publish FY 2024 updates to the PDUFA financial plan. The financial plan update, due by March 31, 2024, was published April 15, 2024.

B. Justification:

Delays occurred because of a heavily manual financial reporting process that hindered performance, resulting in the late publication of the PDUFA Five-Year Financial Plan.

C. FY 2025 Corrective Actions:

FDA has implemented automation for the processes involved in generating the Five-Year Financial Plans. The newly introduced system integrates data from multiple sources and automates complex calculations, significantly reducing the need for manual data entry. By automating these tasks, FDA expects to improve accuracy, minimize errors, and expedite the publication process. This automation not only

reduces the likelihood of future delays but also enhances the overall efficiency and reliability of financial reporting.

IV. Patient-Focused Drug Development

A. Summary of Performance:

FDA missed the goal to conduct the first of two public workshops on methodological issues. The public workshop, due by September 30, 2024, was held December 13, 2024.

B. Justification:

Based on information that was received through the related RFI and information received during a meeting with industry representatives, FDA performed a small internal assessment to better understand specific challenges related to patient experience data. That assessment took several months, and, as such, the scheduling of the public meeting was delayed.

C. FY 2025 Corrective Actions:

This was a one-time incident and is not anticipated to occur again. FDA plans to conduct the subsequent public meeting that is part of this PDUFA commitment during FY 2025 as expected.

V. Cell and Gene Therapy

A. Summary of Performance:

FDA missed the goal to issue a Questions and Answers draft guidance based on frequently asked questions and commonly faced issues identified by sponsors or by public-private partnerships. The guidance, due by September 30, 2024, was published on November 19, 2024.

B. Justification:

FDA needed to coordinate review of this draft guidance across multiple offices, while the Agency balanced many policy priorities that became

particularly acute in the last half of 2024. Unfortunately, this led to a delay in publication.

C. FY 2025 Corrective Actions:

FDA will continue to evaluate and modernize its guidance development processes to streamline the review and clearance process.

This was a one-time commitment; this delay will have no downstream impact on other commitments. At this point, no further corrective actions are planned.

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,[1] FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions when the review of new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

[1] https://www.fda.gov/media/151712/download.

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

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

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

        i. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by 3 months.
        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, Type B(EOP), and Type D meetings or within 21 days of request for Type B, Type C, and Type INTERACT 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, 75 days for Type C and Type INTERACT meetings, and 50 days for Type D meetings. If the requested date for any of these types of meetings is greater than 30, 50, 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), D, and INTERACT 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. A Type D meeting is focused on a narrow set of issues (e.g., often one, but typically not

more than two issues and associated questions).

N. An Initial Targeted Engagement for Regulatory Advice on CBER/CDER Products (INTERACT) meeting is intended for novel questions and unique challenges in early development (i.e., prior to filing of an IND).

O. 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.

P. 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, when 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.

Q. 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.

R. 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.

S. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that FDA may require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.[2]

T. A Use-Related Risk Analysis (URRA) is employed by sponsors to identify the need for risk mitigation strategies and to design a Human Factors validation study. Based on a URRA, a sponsor may propose that a Human Factors validation study is not needed to be submitted to support a safe and effective use of a drug-device or biologic-device combination product.[3]

U. Human Factors validation studies are conducted to evaluate the user interface of a drug device or biologic-device combination product to eliminate or mitigate use-related hazards that may affect the safe and effective use of the combination product.[4]

V. Post-Marketing Requirements (PMRs) include studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations.[5]

[2] For more information on REMS, see https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.
[3] https://www.fda.gov/media/151712/download.
[4] Ibid.
[5] For more information on PMRs, see https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarketing-requirements-and-commitments-introduction.

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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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