Performance Report to Congress

Prescription Drug User Fee Act

FY 2025

U.S. FOOD & DRUG ADMINISTRATION

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 2024 and FY 2025. Specifically, this report updates performance data for submissions received in FY 2024 (initially reported in the FY 2024 PDUFA performance report)[2] and presents preliminary data on FDA's progress in meeting FY 2025 goals. Updates on FDA's accomplishments related to additional PDUFA VII commitments for FY 2025 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 2025, 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 preliminary data show that the percentage of priority and standard applications filed in FY 2024 and approved during the first review cycle were 76 percent and 68 percent, respectively.

[1] https://www.fda.gov/media/151712/download.
[2] http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

A. Achievements in FY 2025

In FY 2025, FDA met or exceeded 8 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 Standard Non-NME NDAs, and Priority NDA and BLA Efficacy Supplements.

B. Review Performance Results

The FY 2024 cohort had a workload of 3,691 goal closing actions. FDA met or exceeded the 90-percent performance level for 10 of the 10 review performance goals for FY 2024.

For the FY 2025 cohort, FDA had completed 2,283 actions as of September 30, 2025. FDA is currently meeting or exceeding 8 of the 10 review performance goals for FY 2025. With 1,672 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 8 of the 10 review performance goals for FY 2025.

C. Procedural and Processing Performance Results

For the FY 2024 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 12,770 actions. FDA met or exceeded the performance level for 25 of the 32 procedural and processing goals for FY 2024.

For the FY 2025 cohort, FDA is currently meeting or exceeding 24 of the 31[3] procedural and processing goals. There are 32 procedural and processing goals, but only 31 had applicable submissions. With 1,526 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 26 of the 30 applicable procedural and processing goal commitments for FY 2025. 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.

[3] 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 2025, including:

- Five guidances,
- Six public meetings or workshops, and
- Five public reports or documents.

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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
OII	Office of Inspections and Investigations

OND	Office of New Drugs
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 User Fee 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 submissions received during the current fiscal year. This report presents the final

[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.

performance results for the FY 2024 cohort of submissions based on actions completed in FY 2024 and FY 2025. In addition, this report includes the preliminary performance results for the FY 2025 cohort of submissions that had actions completed or due for completion in FY 2025. Final performance for the FY 2025 cohort will be presented in the FY 2026 PDUFA performance report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2025.

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 application's receipt by FDA. FDA's review of an application begins once the

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

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 2024 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 2025 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2025, 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 all non-overdue pending reviews are completed within the goal is also

[3] See the PDUFA VII Commitment Letter at https://www.fda.gov/media/151712/download.
[4] There are six processing and procedural performance goals with performance thresholds at 70 percent, and two goals at 80 percent. Therefore, a current performance result at these rates or higher will be shown as currently meeting the goal.

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 2025 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, 2025.

- 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.

II. PDUFA Performance Goals and Commitments

Tables 1 and 2 present the goal timelines and the percentage of submissions that FDA committed to review within those goal timelines for FY 2023 through FY 2027.

Table 1. PDUFA VII Review Goals for FY 2023 to 2027.

PDUFA Submission Type	Goal: Act on Within	FY 23	FY 24	FY 25	FY 26	FY 27
Applications and Submissions						
Original Priority NME and BLA Submissions	6 months from filing date	90%	90%	90%	90%	90%
Original Standard NME and BLA Submissions	10 months from filing date	90%	90%	90%	90%	90%
Original Priority Non-NME NDA Submissions	6 months	90%	90%	90%	90%	90%
Original Standard Non-NME NDA Submissions	10 months	90%	90%	90%	90%	90%
Class 1 Resubmitted NDAs and BLAs	2 months	90%	90%	90%	90%	90%
Class 2 Resubmitted NDAs and BLAs	6 months					
Priority NDA and BLA Efficacy Supplements	6 months	90%	90%	90%	90%	90%
Standard NDA and BLA Efficacy Supplements	10 months	90%	90%	90%	90%	90%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	90%	90%	90%	90%	90%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months					
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	90%	90%	90%	90%	90%
NDA and BLA Manufacturing Supplements not Requiring Prior Approval	6 months	90%	90%	90%	90%	90%

Table 2. PDUFA VII Procedural and Processing Goals for FY 2023 to 2027.

PDUFA Procedural/ Processing Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
Procedural Notifications/Responses						
Responses to Clinical Holds	Respond within 30 days	90%	90%	90%	90%	90%
Major Dispute Resolutions	Respond within 30 days	90%	90%	90%	90%	90%
Special Protocol Assessments	Complete and return within 45 days	90%	90%	90%	90%	90%
Review of Proprietary Names Submitted During IND Phase	Review and notify of tentative acceptance or non-acceptance within 180 days	90%	90%	90%	90%	90%
Review of Proprietary Names Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	90%	90%	90%	90%	90%
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	90%	90%	90%	90%	90%
Use-Related Risk Analysis Submissions	Review and respond within 60 days	--	50%	70%	90%	90%
REMS Assessment Methods and Protocols	Review and respond within 90 days	--	50%	70%	90%	90%
Priority NME NDAs and Original BLAs Approved with PMRs	Communicate anticipated PMRs 6 weeks prior to action goal date	60%	70%	80%	80%	80%
Standard NME NDAs and Original BLAs Approved with PMRs	Communicate anticipated PMRs 8 weeks prior to action goal date	60%	70%	80%	80%	80%

PDUFA Procedural/ Processing Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
Meeting Management						
Type A Meeting Requests	Respond within 14 days	90%	90%	90%	90%	90%
Type B Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
Type B(EOP) Meeting Requests	Respond within 14 days	90%	90%	90%	90%	90%
Type C Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
Type D Meeting Requests	Respond within 14 days	90%	90%	90%	90%	90%
Type INTERACT Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
Type A Meetings Scheduled	Schedule within 30 days	90%	90%	90%	90%	90%
Type B Meetings Scheduled	Schedule within 60 days	90%	90%	90%	90%	90%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	90%	90%	90%	90%	90%
Type C Meetings Scheduled	Schedule within 75 days	90%	90%	90%	90%	90%
Type D Meetings Scheduled	Schedule within 50 days	50%	60%	70%	80%	90%
Type INTERACT Meetings Scheduled	Schedule within 75 days	50%	60%	70%	80%	90%
Type A Written Response	Send within 30 days	90%	90%	90%	90%	90%
Type B Meeting Written Response	Send within 60 days	90%	90%	90%	90%	90%
Type B(EOP) Written Response	Send within 70 days	90%	90%	90%	90%	90%
Type C Written Response	Send within 75 days	90%	90%	90%	90%	90%
Type D Written Response	Send within 50 days	50%	60%	70%	80%	90%
Type INTERACT Written Response	Send within 75 days	50%	60%	70%	80%	90%

PDUFA Procedural/ Processing Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Meeting Minutes for All Meeting Types	Issue within 30 Days After Meeting Date	90%	90%	90%	90%	90%

III. PDUFA Review Goals

A. Review Workload: FY 2020 to FY 2025

In the table below, preliminary workload numbers from FY 2025 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.

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 3.

Table 3. Workload for Applications and Submissions.

Submission Type	FY 20	FY 21	FY 22	FY 23	FY 24*	FY 25	FY 20 to FY 24 5-Year Average	FY 25 Compared to 5-Year Average
Original Priority NMEs and BLAs	54	52	43	38	40	45†	45	0%‡
Original Standard NMEs and BLAs	29	29	33	27	33	30	30	0%
Original Priority Non-NME NDAs	14	22	11	18	9	21†	15	40%‡
Original Standard Non-NME NDAs	59	72	44	72	47	61	59	3%
Class 1 Resubmitted NDAs and BLAs	5	5	8	10	6	6	7	-14%
Class 2 Resubmitted NDAs and BLAs	57	51	59	66	47	50	56	-11%
Priority NDA and BLA Efficacy Supplements	112	100	77	67	90	95†	89	7%‡
Standard NDA and BLA Efficacy Supplements	195	173	171	178	207	185	185	0%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3	3	1	2	2	3	2	50%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	20	10	11	4	7	5	10	-50%

Submission Type	FY 20	FY 21	FY 22	FY 23	FY 24*	FY 25	FY 20 to FY 24 5-Year Average	FY 25 Compared to 5-Year Average
NDA and BLA Manufacturing Supplements Requiring Prior Approval	1,168	1,243	1,155	1,275	1,411	1,667	1,250	33%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,717	1,779	1,518	1,738	1,796	1,787	1,710	5%

* FY 2024 numbers were changed to reflect updates to the data presented in the FY 2024 PDUFA performance report.

† Some applications have not yet received a review priority designation. There were six undesignated NMEs and BLAs counted as Priority NMEs and BLAs, 13 undesignated Non-NME NDAs counted as Priority Non-NME NDAs, and nine 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 2026 PDUFA performance report.

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

B. Final FY 2024 Review Goal Performance Results

The final FY 2024 review goal performance results are presented in Table 4. 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 10 of 10 review performance goals in FY 2024.

Table 4. FY 2024 Final Review Goal Performance Results.

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2024 Performance
Original Priority NMEs and BLAs	6 months of filing date	38 of 40 on time	**95%**
Original Standard NMEs and BLAs	10 months of filing date	27 of 29 on time	**93%**
Original Priority Non-NME NDAs	6 months	9 of 9 on time	**100%**
Original Standard Non-NME NDAs	10 months	46 of 47 on time	**98%**

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2024 Performance
Class 1 Resubmitted NDAs and BLAs	2 months	5 of 6 on time	**96%**
Class 2 Resubmitted NDAs and BLAs	6 months	46 of 47 on time	
Priority NDA and BLA Efficacy Supplements	6 months	86 of 90 on time	**96%**
Standard NDA and BLA Efficacy Supplements	10 months	197 of 207 on time	**95%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	2 of 2 complete	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	7 of 7 complete	
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	1,363 of 1,411 complete	**97%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,759 of 1,796 complete	**98%**

C. Final FY 2024 Review Goal Performance Details

Tables 5 to 9 detail the final performance data for the FY 2024 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 2024 PDUFA performance report.

Table 5. FY 2024 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	40	38	2	95%
Standard NMEs & BLAs	10 months of filing date	33	27	2	93%*
Priority Non-NME NDAs	6 months	9	9	0	100%
Standard Non-NME NDAs	10 months	47	46	1	98%

* Four standard NMEs & BLAs are pending within goal as of September 30, 2025.

Table 6. FY 2024 Resubmitted Original Applications.

Resubmitted Application Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	6	5	1	96%
Class 2	6 months	47	46	1	

Table 7. FY 2024 Efficacy Supplements.

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	90	86	4	96%
Standard	10 months	207	197	10	95%

Table 8. FY 2024 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	2	0	100%
Class 2	6 months	7	7	0	

Table 9. FY 2024 Manufacturing Supplements.

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	1,411	1,363	48	97%
Prior Approval Not Required	6 months	1,796	1,759	37	98%

D. Preliminary FY 2025 Review Goal Performance Results

The preliminary FY 2025 review goal performance results are presented in Table 10.

- 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 2025 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, 2025, are shown in bold text. FDA is currently meeting or exceeding the 90-percent performance level for 8 of the 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 8 of the 10 review performance goals.

Table 10. FY 2025 Preliminary Review Goal Performance Results.

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2025 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	18 of 39 complete	6 months of filing date	**100%**	100%
Original Standard NMEs and BLAs	4 of 30 complete	10 months of filing date	**100%**	100%
Original Priority Non-NME NDAs	7 of 8 complete	6 months	86%	88%
Original Standard Non-NME NDAs	11 of 61 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	5 of 6 complete	2 months	**94%**	96%
Class 2 Resubmitted NDAs and BLAs	30 of 50 complete	6 months		
Priority NDA and BLA Efficacy Supplements	39 of 86 complete	6 months	**100%**	100%
Standard NDA and BLA Efficacy Supplements	53 of 185 complete	10 months	**96%**	99%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3 of 3 complete	2 months	83%	88%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	3 of 5 complete	6 months		
NDA and BLA Manufacturing Supplements Requiring Prior Approval	1,045 of 1,667 complete	4 months	**96%**	97%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,065 of 1,787 complete	6 months	**98%**	99%

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

E. Preliminary FY 2025 Review Goal Performance Details

The following detailed performance information for the FY 2025 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 11. FY 2025 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	18	0	21	100%	100%
Standard NMEs & BLAs	10 months of filing date	30	4	0	26	100%	100%
Priority Non-NME NDAs	6 months	8	6	1	1	86%	88%
Standard Non-NME NDAs	10 months	61	11	0	50	100%	100%
Review Priority Undesignated*	N/A	19	--	--	--	--	--
Total	N/A	157	39	1	98	--†	--†

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

Table 12. FY 2025 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	5	0	1	94%	96%
Class 2	6 months	50	28	2	20		

Table 13. FY 2025 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	86	39	0	47	100%	100%
Standard	10 months	185	51	2	132	96%	99%
Review Priority Undesignated*	N/A	9	--	--	--	--	--

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

Table 14. FY 2025 Resubmitted Efficacy Supplements.

Resubmitted Efficacy Supplement Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Class 1	2 months	3	3	0	0	83%	88%
Class 2	6 months	5	2	1	2		

Table 15. FY 2025 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	1,667	1,003	42	622	96%	97%
Prior Approval Not Required	6 months	1,787	1,049	16	722	98%	99%
Review Priority Undesignated*	N/A	0	--	--	--	--	--

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

IV. PDUFA Procedural and Processing Goals and Commitments

A. Procedural and Processing Workload: FY 2020 to FY 2025

The FY 2025 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 16.

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 2024 performance and presents new reporting required under PDUFA VII.

The agency notes that undesignated meeting requests have not been assigned a meeting type prior to the fiscal year closing. Any meeting that was not assigned at the fiscal year close is considered Type A in Table 16. In subsequent performance reports, these meetings will be categorized in Table 16 by their assigned meeting type.

Table 16. Meeting Management, Procedural Responses, and Procedural Notifications Workload.

Submission/ Request Type	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025	FY 2020 to FY 2024 5-Year Average	FY 2025 Compared to 5-Year Average
Meeting Management								
Type A Meeting Requests‡	182	178	211	176	178	238†	185	29%§
Type B Meeting Requests‡	2,438	2,332	2,174	1,940	1,954	2,016	2,168	-7%
Type B(EOP) Meeting Requests‡	350	347	304	301	325	309	325	-5%

Submission/ Request Type	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025	FY 2020 to FY 2024 5-Year Average	FY 2025 Compared to 5-Year Average
Type C Meeting Requests‡	1,716	1,706	1,699	1,510	1,534	1,534	1,633	-6%
Type D Meeting Requests‡	--	--	--	390	764	873	--	--
Type INTERACT Requests‡	--	--	--	115	181	217	--	--
Type A Meetings Scheduled	147	143	157	140	144	217†	146	49%§
Type B Meetings Scheduled	869	741	714	626	829	905	756	20%
Type B(EOP) Meetings Scheduled	322	282	259	260	297	277	284	-2%
Type C Meetings Scheduled	699	648	619	575	690	700	646	8%
Type D Meetings Scheduled¶	--	--	--	90	192	249	--	--
Type INTERACT Meetings Scheduled¶	--	--	--	28	63	82	--	--
Type A Written Response	13	11	19	12	10	10	13	-23%
Type B Written Response	1,430	1,451	1,341	1,214	1,044	998	1,296	-23%
Type B(EOP) Written Response	23	49	38	30	24	26	33	-21%
Type C Written Response	905	918	974	839	786	739	884	-16%
Type D Written Response¶	--	--	--	276	512	559	--	--
Type INTERACT Written Response¶	--	--	--	31	65	81	--	--
Preliminary Response for Type B(EOP) Meetings	309	271	246	254	290	258	274	-6%
Preliminary Response for Type D Meetings¶	--	--	--	90	191	240	--	--
Preliminary Response for Type INTERACT Meetings¶	--	--	--	28	63	66	--	--

Submission/ Request Type	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025	FY 2020 to FY 2024 5-Year Average	FY 2025 Compared to 5-Year Average
Meeting Minutes	1,515	1,363	1,281	1,251	1,556	1,587	1,393	14%
Procedural Notifications and Responses								
Responses to Clinical Holds	261	275	344	282	288	239	290	-18%
Major Dispute Resolutions	35	14	12	19	16	7	19	-63%
Special Protocol Assessments	148	150	167	139	107	133	142	-6%
Review of Proprietary Names Submitted During IND Phase	224	211	188	154	176	202	191	6%
Review of Proprietary Names Submitted During NDA/BLA Phase	255	223	206	239	238	241	232	4%
Human Factors Validation Protocol Submissions to NDAs, BLAs, or INDs#	79	79	59	--	--	--	--	--
Human Factors Validation Protocol Submissions to INDs¶#	--	--	--	64	61	44	--	--
Use-Related Risk Analysis Submissions¶	--	--	--	--	23	29	--	--
REMS Assessment Methods and Protocols¶	--	--	--	--	129	259	--	--

* FY 2024 numbers were changed to reflect updates to the data presented in the FY 2024 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 111 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 2026 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 2024 Procedural and Processing Performance Results

Table 17 presents the final performance results for FY 2024 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 25 of the 32 procedural and processing goals in FY 2024.

Table 17. FY 2024 Final Procedural and Processing Performance Results.

Submission/Request Type	Goal: 90 Percent	Total	FY 2024 Performance
Type A Meeting Requests*	Respond within 14 days	165 of 178 on time	**93%**
Type B Meeting Requests*	Respond within 21 days	1,876 of 1,954 on time	**96%**
Type B(EOP) Meeting Requests*	Respond within 14 days	298 of 325 on time	**92%**
Type C Meeting Requests*	Respond within 21 days	1,457 of 1,534 on time	**95%**
Type D Meeting Requests*	Respond within 14 days	706 of 764 on time	**92%**
Type INTERACT Meeting Requests*	Respond within 21 days	163 of 181 on time	**90%**
Type A Meetings Scheduled	Schedule within 30 days	114 of 144 on time	79%
Type B Meetings Scheduled	Schedule within 60 days	664 of 829 on time	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	246 of 297 on time	83%
Type C Meetings Scheduled	Schedule within 75 days	601 of 690 on time	87%
Type A Written Response	Send within 30 days	6 of 10 on time	60%
Type B Written Response	Send within 60 days	924 of 1,044 on time	89%
Type B(EOP) Written Response	Send within 70 days	24 of 24 on time	**100%**
Type C Written Response	Send within 75 days	706 of 786 on time	**90%**

Submission/Request Type	Goal: 90 Percent	Total	FY 2024 Performance
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	267 of 290 on time	**92%**
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	180 of 191 on time	**94%**
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	59 of 63 on time	**94%**
Meeting Minutes	Issue within 30 days after meeting date	1,464 of 1,556 on time	**94%**
Responses to Clinical Holds	Respond within 30 days	263 of 288 on time	**91%**
Major Dispute Resolutions	Respond within 30 days	15 of 16 on time	**94%**
Special Protocol Assessments	Complete and return within 45 days	102 of 107 on time	**95%**
Proprietary Name Submitted During IND Phase	Review and notify of tentative acceptance or non-acceptance within 180 days	169 of 176 on time	**96%**
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	230 of 238 on time	**97%**
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	44 of 61 on time	72%

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

Submission/Request Type	Goal: 60 Percent	Total	FY 2024 Performance
Type D Meetings Scheduled	Schedule within 50 days	169 of 192 on time	**88%**
Type INTERACT Scheduled	Schedule within 75 days	61 of 63 on time	**97%**
Type D Written Response	Send within 50 days	461 of 512 on time	**90%**

Submission/Request Type	Goal: 60 Percent	Total	FY 2024 Performance
Type INTERACT Written Response	Send within 75 days	63 of 65 on time	**97%**

Submission/Request Type	Goal: 50 Percent	Total	FY 2024 Performance
Use-Related Risk Analysis Submissions	Review and respond within 60 days	20 of 23 on time	**87%**
REMS Assessment Methods and Protocols	Review and respond within 90 days	86 of 129 on time	**67%**

Application Type	Goal: 70 Percent	Total	FY 2024 Performance
Priority NME NDAs and Original BLAs Approved with PMRs*	Communicate anticipated PMRs 6 weeks prior to action goal date	20 of 26 on time	**77%**
Standard NME NDAs and Original BLAs Approved with PMRs*	Communicate anticipated PMRs 8 weeks prior to action goal date	13 of 14 on time	**93%**

* 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.

C. Final FY 2024 Procedural and Processing Performance Details

Tables 18 to 27 detail the final performance data for the FY 2024 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 2024 PDUFA performance report.

Table 18. FY 2024 Meeting Management.

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests†	Respond within 14 days	178	165	13	93%
Type B Meeting Requests†	Respond within 21 days	1,954	1,876	78	96%
Type B(EOP) Meeting Requests†	Respond within 14 days	325	298	27	92%
Type C Meeting Requests†	Respond within 21 days	1,534	1,457	77	95%
Type D Meeting Requests†	Respond within 14 days	764	706	58	92%
Type INTERACT Meeting Requests†	Respond within 21 days	181	163	18	90%
Type A Meetings Scheduled	Schedule within 30 days	144	114	30	79%
Type B Meetings Scheduled	Schedule within 60 days	829	664	165	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	297	246	51	83%
Type C Meetings Scheduled	Schedule within 75 days	690	601	89	87%
Type A Written Response	Send within 30 days	10	6	4	60%
Type B Written Response	Send within 60 days	1,044	924	120	89%
Type B(EOP) Written Response	Send within 70 days	24	24	0	100%
Type C Written Response	Send within 75 days	786	706	80	90%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	290	267	23	92%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	191	180	11	94%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	63	59	4	94%
Meeting Minutes	Issue within 30 days after meeting date	1,556	1,464	92	94%

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.
† Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Type	Goal: 60 Percent	Received*	On Time	Overdue	Percent on Time
Type D Meetings Scheduled	Schedule within 50 days	192	169	23	88%
Type INTERACT Scheduled	Schedule within 75 days	63	61	2	97%
Type D Written Response	Send within 50 days	512	461	51	90%
Type INTERACT Written Response	Send within 75 days	65	63	2	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 19. FY 2024 Responses to Clinical Holds.

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	288	263	25	91%

Table 20. FY 2024 Major Dispute Resolutions.

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	16	15	1	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 21. FY 2024 Special Protocol Assessments.

Goal	Received	On Time	Overdue	Percent on Time
Complete and return 90 percent within 45 days	107	102	5	95%

Table 22. 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 23. FY 2024 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	176	169	7	96%
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	238	230	8	97%

Table 24. FY 2024 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	61	44	17	72%

Table 25. FY 2024 Use-Related Risk Analysis Submissions.

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Percent on Time
Use-Related Risk Analysis Submissions	Review and respond within 60 days	23	20	3	87%

Table 26. FY 2024 REMS Assessment Methods and Protocols.

Submission Type	Goal: 50 Percent	Received	On Time	Overdue	Percent on Time
REMS Assessment Methods and Protocols	Review and respond within 90 days	129	86	43	67%

Table 27. FY 2024 Communication of Anticipated Postmarketing Requirements (PMRs).

Application Type	Goal: 70 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	26	20	6	77%
Standard NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 8 weeks prior to action goal date	14	13	1	93%

* *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.

D. Preliminary FY 2025 Procedural and Processing Performance Results

Table 28 presents preliminary performance results for FY 2025 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, 2025, are shown in bold text. FDA is currently meeting or exceeding the performance level for 24 of the 31 applicable procedural and processing goals (e.g., 90 percent or more reviews were completed by the goal date). There are 32 procedural and processing goals, but only 31 had applicable submissions. If all pending submissions are reviewed on time, FDA has the potential to meet 26 of the 30 applicable goals, as seen in the Highest Possible Final Performance column.[5]

[5] The highest potential 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.

Table 28. FY 2025 Preliminary Procedural and Processing Performance Results.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2025 Current Performance	Highest Possible Final Performance
Type A Meeting Requests*†	129 of 238 complete	Respond within 14 days	**94%**	97%
Type B Meeting Requests*	1,976 of 2,016 complete	Respond within 21 days	**98%**	98%
Type B(EOP) Meeting Requests*	302 of 309 complete	Respond within 14 days	**93%**	93%
Type C Meeting Requests*	1,512 of 1,534 complete	Respond within 21 days	**97%**	97%
Type D Meeting Requests*	866 of 873 complete	Respond within 14 days	**92%**	92%
Type INTERACT Requests*	211 of 217 complete	Respond within 21 days	**95%**	95%
Type A Meetings Scheduled†	106 of 217 complete	Schedule within 30 days	79%	90%
Type B Meetings Scheduled	838 of 905 complete	Schedule within 60 days	83%	85%
Type B(EOP) Meetings Scheduled	265 of 277 complete	Schedule within 70 days	**91%**	91%
Type C Meetings Scheduled	662 of 700 complete	Schedule within 75 days	87%	88%
Type A Written Response	10 of 10 complete	Send within 30 days	**90%**	90%
Type B Written Response	844 of 998 complete	Send within 60 days	85%	87%
Type B(EOP) Written Response	22 of 26 complete	Send within 70 days	**91%**	92%
Type C Written Response	597 of 739 complete	Send within 75 days	88%	90%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2025 Current Performance	Highest Possible Final Performance
Preliminary Response for Type B(EOP) Meetings	209 of 258 complete	Issue no later than 5 days prior to meeting date	**97%**	97%
Preliminary Response for Type D Meetings	216 of 240 complete	Issue no later than 5 days prior to meeting date	**97%**	98%
Preliminary Response for Type INTERACT Meetings	63 of 66 complete	Issue no later than 5 days prior to meeting date	**98%**	98%
Meeting Minutes	1,197 of 1,587 complete	Issue within 30 days after meeting date	**96%**	97%
Responses to Clinical Holds	222 of 239 complete	Respond within 30 days	89%	90%
Major Dispute Resolutions	6 of 7 complete	Respond within 30 days	**100%**	100%
Special Protocol Assessments	121 of 133 complete	Complete and return within 45 days	**97%**	97%
Proprietary Name Submitted During IND Phase	99 of 202 complete	Review and notify of tentative acceptance or non-acceptance within 180 days	**97%**	99%
Proprietary Name Submitted During NDA/BLA Phase	198 of 241 complete	Review and notify of tentative acceptance or non-acceptance within 90 days	**94%**	95%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2025 Current Performance	Highest Possible Final Performance
Human Factors Validation Protocol Submissions to INDs	36 of 44 complete	Review and provide comments within 60 days	86%	89%

* 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 111 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: 70 Percent	FY 2025 Current Performance	Highest Possible Final Performance
Type D Meetings Scheduled	239 of 249 complete	Schedule within 50 days	**93%**	93%
Type INTERACT Scheduled	63 of 82 complete	Schedule within 75 days	**84%**	88%
Type D Written Response	494 of 559 complete	Send within 50 days	**91%**	92%
Type INTERACT Written Response	65 of 81 complete	Send within 75 days	**91%**	93%
Use-Related Risk Analysis Submissions	21 of 29 complete	Review and respond within 60 days	**81%**	86%
REMS Assessment Methods and Protocols	220 of 259 complete	Review and respond within 90 days	**85%**	87%

Application Type	Progress	Goal: 80 Percent	FY 2025 Current Performance	Highest Possible Final Performance
Priority NME NDAs and Original BLAs Approved with PMRs*	10 of 10 complete	Communicate anticipated PMRs 6 weeks prior to action goal date	**80%**	N/A†
Standard NME NDAs and Original BLAs Approved with PMRs*	0 of 0 complete	Communicate anticipated PMRs 8 weeks prior to action goal date	N/A‡	N/A†

* Data reflect the communication of anticipated PMRs for NME NDAs and Original BLAs that were received in FY 2025 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.

‡ Performance goal does not apply because no submissions were received.

E. Preliminary FY 2025 Procedural and Processing Performance Details

The following detailed performance information for FY 2025 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 29. FY 2025 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	238	121	8	109	94%	97%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Type B Meeting Requests‡	Respond within 21 days	2,016	1,927	49	40	98%	98%
Type B(EOP) Meeting Requests‡	Respond within 14 days	309	281	21	7	93%	93%
Type C Meeting Requests‡	Respond within 21 days	1,534	1,465	47	22	97%	97%
Type D Meeting Requests‡	Respond within 14 days	873	795	71	7	92%	92%
Type INTERACT Meeting Requests‡	Respond within 21 days	217	201	10	6	95%	95%
Type A Meetings Scheduled†	Schedule within 30 days	217	84	22	111	79%	90%
Type B Meetings Scheduled	Schedule within 60 days	905	699	139	67	83%	85%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	277	240	25	12	91%	91%
Type C Meetings Scheduled	Schedule within 75 days	700	577	85	38	87%	88%
Type A Written Response	Send within 30 days	10	9	1	0	90%	90%
Type B Written Response	Send within 60 days	998	718	126	154	85%	87%
Type B(EOP) Written Response	Send within 70 days	26	20	2	4	91%	92%
Type C Written Response	Send within 75 days	739	523	74	142	88%	90%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	258	202	7	49	97%	97%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	240	210	6	24	97%	98%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	66	62	1	3	98%	98%
Meeting Minutes	Issue within 30 days after meeting date	1,587	1,147	50	390	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.

† Some meeting requests and subsequent scheduling of meetings are for requests for which the type cannot be initially determined. There were 111 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 2026 PDUFA performance report.

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

Type	Goal: 70 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	249	222	17	10	93%	93%
Type INTERACT Scheduled	Schedule within 75 days	82	53	10	19	84%	88%
Type D Written Response	Send within 50 days	559	449	45	65	91%	92%
Type INTERACT Written Response	Send within 75 days	81	59	6	16	91%	93%

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

Table 30. FY 2025 Responses to Clinical Holds.

Submission Type	Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Responses to Clinical Holds	Respond to 90 percent within 30 days	239	197	25	17	89%	90%

Table 31. FY 2025 Major Dispute Resolutions.

Submission Type	Goal	Responses*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Major Dispute Resolutions	Respond to 90 percent within 30 days	7	6	0	1	100%	100%

* This figure represents the number of FDA-generated 30-day responses to requests for review that have been received. This figure is not representative of the number of unique appeals received that have been reviewed as there may be more than one response to an original appeal.

Table 32. FY 2025 Special Protocol Assessments.

Submission Type	Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Special Protocol Assessments	Complete and return 90 percent within 45 days	133	117	4	12	97%	97%

Table 33. FY 2025 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
16	12	4	0	0	20

Table 34. FY 2025 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	202	96	3	103	97%	99%
Proprietary Name Submitted During NDA/BLA Phase	Review and notify of tentative acceptance or non-acceptance within 90 days	241	187	11	43	94%	95%

Table 35. FY 2025 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	44	31	5	8	86%	89%

Table 36. FY 2025 Use-Related Risk Analysis Submissions.

Submission Type	Goal: 70 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	29	17	4	8	81%	86%

Table 37. FY 2025 REMS Assessment Methods and Protocols.

Submission Type	Goal: 70 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	259	187	33	39	85%	87%

Table 38. FY 2025 Communication of Anticipated Postmarketing Requirements (PMRs).

Application Type	Goal: 80 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	10	8	2	80%
Standard NME NDAs and Original BLAs Approved with PMRs‡	Communicate anticipated PMRs 8 weeks prior to action goal date	0	0	0	N/A**

* *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 2025 and approved with PMRs, regardless of approval date.

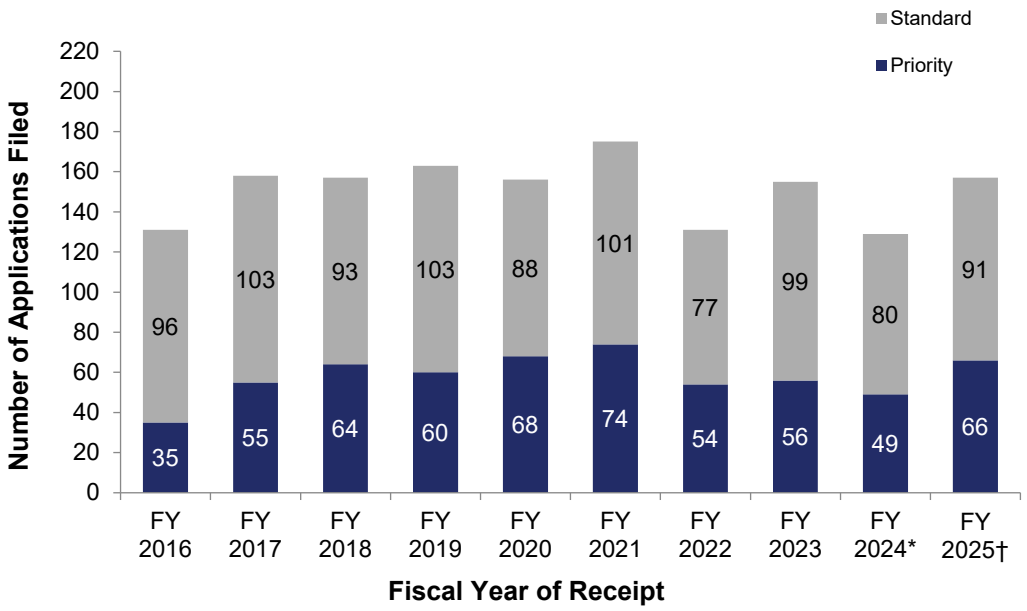
** Performance goal does not apply because no submissions were received.

V. PDUFA Trend Graphs

A. Total NDAs and BLAs Filed

The number of NDAs and BLAs filed from FY 2016 to FY 2025 is presented in Figure 1. The total number of all original applications (NDAs and BLAs) filed in FY 2025 increased from the number filed in FY 2024.

Figure 1. Total NDAs and BLAs Filed.



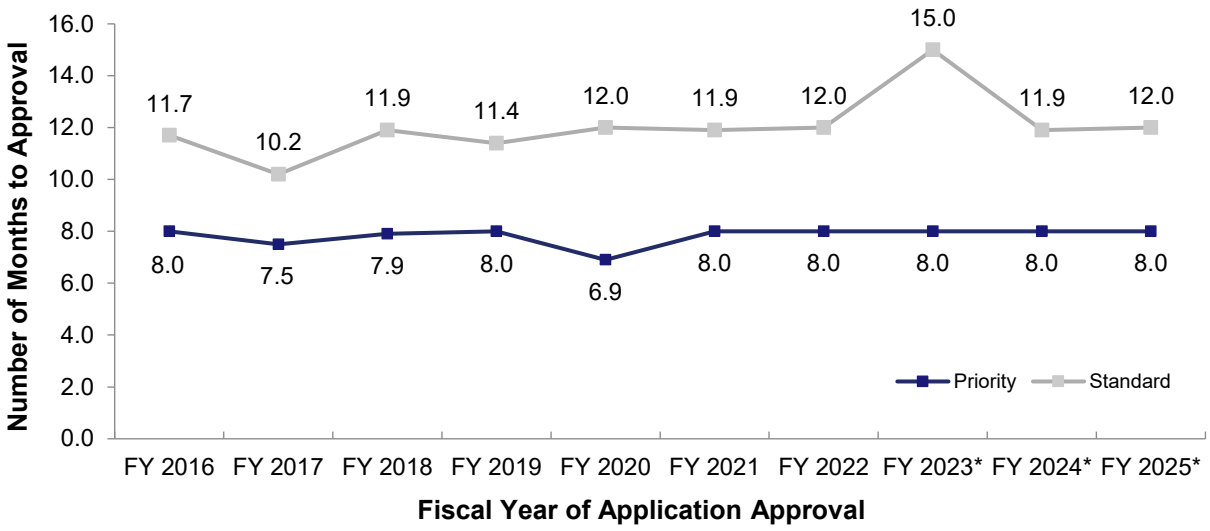
* FY 2024 numbers were changed to reflect updates to the data presented in the FY 2024 PDUFA performance report.

† Some applications filed in FY 2025 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 2026 PDUFA performance report.

B. Median Total Times to Approval

The median total times to approval for priority and standard applications received from FY 2016 through FY 2025 are presented in the graph below.[6] The data represented in Figure 2 are updated based on the approvals reported in Appendix A. The increase in median time to approval for standard applications in FY2023 was due, in part, to a higher proportion of the applications in that year having NME goals, many of which also had 3-month extensions, leading to a median time that was much higher compared to other years.

Figure 2. Median Time to Application Approval for First Approval 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.

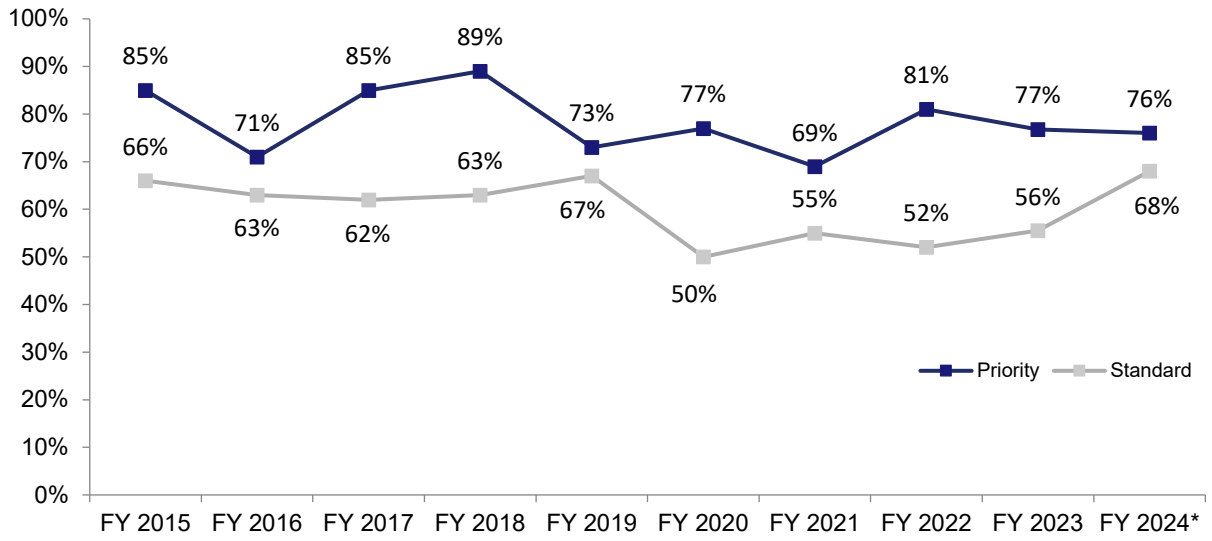
C. Percent of NDAs and BLAs Approved on the First Cycle

Figure 3 depicts the percentages of priority and standard NDAs and BLAs approved in the first review cycle for the receipt cohorts from FY 2015 to FY 2024. These

[6] The *median time to application approval* is calculated from the date of receipt to the date of first approval. For applications with both tentative and full approvals, the first tentative approval date is used to calculate the median response time. Applications approved in the first cycle include only FDA review time, while those approved after multiple cycles include both FDA and sponsor response times.

percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals increased in FY 2024. For the FY 2024 cohort, which is still preliminary, 68 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications decreased in FY 2024, with 76 percent of approved priority applications being approved on the first cycle. The FY 2025 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 2024 standard applications, so the data are preliminary.
† The data were changed to reflect updates to the data presented in the FY 2024 PDUFA performance report.
‡ The data represented in this graph are based on the approvals reported in Appendix A.

VI. 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 2025 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 39. Section I.A - I.J's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 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	• Conduct STAR Interim Assessment: FDA assessed the requests received for the STAR pilot program. FDA plans to provide a summary of the findings in the next fiscal year.
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 40. Section I.K's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
I.K.1 Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development	• There were no commitments due
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** • Advancing drug development for rare diseases is an intra-Agency collaborative effort. In FY 2025, CDER's Rare Diseases Team (RDT), CBER's Rare Disease Program and others engaged in critical rare disease drug development enhancement activities. • In FY 2025, the CDER Accelerating Rare disease Cures Program (https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program)(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 2025 annual report that will be posted to the ARC webpage.[8] • The Rare Disease Innovation Hub (the Hub), a joint CDER-CBER initiative, facilitates development of rare disease treatments.[9] The Hub's activities are distinct from, yet complementary to the PDUFA work of the CDER Rare Diseases Team and CBER Rare Disease Program. The Hub builds on and leverages the activities of the CDER Rare Diseases Team and the CBER Rare Disease Program to enhance existing cross-Center collaborations and to strengthen CDER-CBER policy coordination. The Hub provides external parties with a single cross-Center point of contact, which helps ensure CDER and CBER coordination and reduce silos on cross-cutting rare disease issues related to product development. Toward the Hub's strategic goal to further advance regulatory science of rare disease therapies, on September 3, 2025, the inaugural Rare Disease Innovation, Science, and Exploration (RISE) public workshop, "On the RISE: Controls in Rare Disease Clinical Trials for Small and Diminishing Populations" was held in collaboration with the Duke Margolis Institute for Health Policy.[10]

[8] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program
[9] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/fda-rare-disease-innovation-hub
[10] https://healthpolicy.duke.edu/events/rise-controls-rare-disease-clinical-trials-small-and-diminishing-populations

	EXPERTISE IN REVIEW • In FY 2025, the RDT continued to consult on and contribute to the review of rare disease drug applications across the review divisions through the CDER ARC Program's workstreams, such as CDER's Translational Science Team and Rare Disease Drug Development Design (RD4) Workgroup, and by working directly with OND review divisions regarding the design of trials for small populations, the assessment of biomarkers as reasonably likely surrogate endpoints, assessment of 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. For example, division meetings for clinical and statistical review staff in CBER have continued to serve as a forum for discussion of such approaches and issues concerning rare disease drug development. • CDER's Rare Disease Team and CBER's Rare Disease Program staff co-lead the development and implementation of the PDUFA Rare Disease Endpoint Advancement (RDEA) Pilot Program. This joint CDER/CBER pilot program continues to support novel efficacy endpoint development for rare disease treatments. Since the launch of the RDEA Pilot Program on July 1, 2023 to September 30, 2025, CDER has admitted 3 proposals and CBER has admitted 3 proposals. The RDEA Selection Committee Meeting for FY25 was last held on August 21, 2025. • 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 due to inborn errors of metabolism. This forum serves as an opportunity for CBER's and CDER's medical officers to interact and work more closely on rare disease specific review issues that are relevant to both Centers. **EDUCATION AND TRAINING** • In FY 2025, the RDT and CBER continued to develop and provide training on rare disease drug development to CDER and CBER review staff, and other staff, from across FDA. • In September 2025, CDER's RDT—in collaboration with CBER, and other FDA offices—held a 2-day annual reviewer training. This training focused on presentations, discussion, and rare disease case examples of challenges encountered when reviewing applications. Approximately 700 staff across the centers attended the training. • CDER's RDT hosts a rare diseases seminar series. During these seminars, timely and innovative topics pertaining to rare diseases are presented, such as challenges encountered in rare disease drug development programs and approaches used to resolve those challenges. CBER staff were integral contributors of topic ideas to this series. These seminars are for FDA staff and include presentations by internal and external speakers. • The CDER RDT distributes the CDER ARC Program's internal FDA rare disease newsletter, *Zebragram*. In 2025, 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 and ensured a wide distribution of the newsletter within the Center. **EXTERNAL OUTREACH** • In FY 2025, 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, including poster presentations, and speaking engagements, and by publishing on regulatory rare disease topics. • In FY 2025, CDER, in conjunction with its RDT, further enhanced the CDER ARC Program website with rare disease information and resources to create a "one-stop site" for the rare disease drug development community and FDA staff.[11] CDER also continued to distribute its quarterly CDER ARC Program newsletter to provide the rare disease community 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. • CDER ARC Program's Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) 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*. The RDT used the community's valuable feedback to create educational materials that provide fundamental information to aid drug developers in navigating the challenges inherent to rare disease drug development and illustrate relevant regulatory considerations for rare disease drugs and biologics regulated by CDER. All educational materials were developed with the assistance of agency subject matter experts and reside on a newly developed webpage dedicated to LEADER 3D information and educational materials.[12] The newly

[11] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/accelerating-rare-disease-cures-arc-program
[12] https://www.fda.gov/about-fda/accelerating-rare-disease-cures-arc-program/learning-and-education-advance-and-empower-rare-disease-drug-developers-leader-3d

	published materials include: three animated videos, and six case studies accompanied by a user guide. • The RDT coordinates FDA's Critical Path for Lysosomal Storage Diseases Consortium, working 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 by developing novel tools such as clinical outcome assessments and biomarkers. • The RDT, in collaboration with OND's Office of Neurology, also coordinates FDA's Critical Path Rare Disease Cures Accelerator-Data Analytics Platform (RDCA-DAP). The RDCA-DAP provides a centralized and standardized data infrastructure to support characterization of rare diseases with the goal of accelerating development of treatments for these diseases. Specifically, RDCA-DAP makes available a collaborative, non-competitive space to share rare disease patient-level data from diverse sources, including clinical trials, longitudinal observational studies, patient registries and real-world data (e.g., electronic health data). FDA and sponsors benefit from access to the platform as a means to access good quality data, including standardized datasets that are suitable for supporting reviews and evaluating regulatory approaches. • 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 2025, there were seven cluster meetings discussing 13 topics spanning both CDER and CBER. • CDER's RDT and CBER's 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 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. o Since the previous report, CDER published Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics[13] and o Accelerated Approval – Expedited Program for Serious Conditions[14] CDER and CBER published the draft guidance for industry, Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment, *July 2025*.[15] • CBER published the following draft guidances for industry, which are relevant to the development of certain CBER-regulated biologics for rare diseases: o Frequently Asked Questions – Developing Potential Cellular and Gene Therapy Products, *November 2024*[16] o Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations, *September 2025* [17] o Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products, *September 2025* [18]

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/nonclinical-safety-assessment-oligonucleotide-based-therapeutics
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accelerated-approval-expedited-program-serious-conditions
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/myelodysplastic-syndromes-developing-drug-and-biological-products-treatment
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-developing-potential-cellular-and-gene-therapy-products
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/innovative-designs-clinical-trials-cellular-and-gene-therapy-products-small-populations?utm_medium=email&utm_source=govdelivery
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postapproval-methods-capture-safety-and-efficacy-data-cell-and-gene-therapy-products

	○ Expedited Programs for Regenerative Medicine Therapies for Serious Conditions, *September 2025* [19] The RDT continues to provide quarterly updates to CDER's Drugs and Biologics Dashboard on FDA-TRACK, the Agency-wide performance management program that reports on performance measures and key projects for various FDA Centers and programs.[20] 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 September 30, 2024. Between the staff of the CDER ARC Program, Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, DRDMG and RDT staff, collectively over 30 presentations were made to support rare disease drug development. • In FY 2025, CBER staff participated in a minimum of 78 outreach activities intended to support the development of biological products for rare diseases. These stakeholder engagement activities included presentations, publications, and posters/abstracts. • The RDT and CBER staff attended multiple Patient-Focused Drug Development (PFDD) meetings[21] and Patient Listening Sessions for rare diseases.[22] 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

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions-0
[20] 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
[21] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/externally-led-patient-focused-drug-development-meetings
[22] https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-patient-listening-sessions

	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 by informing medical product development, clinical trial design, patient preferences, and regulatory thinking. • In FY 2025, CDER and CDER jointly held a rare disease-related workshop, titled "Assessing Novel Efficacy Endpoints in Ophthalmologic Rare Disease Drug and Biologics Development, on September 17, 2025" to engage the public and key stakeholders to discuss the development of novel endpoints for rare ophthalmologic diseases.[23] • In FY 2025, CBER held the following rare disease-relevant workshops and webinars on topics regarding CBER-regulated biological products for industry and patient stakeholders: o CBER OTP Public Listening Meeting: Leveraging Knowledge for Facilitating the Development and Review of Cell and Gene Therapies, September 18, 2025[24] o CBER Patient Listening Meeting-Patient and Care Partner Perspectives on Early Enrollment into Gene Therapy Clinical Trials for Rare Diseases, December 4, 2024 [25] o Finding Your Support Team While Participating in a Clinical Trial, October 30, 2024, as part of CBER's Office of Therapeutic Products' educational RegenMedEd seminar series on regenerative medicine therapies for patients, care partners and advocates.[26] o Workshop on Integration Site Analysis During Long Term Follow-Up for Gene Therapies with Integrating Viral Vectors [27]

[23] https://www.fda.gov/drugs/news-events-human-drugs/assessing-novel-efficacy-endpoints-ophthalmologic-rare-disease-drug-and-biologics-development
[24] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/fda-cber-otp-public-listening-meeting-leveraging-knowledge-facilitating-development-and-review-cell
[25] https://www.fda.gov/news-events/meeting-2-patient-and-care-partner-perspectives-early-enrollment-gene-therapy-clinical-trials-rare
[26] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/finding-your-support-team-while-participating-clinical-trial-10302024
[27] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/workshop-integration-site-analysis-during-long-term-follow-gene-therapies-integrating-viral-vectors

	○ Live Biotherapeutic Products to Prevent Necrotizing Enterocolitis in Very Low Birth Weight Infants, October 25, 2024.[28] • The CBER Rare Disease Program [29] web page continues to be updated with timely and relevant information about CBER's rare disease-focused activities, such as collaborative efforts with partners at FDA and beyond, annual listings of CBER's recent orphan approvals starting from 2022 and currently to the end of FY 2025, and a section with Frequently Asked Questions | FDA.[30]
Would I.K.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• There were no commitments due
I.K.6 Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making	• FDA completed a total of six submission cycles of the Advancing RWE Program. • FDA published the FY24 report on RWE Submissions to CDER and CBER.[31] • FDA conducted the RWE Program Public Workshop on September 23, 2025.[32]

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

Table 41. Section I.L's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments

[28] https://www.fda.gov/news-events/live-biotherapeutic-products-prevent-necrotizing-enterocolitis-very-low-birth-weight-infants
[29] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program
[30] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program-frequently-asked-questions
[31] https://www.fda.gov/science-research/real-world-evidence/real-world-evidence-submissions-center-drug-evaluation-and-research
[32] https://healthpolicy.duke.edu/events/regulatory-submissions-real-world-evidence-successes-challenges-and-lessons-learned

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 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 of Health Economics and Outcomes Research (ISPOR), the Drug Information Association (DIA) Annual Global Meeting, the Critical Path Institute (C-Path) Patient-Reported Outcome Consortium, the American Statistical Association BioPharmaceutial Section Short Course, and the Centre for Innovation in Regulatory Science (CIRS). FDA continued to engage an external expert through the Intergovernmental Personnel Act to support the review of patient experience data. ○ FDA provided staff trainings on patient preference information. These trainings included a widely attended training on the regulatory applications of patient preference information for staff across the Center for Drug Evaluation and Research that was hosted in October 2024 and a series of in-service trainings on patient preference information to review divisions. ○ Triangle CERSI, in collaboration with FDA, is developing educational materials to support the Patient-Focused Drug Development Guidance Series.[33] ○ Methodological Issues: ○ In December 2024, FDA held a public workshop, Patient-Focused Drug Development: Workshop to

[33] https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical.

	Discuss Methodologic and Other Challenges Related to Patient Experience Data.[34] ○ In September 2025, as a follow-up to the December 2024 workshop, FDA held a second public workshop, Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data.[35] ○ 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. Multiple scientific presentations and publicly available publications have resulted from these programs. ○ FDA staff members continued to interact with stakeholders to systematically obtain the patient perspective on specific diseases and their treatments. These interactions included participating in 9 Patient Listening Sessions and 12 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 (NORD) Annual Summit, Patients as Partners, the Alzheimer's Association, the Lupus Alliance ABC Patient Reported Outcomes meeting, the Global Liver Alliance A3 meeting, the Association for Frontotemporal Degeneration (AFTD) 2025 Research Roundtable, the Combined Brain Summit, and many others.
I.L.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• There were no commitments due
I.L.3 Advancing Model-Informed Drug Development	• Under PDUFA VII, FDA has granted 26 meeting requests as part of the MIDD Paired Meeting Program as of September 30, 2025.

[34] https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-discuss-methodologic-and-other-challenges-related-patient
[35] https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-2-discuss-methodologic-and-other-challenges-related

I.L.4 Enhancing Capacity to Review Complex Innovative Designs	• Publish Draft Guidance on Complex Innovative Trial Designs (CID): As of September 30, 2025, a guidance on the use of Bayesian methodology in clinical trials of drugs and biologics is in development. The FDA anticipates this guidance will be published in FY26. • In FY 2025, FDA held one meeting as part of the Complex Innovative Trial Design (CID) Paired Meeting Program. • In FY 2025, to promote innovation in this area, a new CID Meeting Program case study was published on the program's external website, for a total of six case studies. • FDA continued to develop CDER and CBER staff by a hosting a CID Seminar Training and engaged with an external expert through Intergovernmental Personnel Act assignment to support the review of complex innovative designs.
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

Table 42. Section I.M's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
I.M.1 Modernization and Improvement of REMS Assessments	• There were no commitments due
I.M.2 Optimization of the Sentinel Initiative	• Contribute Information on Sentinel to PDUFA Financial Report FY24: CDER reported in the FY 2024 PDUFA Financial Report a total of $7.5M for the Sentinel System for data, analytical capabilities, safety issue analyses, dissemination of relevant product and safety information, and Sentinel system operations / maintenance and

	development. CDER provided information on Sentinel for reporting in the PDUFA Financial Report in September 2024 and in September 2025. CBER reported the $2.5M under Sentinel System Operations/Maintenance and Development: infrastructure, operations, FDA staff training, and program management support. The funds were used to exercise an option year for the "CBER Biologics Effectiveness and Safety (BEST) Initiative: Infrastructure and Data for Surveillance of Biologics" contract. • Publish Report on Use of Sentinel: The CDER report, "An Assessment of the Sentinel System (2022 to 2024)," was posted on September 30, 2025.[36] CBER reports this commitment is in progress and will miss the September 30, 2025, deadline due to personnel loses in the office. On the www.bestinitiative.org website, the Announcements section was updated to indicate "The BEST Initiative posts reports and protocols that utilize BEST."[37] The reports and protocols language links to https://bestinitiative.org/vaccines-and-allergenics. • Publish Update on Public and Sponsor Access on FDA.gov website: The CDER report was posted on September 24, 2025.[38] The BEST Initiative website (http://www.bestinitiative.org) issued an Announcement with new content stating: "For more information on our collaborators and distributed network of data sources, see BEST data sources." This statement contains two hyperlinked elements: "BEST data sources" directs users to information about the distributed data network used to conduct safety surveillance activities, while "collaborators" links to details about the institutions that provide access to healthcare data to the BEST Initiative. [39]

[36] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-commitment-assessment-sentinel-system-2022-2024
[37] https://bestinitiative.org/vaccines-and-allergenics
[38] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vii-deliverables
[39] https://bestinitiative.org/best/data-and-surveillance-activities/distributed-network-and-common-data-model

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

Table 43. Section I.N's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
I. N.1 Enhancing Communication Between FDA and Sponsors During Application Review	• Conduct Assessment of Chemistry, Manufacturing, and Controls (CMC) Information Requests (IRs): FDA partnered with Eastern Research Group (ERG) to assess the practices of CDER, CBER, and sponsors in communicating through product quality information requests (IRs) during application review. ERG specifically assessed the implementation and effectiveness of Four-Part Harmony, in which reviewers are expected to communicate (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. • Publish CMC IR Assessment Report: FDA published a report of the above assessment on its public webpage: "PDUFA VII: Assessment of FDA and Sponsor Communications Through Product Quality Information Requests."[40] The report describes assessment methods, findings, and recommendations. FDA posted the report in the Federal Register for public comment and is currently considering the comments received.[41]
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	• On September 11, 2025, the FDA published a final guidance on Alternative Tools to Assess Manufacturing Facilities.[42]

[40] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests
[41] Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Final Report; Availability; Request for Comments
[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications

	○ Requesting records and other information, pursuant to section 704(a)(4) of the FD&C Act (21 U.S.C. 374(a)(4)), directly from facilities and other entities subject to inspection ○ Performing remote interactive evaluations (RIEs) (e.g., remote livestreaming video of operations, teleconferences, screen sharing) • Requesting existing inspection reports and other information from trusted foreign regulatory partners through mutual recognition agreements and other agreement
I.N.4 Facilitating Chemistry, Manufacturing, and Controls Readiness for Products with Accelerated Clinical Development	• Conducted the Public Workshop on CMC Development and Readiness Pilot on September 10, 2025.[43] • Published the Federal Register Notice (FRN) announcing the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Public Workshop on August 18, 2025.[44] • Published the Year 4 FRN for CMC Development and Readiness Pilot on August 28, 2025.[45] • Updated the website: Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program | FDA [46] • Accepted two new INDs into the CDRP program for FY25, totaling six for the program.
I.N.5 Advancing Utilization and Implementation of Innovative Manufacturing	• Finalized Innovative Manufacturing Strategy Document: • On June 8, 2023, FDA participated in a public workshop on the use of innovative manufacturing technologies for products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), including barriers to their adoption. FDA also committed to issuing the draft Strategy Document for public comment. • On September 12, 2024, FDA announced the publication of a draft Strategy Document for public comment outlining specific actions FDA will take

[43] https://healthpolicy.duke.edu/events/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-0
[44] https://www.federalregister.gov/documents/2025/08/19/2025-15799/lessons-learned-from-the-chemistry-manufacturing-and-controls-development-and-readiness-pilot
[45] https://www.federalregister.gov/documents/2025/08/28/2025-16513/chemistry-manufacturing-and-controls-development-and-readiness-pilot-program-program-announcement
[46] https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program

	during fiscal years 2023-2027 to facilitate the use of innovative manufacturing technologies. • In FY 2026, FDA will announce the publication of the final Strategy Document. Access to the document will be made available on external facing webpages within CDER and CBER related to advanced manufacturing.

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

Table 44. Section I.O's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
I.O.1 Patient-Focused Drug Development	• No commitments due
I.O.2 Novel Approaches to Development of Cell and Gene Therapy	• On November 19, 2024, FDA published Federal Register Notice (FRN)[47] of Draft Guidance for Industry (GFI): Q&A CGT. FDA published the announcement of the Draft GFI: Frequently Asked Questions — Developing Potential Cellular and Gene Therapy Products | FDA.[48] • On September 25, 2025, FDA published FRN and Draft GFI: Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations[49].[50] FDA published the announcement of the Draft GFI, Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations | FDA.[51] • On September 25, 2025, FDA published FRN and Draft GFI on Post-Approval Cell and Gene Therapy: Postapproval Methods to Capture Safety and Efficacy Data for Cell and

[47] https://www.federalregister.gov/documents/2024/11/19/2024-26918/frequently-asked-questions-developing-potential-cellular-and-gene-therapy-products-draft-guidance
[48] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-developing-potential-cellular-and-gene-therapy-products
[49] https://www.fda.gov/media/188892/download
[50] https://www.federalregister.gov/documents/2025/09/25/2025-18651/innovative-designs-for-clinical-trials-of-cellular-and-gene-therapy-products-in-small-populations
[51] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/innovative-designs-clinical-trials-cellular-and-gene-therapy-products-small-populations

	Gene Therapy Products[52].[53] FDA published the announcement of the Draft GFI: Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products | FDA.[54]
I.O.3 Expedited Programs for the Development of Regenerative Medicine Therapies	• On September 25, 2025, FDA published FRN and Draft GFI on Regenerative Medicine Therapies: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions.[55,56] On September 25, 2025, FDA published FRN and Draft GFI on Regenerative Medicine Therapies: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions.[57,58] FDA published the announcement of the Draft GFI, Expedited Programs for Regenerative Medicine Therapies for Serious Conditions | FDA.[59]
I. O.4 Leveraging Knowledge	• Conducted Public Meeting CGT Manufacturers: The FDA CBER OTP Public Listening Meeting: Leveraging Knowledge for Facilitating the Development and Review of Cell and Gene Therapies, was held virtually on September 18, 2025, from 10 a.m. – 4 p.m., EST.[60] A livestream of the event can be reached via FDA's YouTube channel.[61]

[52] https://www.fda.gov/media/188891/download
[53] https://www.federalregister.gov/documents/2025/09/25/2025-18650/postapproval-methods-to-capture-safety-and-efficacy-data-for-cell-and-gene-therapy-products-draft
[54] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postapproval-methods-capture-safety-and-efficacy-data-cell-and-gene-therapy-products
[55] https://www.fda.gov/media/188874/download
[56] https://www.federalregister.gov/documents/2025/09/25/2025-18653/expedited-programs-for-regenerative-medicine-therapies-for-serious-conditions-draft-guidance-for
[57] https://www.fda.gov/media/188874/download
[58] https://www.federalregister.gov/documents/2025/09/25/2025-18653/expedited-programs-for-regenerative-medicine-therapies-for-serious-conditions-draft-guidance-for
[59] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions-0
[60] https://www.fda.gov/news-events/otp-events-meetings-and-workshops/fda-cber-otp-public-listening-meeting-leveraging-knowledge-facilitating-development-and-review-cell
[61] https://www.youtube.com/live/yNafnXPaOHY

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

Table 45. Section I.P's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
I.P.1 Allergenic Extract Products Licensed After October 1, 2022	• There were no commitments due.
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 46. Section II's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• Information on the use of the capacity planning adjustment (CPA) revenue to was published in the FY24 PDUFA Annual Financial Report.[62] • The annual update to the Resource Capacity Planning (RCP) Implementation Plan was published on 3/31/2025.[63] • The independent assessment of Resource Capacity Planning was published on 9/26/2025.[64]
II.B Financial Transparency and Efficiency	• Publish Financial Plan Updates FY25: PDUFA VII Five-Year Financial Plan - 2025 update was published on July 30, 2025.[65]

[62] https://www.fda.gov/media/185331/download?attachment
[63] https://www.fda.gov/media/186035/download?attachment
[64] https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting
[65] https://www.fda.gov/media/187933/download?attachment

	• Provide Information on Appropriated User Fee Funds Financial Report FY24: Information was included in the FY 2024 PDUFA Financial Report which was transmitted to Congress on January 10, 2025 and published on March 31, 2025.[66] • Conduct Public Meeting Financial Plan FY25: FDA Financial Public Meeting focused on Financial Transparency and Efficiency of the Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BsUFA), and Generic Drug User Fee Amendments (GDUFA) was held on September 30, 2025.[67] During the public meeting, the FDA: • Updated interested public stakeholders on topics related to the financial management of PDUFA VII, BsUFA III, and GDUFA III • Presented an update on the 5-year financial plans for each of these programs • Updated participants on the progress towards implementing resource capacity planning as part of fee setting and modernized time reporting

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

Table 47. Section III's FY 2025 Commitments and Accomplishments.

Commitment Title	FY 2025 Accomplishments
III.A Set Clear Goals for Human Drug Review Program Hiring	• CBER was allocated 29 PDUFA VII positions for FY2025. As of September 30, 2025, 8 were on board. • CDER was allocated 15 PDUFA VII positions for FY2025. As of September 30, 2025, 9 were on board. • Quarterly hiring data for PDUFA VII is posted on the public website (PDUFA and BsUFA Quarterly Hiring Updates | FDA).[68]

[66] https://www.fda.gov/media/185331/download?attachment
[67] https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and
[68] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates

III.B Assessment of Hiring and Retention	• Conduct Independent Assessment of Hiring: FDA hired a contractor to assess its hiring and retention of program staff. The assessment concluded March 28, 2025. • Publish Independent Assessment of Hiring Report: The assessment report was published on August 25, 2025.[69] • Hold Public Meeting for Independent Assessment of Hiring: The public meeting was held on September 24, 2025.[70]

J. Section IV: Information Technology and Bioinformatics Goals

Table 48. Section IV's FY 2025 Commitments and Accomplishments.

Goal	FY 2025 Accomplishments
IV.A Enhancing Transparency and Leveraging Modern Technology	• Publish Data Standards Action Plan Q4 FY24: The CBER-CDER FY24 Q4 Data Standards Action Plan was approved by the Data Standards Operations Subcommittee on November 13, 2024, and published on November 20, 2024. • Publish Data Standards Action Plan Q1 FY25: The CBER-CDER FY25 Q1 Data Standards Action Plan was approved by the Data Standards Operations Subcommittee on February 19, 2025, and published on March 27, 2025. • Publish Data Standards Action Plan Q2 FY25: The CBER-CDER FY25 Q2 Data Standards Action Plan was approved by the Data Standards Operations Subcommittee on July 25, 2025, and was published on August 5, 2025. • Publish Data Standards Action Plan Q3 FY25: The CBER-CDER FY25 Q3 Data Standards Action Plan was approved by the Data Standards Operations Subcommittee on September 17, 2025, and was published on September 26, 2025.

[69] https://www.fda.gov/media/188083/download?attachment
[70] https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment

	• Annually the FDA meets with Industry IT Leadership to review PDUFA IT initiatives and provide an opportunity for industry input. The FY25 meeting was held on June 3, 2025. • Electronic Submission Gateway (ESG) Website Update FY24: FDA posted quarterly updates on transaction times for PDUFA submissions via ESG on a public website: Submission Times.[71] FDA also posted monthly summary statistics about ESG submission volume (e.g., total submissions, acknowledgements, traffic) on a public website: Submission Statistics.[72] • Complete ESG Transition to Cloud: CBER-CDER will follow and leverage the Office of Digital Transformation's (ODT) efforts with ESG and the cloud-based ESG NG (Next Generation). CBER-CDER is actively participating in the ESG NG Integrated Project Team. ESG NextGen went live on April 14, 2025. • CDER Testing of ESG Transition to Cloud (ESG NextGen) FY25: CDER participated in 3rd Wave of User Acceptance Testing in October-November 2024, Signoff sessions and cutover weekend in March 2025, and production cutover in April 2025. • Quarterly PDUFA Standing Meetings With Industry FY25: FDA held a meeting each quarter to update and discuss FDA's IT priorities. These meetings occurred on: 10/08/2024, 02/25/2025, 06/18/2025 (in-person), and 09/30/2025. • CBER Roadmap Updates FY25: CBER halted all work on Modernization in accordance with the new Administration's directions. CBER is performing operations and maintenance activities for its existing business capabilities deployed in PROD. As of June 2025, FDA-Industry updates are being conducted by Sri Mantha, Acting FDA Chief Information Officer (CIO). Additionally, the FDA is in the process of consolidating its IT portfolio across all Centers Offices and Programs (COPs), and CBER IT is actively engaged with these efforts.

[71] https://www.fda.gov/industry/resources/submission-times
[72] https://www.fda.gov/industry/resources/submission-statistics

	• Assess and Share Bioinformatics Capabilities FY25: CBER plans to share the Center's bioinformatics capabilities at the next regularly scheduled FDA-Industry meeting. • Develop and Update Data and Tech Modernization Strategy FY25: Due to the highly fluid nature of current IT initiatives, FDA is no longer updating and publishing a "Data and Tech Modernization" strategy as such a document would quickly become obsolete. Rather, FDA is providing frequent updates to various stakeholders on the current direction and status of IT initiatives.
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	• In FY2025, CDER's Office of Biostatistics held a year-long training program and created a training material repository on the statistical analysis of DHT data for statistical reviewers and analysts to aid their regulatory review efforts. The program focused on statistical considerations of the use of endpoints derived from DHT data with instruction by an external expert in academia.

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.[73] 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.

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

VII. 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 Inspections and Investigations, 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 Inspections and Investigation, 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, OII, 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 275 FTEs of the 352 FTEs (78 percent) as of September 30, 2025. The data in the following table show the total number of FTEs hired towards the FY 2024 and FY 2025 hiring targets as agreed upon in the PDUFA VII Commitment Letter and the change in the number of FTE hires from FY 2024 to FY 2025.

Table 49. Number of Individuals Hired as Agreed Upon in the PDUFA VII Commitment Letter and Remaining Vacancies.

Center	Number Hired in FY 2024	Number Hired in FY 2025	Change in Number Hired	Remaining Vacancies in FY 2024	Remaining Vacancies in FY 2025	Change in Number of Remaining Vacancies
CDER	49	9	-40	18	24	6
CBER	51	15	-36	20	34	14
OC	N/A	N/A	N/A	0	N/A	N/A
OII	0	0	0	0	0	0
Total	**100**	**24**	**-76**	**38**	**58**	**20**

* 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, OII, 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, OII 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, OII, 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 2025 represent the number of FTEs committed to PDUFA work. The number of FTEs funded by User Fee and budget authority for FY 2025 are those FTEs as of September 30, 2025.

Table 50. Number of FTEs Funded by Budget Authority and Number of FTEs funded by Fees by Division Within CDER, CBER, OII, and OC.

Center and Office	Number of FTEs Funded by Budget Authority in FY 2024	Number of FTEs Funded by Budget Authority in FY 2025	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2024	Number of FTEs Funded by Fees in FY 2025	Change in the Number of FTEs Funded by Fees
CDER						
Office of Communications	10.05	9.08	-0.97	44.21	40.81	-3.40
Office of Compliance	15.16	15.66	0.50	81.43	78.93	-2.50
Office of the Center Director	4.67	1.07	-3.60	33.23	36.42	3.19
Office of Executive Programs	3.36	4.12	0.76	61.95	47.50	-14.45
Office of Generic Drugs	3.66	2.31	-1.35	3.61	4.83	1.22
Office of Management	8.70	10.85	2.15	80.65	73.85	-6.80
Office of Medical Policy	8.22	5.98	-2.24	116.27	111.79	-4.48
Office of New Drugs	64.03	88.30	24.27	1,269.48	1,224.29	-45.19
Office of Pharmaceutical Quality	51.72	55.81	4.09	407.85	387.21	-20.64

Center and Office	Number of FTEs Funded by Budget Authority in FY 2024	Number of FTEs Funded by Budget Authority in FY 2025	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2024	Number of FTEs Funded by Fees in FY 2025	Change in the Number of FTEs Funded by Fees
Office of Regulatory Policy	3.10	2.37	-0.73	59.15	59.89	0.74
Office of Surveillance and Epidemiology	38.59	27.51	-11.08	227.30	240.56	13.26
Office of Strategic Programs	9.56	10.58	1.02	81.92	87.97	6.05
Office of Information Management and Technology	0.00	0.00	0.00	0.00	0.02	0.02
Office of Translational Sciences	69.36	47.65	-21.71	511.80	549.25	37.45
Other Offices	0.15	0.00	-0.15	3.88	0.00	-3.88
Working Capital Fund (WCF)	59.64	58.90	-0.74	195.20	203.53	8.33
CDRH						
Office of Product Evaluation and Quality	0.19	3.66	3.47	12.48	13.48	1.00
Office of Management	0.08	0.03	-0.05	0.97	0.63	-0.34
Office of Science and Engineering Laboratories	0.04	0.17	0.13	0.06	0.04	-0.02
Office of Communication, Information Disclosure, Training and Education[†]	0.11	0.00	-0.11	0.57	0.40	-0.17
Office of Policy	0.02	0.07	0.05	0.21	0.15	-0.06
Office of Strategic Partnership and	0.19	0.08	-0.11	0.03	0.00	-0.03

Center and Office	Number of FTEs Funded by Budget Authority in FY 2024	Number of FTEs Funded by Budget Authority in FY 2025	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2024	Number of FTEs Funded by Fees in FY 2025	Change in the Number of FTEs Funded by Fees
Technology Innovation						
Office of the Center Director	0.01	0.02	0.01	0.30	0.21	-0.09
Office of Digital Transformation‡	0.04	0.00	-0.04	0.00	0.00	0.00
WCF	0.55	0.79	0.24	1.13	1.12	-0.01
CBER						
Office of Biostatistics and Pharmacovigilance	17.12	19.33	2.21	82.85	105.04	22.19
Office of Blood Research and Review	3.69	5.93	2.24	6.15	4.02	-2.13
Office of Compliance and Biologics Quality	15.23	13.29	-1.94	87.74	97.62	9.88
Office of Therapeutic Products	50.86	52.32	1.46	216.18	247.94	31.76
Office of Vaccines Research and Review	69.39	80.55	11.16	147.29	163.20	15.91
Office of Communication Outreach and Development	4.53	1.45	-3.08	39.04	37.39	-1.65
Office of the Center Director	3.86	13.54	9.68	25.61	25.72	0.11
Office of Regulatory Operations	6.74	3.72	-3.02	44.55	47.57	3.02
Office of Management	11.36	11.68	0.32	63.05	56.38	-6.67
Office of Information	0.92	0.06	-0.86	3.12	0.16	-2.96

Center and Office	Number of FTEs Funded by Budget Authority in FY 2024	Number of FTEs Funded by Budget Authority in FY 2025	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2024	Number of FTEs Funded by Fees in FY 2025	Change in the Number of FTEs Funded by Fees
Management and Technology						
WCF	34.77	37.57	2.80	64.63	70.14	5.51
OC						
OC Immediate Office	9.12	18.64	9.52	16.05	11.70	-4.35
Office of the Chief Counsel	18.09	50.28	32.19	31.83	31.56	-0.27
Office of the Chief Medical Officer	0.00	57.76	57.76	31.83	36.19	4.36
Office of the Chief Scientist	11.97	28.34	16.37	21.06	17.79	-3.28
Office of Clinical Policy and Programs	25.53	0.00	-25.53	44.91	0.00	-44.91
Office of Digital Transformation	1.58	0.00	-1.58	2.78	0.00	-2.78
Office of Enterprise Management Services	0.00	0.00	0.00	0.00	0.00	0.00
Office of External Affairs	9.77	26.14	16.37	17.19	16.41	-0.78
Office of Global Policy and Strategy	0.56	2.94	2.38	0.99	1.84	0.85
Office of International Programs	0.00	0.00	0.00	0.00	0.00	0.00
Office of Operations	3.99	5.58	1.59	7.03	3.50	-3.53
Office of Policy, Legislation, and International Affairs	12.80	32.37	19.57	22.52	20.31	-2.21
WCF	18.29	23.63	5.34	23.53	25.92	2.39

Center and Office	Number of FTEs Funded by Budget Authority in FY 2024	Number of FTEs Funded by Budget Authority in FY 2025	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2024	Number of FTEs Funded by Fees in FY 2025	Change in the Number of FTEs Funded by Fees
OII						
Office of Pharmaceutical Quality Operations	107.90	88.70	-19.20	46.72	38.80	-7.92
WCF	10.38	9.12	-1.26	4.37	2.62	-1.75

* This table includes PDUFA program FTEs calculated through WCF assessments for certain centrally administered services provided to CDER, CDRH, CBER, OII, 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 2024 and FY 2025, as well as the changes in these amounts from FY 2024 to FY 2025. 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 2025) and the prior fiscal year (FY 2024). 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 2025, FDA had net collections of $1,457,945,602 in prescription drug user fees, spent $1,359,676,908.in user fees for the human drug review process, and carried a cumulative balance of $413,940,928 forward for future fiscal years. Detailed financial information for the PDUFA user fee program can be found in the FY 2025 PDUFA financial report.[74]

The process for setting the annual target revenue is set forth in the statute. For FY 2025, the base revenue amount was $1,358,764,346. The FY 2025 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 2025 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 $1,478,740,000 (rounded to the nearest thousand dollars).

In FY 2025, PDUFA review process costs decreased from FY 2024.

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

Table 51. Changes in the Average Total Cost Per FTE in the Prescription Drug Review Program.

Revenue/Cost	FY 2024	FY 2025	Change from FY 2024 to FY 2025
Fee Revenue Amounts (Net Collections)	$1,381,243,203	$ 1,457,945,602	6%
Process Cost (Cost of Activities)	$1,772,198,497	$ 1,758,633,360	-1%
Average Total Cost Per FTE	**$227,401**	**$ 236,465**	4%

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, OII, 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, OII, and OC who are required to report their time and those who are not required to report their time as of September 30, 2025.

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

Table 52. Time Reporting Requirement for FY 2025.

Center	FTEs for Whom Time Reporting is Required	FTEs for Whom Time Reporting is Not Required
CDER	4,951	0
CBER	1,149	0
CDRH	1,782	0
OC	61	2,343
OII	2,901	0
Total	**10,844**	**2,343**

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 53. 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 2024	Average FTE Hours Required to Complete Human Drug Application Reviews in FY 2025	Change from FY 2024 to FY 2025
PDUFA NME and BLA Applications	7,718	7,849	131
PDUFA Non-NME Applications	2,869	2,922	53
Total	**10,587**	10,771	184

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 2024 to the 3-year average ending in FY 2025. 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 2025. 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 2025 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 considers leap years, to calculate review time in months. Prior to FY 2022, FDA did not consider leap years in our calculations, which may have caused a submission to appear overdue even though it was approved on the goal date.

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

Terms and Coding Used in Tables in This Appendix

Action Codes:
AE = Approvable
AP = Approved
CR = Complete Response
NA = Not Approvable
TA = Tentative Approval
WD = Withdrawn

▲ Denotes Class 1 Resubmission (2-month review-time goal)
△ Denotes Class 2 Resubmission (6-month review-time goal)
◊ Expedited review and TA of an NDA by FDA for fixed dose combinations and co-packaged antiretroviral medications as part of the President's Emergency Plan for AIDS Relief
♦ Application reviewed under the program with review goals starting from the 60-day filing date, rather than the submission date
♯ Major amendment was received, which extended the action goal date by 3 months[2]

Table A-1. FY 2025 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 2025							
INLEXZO (gemcitabine)	JANSSEN BIOTECH INC	N	First	5.9	AP	5.9	Y
YEZTUGO (lenacapavir)	GILEAD SCIENCES INC	N	First	5.9	AP	5.9	Y
YEZTUGO (lenacapavir)[3]	GILEAD SCIENCES INC	N	First	5.9	AP	5.9	Y
ELIQUIS SPRINKLE (apixaban)	BRISTOL MYERS SQUIBB CO	N	First	6.0	AP	6.0	Y
AVMAPKI FAKZYNJA CO-PACK (avutometinib and defactinib)	VERASTEM INC	Y	First	6.2	AP	6.2	Y♦
DATROWAY (datopotamab deruxtecan-dlnk)	DAIICHI SANKYO, INC.	Y	First	7.3	AP	7.3	Y♦
IBTROZI (taletrectinib)	NUVATION BIO INC	Y	First	7.6	AP	7.6	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.
[3] These two NDAs are for the same active moiety but different dosage forms (i.e., Injection versus Tablet).

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
MODEYSO (dordaviprone)	CHIMERIX INC	Y	First	7.6	AP	7.6	Y♦
PAPZIMEOS (zopapogene imadenovec-drba)	PRECIGEN, INC.	Y	First	7.6	AP	7.6	Y♦
HERNEXEOS (zongertinib)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	Y	First	7.7	AP	7.7	Y♦
ZEGFROVY (sunvozertinib)	DIZAL (JIANGSU) PHARMACEUTICAL CO LTD	Y	First	7.8	AP	7.8	Y♦
KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph)	MERCK SHARP & DOHME LLC	Y	First	7.9	AP	7.9	Y♦
ENFLONSIA (clesrovimab-cfor)	MERCK SHARP & DOHME LLC	Y	First	8.0	AP	8.0	Y♦
BRINSUPRI (brensocatib)	INSMED INC	Y	First	8.0	AP	8.0	Y♦
RHAPSIDO (remibrutinib)	NOVARTIS PHARMACEUTICALS CORP	Y	First	8.0	AP	8.0	Y♦
KOSELUGO (selumetinib)	ASTRAZENECA PHARMACEUTICALS LP	N	First	8.8	AP	8.8	Y#
Submitted in FY 2024							
EMBLAVEO (aztreonam and avibactam)	ABBVIE INC	N	First	6.0	AP	6.0	Y
ITOVEBI (inavolisib)	GENENTECH INC	Y	First	6.5	AP	6.5	Y♦
EMRELIS (telisotuzumab vedotin-tllv)	ABBVIE INC.	Y	First	7.5	AP	7.5	Y♦
CRENESSITY (crinecerfont)	NEUROCRINE BIOSCIENCES INC	Y	First	7.5	AP	7.5	Y♦
CRENESSITY (crinecerfont) [4]	NEUROCRINE BIOSCIENCES INC	N	First	7.5	AP	7.5	Y♦
GOMEKLI (mirdametinib)	SPRINGWORKS THERAPEUTICS INC	Y	First	7.5	AP	7.5	Y♦
GOMEKLI (mirdametinib) [5]	SPRINGWORKS THERAPEUTICS INC	N	First	7.5	AP	7.5	Y♦

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

[5] These two NDAs are for the same active moiety but different dosage forms (i.e.Tablet versus Capsule), and only one retains the NME designation upon approval; in this case, the NDA for the Tablet 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
ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor)	VERTEX PHARMACEUTICALS INC	Y	First	7.6	AP	7.6	Y♦
ZIIHERA (zanidatamab)	JAZZ PHARMACEUTICALS IRELAND LIMITED	Y	First	7.8	AP	7.8	Y♦
CTEXLI (chenodiol)	MIRUM PHARMACEUTICALS INC	N	First	7.8	AP	7.8	Y#
IMAAVY (nipocalimab-aahu)	JANSSEN BIOTECH, INC.	Y	First	8.0	AP	8.0	Y♦
BLUJEPA (gepotidacin)	GLAXOSMITHKLINE LLC	Y	First	8.0	AP	8.0	Y♦
TRYNGOLZA (olezarsen)	IONIS PHARMACEUTICALS INC	Y	First	8.0	AP	8.0	Y♦
JOURNAVX (suzetrigine)	VERTEX PHARMACEUTICALS INC	Y	First	8.0	AP	8.0	Y♦
ROMVIMZA (vimsetinib)	DECIPHERA PHARMACEUTICALS LLC	Y	First	8.0	AP	8.0	Y♦
KEBILIDI (eladocagene exuparvovec-tneq)	PTC THERAPEUTICS	Y	First	8.0	AP	8.0	Y♦
VIMKUNYA (chikungunya vaccine, recombinant)	BAVARIAN NORDIC A/S	Y	First	8.0	AP	8.0	Y♦
MNEXSPIKE (covid-19 vaccine, mrna)	MODERNATX, INC.	Y	First	8.0	AP	8.0	Y♦
VYKAT XR (diazoxide choline)	SOLENO THERAPEUTICS INC	N	First	8.9	AP	8.9	Y#
BIZENGRI (ZENOCUTUZUMAB-ZBCO) (zenocutuzumab-zbco)	PARTNER THERAPEUTICS INC.	Y	First	9.0	AP	9.0	Y♦#
REVUFORJ (revumenib)	SYNDAX PHARMACEUTICALS INC	Y	First	9.7	AP	9.7	Y♦#
ENCELTO (revakinagene taroretcel-lwey)	NEUROTECH PHARMACEUTICALS INC.	Y	First	10.5	AP	10.5	Y♦#
SYMVESS (acellular tissue engineered vessel-tyod)	HUMACYTE GLOBAL INC.	Y	First	12.3	AP	12.3	N♦
LYNOZYFIC (linvoseltamab-gcpt)	REGENERON PHARMACEUTICALS, INC.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	4.7		12.7	
			Second	5.7	AP	18.4	Y△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
FORZINITY (elamipretide)	STEALTH BIOTHERAPEUTICS INC	Y	First	15.5	CR	15.5	N♦#
			Sponsor	3.0		18.5	
			Second	1.1	AP	19.6	Y∆
Submitted in FY 2023							
VYLOY (zolbetuximab-clzb)	ASTELLAS PHARMA US, INC.	Y	First	7.8	CR	7.8	Y♦
			Sponsor	4.1		11.9	
			Second	5.3	AP	17.2	Y∆
ZEVASKYN (prademagene zamikeracel)	ABEONA THERAPEUTICS INC.	Y	First	6.7	CR	6.7	Y♦
			Sponsor	6.4		13.1	
			Second	6.0	AP	19.1	Y∆
CLOTIC (clotrimazole)	LABORATORIOS SALVAT SA	N	First	5.9	CR	5.9	Y
			Sponsor	24.0		29.9	
			Second	5.7	AP	35.6	Y∆
Submitted in FY 2022							
ALHEMO (concizumab-mtci)	NOVO NORDISK INC.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	13.9		21.9	
			Second	6.0	AP	27.9	Y∆
Submitted in FY 2021							
ORLYNVAH (sulopenem etzadroxil and probenecid)	ITERUM THERAPEUTICS US LTD	Y	First	7.9	CR	7.9	Y♦
			Sponsor	33.1		41.0	
			Second	6.0	AP	47.0	Y∆
Submitted in FY 2020							
RYONCIL (remestemcel-l-rknd)	MESOBLAST, INC.	Y	First	8.0	CR	8.0	Y♦
			Sponsor	28.0		36.0	
			Second	6.0	CR	42.0	Y∆
			Sponsor	11.2		53.2	
			Third	5.4	AP	58.6	Y∆

Table A-2. FY 2025 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 2025							
E-Z-DISK (barium sulfate)	BRACCO DIAGNOSTICS INC	N	First	8.3	AP	8.3	Y
KYXATA (carboplatin)	AVYXA HOLDINGS LLC	N	First	8.4	AP	8.4	Y
LEQEMBI IQLIK (lecanemab-irmb)	EISAI, INCORPORATED	N	First	9.9	AP	9.9	Y
ZOLYMBUS (bimatoprost)	THEA PHARMA INC	N	First	9.9	AP	9.9	Y
escitalopram	ALMATICA PHARMA LLC	N	First	9.9	AP	9.9	Y
ENBUMYST (bumetanide)	CORSTASIS THERAPEUTICS INC	N	First	9.9	AP	9.9	Y
CAMCEVI ETM (leuprolide mesylate)	FORESEE PHARMACEUTICALS CO LTD	N	First	9.9	AP	9.9	Y
CYKLX (articaine)	AMERICAN GENOMICS LLC	N	First	10.0	AP	10.0	Y
TONMYA (cyclobenzaprine hydrochloride)	TONIX PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
INLURIYO (imlunestrant)	ELI LILLY AND CO	Y	First	10.8	AP	10.8	Y♦
Submitted in FY 2024							
BRUKINSA (zanubrutinib)	BEONE MEDICINES USA INC	N	First	9.3	AP	9.3	Y
DANZITEN (nilotinib)	AZURITY PHARMACEUTICALS INC	N	First	9.3	AP	9.3	Y
AVGEMSI (gemcitabine)	AVYXA HOLDINGS LLC	N	First	9.3	AP	9.3	Y
famotidine	SAGENT PHARMACEUTICALS	N	First	9.5	AP	9.5	Y
IMKELDI (imatinib)	SHORLA ONCOLOGY	N	First	9.7	AP	9.7	Y
LOPRESSOR (metoprolol tartrate)	RUBICON RESEARCH LTD	N	First	9.7	AP	9.7	Y
OPDIVO QVANTIG (nivolumab and hyaluronidase-nvhy)	BRISTOL-MYERS SQUIBB COMPANY	N	First	9.9	AP	9.9	Y
piperacillin-tazobactam and sodium chloride	B BRAUN MEDICAL INC	N	First	9.9	AP	9.9	Y
VYSCOXA (celecoxib)	CARWIN PHARMACEUTICAL ASSOCIATES LLC	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
RALDESY (trazodone hydrochloride)	KAMAT PHARMATECH LLC	N	First	9.9	AP	9.9	Y
EMROSI (minocycline hydrochloride)	JOURNEY MEDICAL CORP	N	First	9.9	AP	9.9	Y
GOZELLIX (kit for the preparation of gallium ga 68 gozetotide)	TELIX INNOVATIONS SA	N	First	9.9	AP	9.9	Y
ZUSDURI (mitomycin)	UROGEN PHARMA LTD	N	First	10.0	AP	10.0	Y
phenylephrine hydrochloride in sodium chloride	DR REDDYS LABORATORIES SA	N	First	10.0	AP	10.0	Y
rocuronium bromide	FRESENIUS KABI USA LLC	N	First	10.0	AP	10.0	Y
pyridostigmine bromide	AMNEAL PHARMACEUTICALS LLC	N	First	10.0	AP	10.0	Y
daptomycin	MAIA PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
WIDAPLIK (telmisartan, amlodipine, and indapamide)	AZURITY PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
LIVMARLI (maralixibat)	MIRUM PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
SDAMLO (amlodipine)	BRILLIAN PHARMA INC	N	First	10.0	AP	10.0	Y
trabectedin	EVER VALINJECT GMBH	N	First	10.0	TA	10.0	Y
DOPTELET SPRINKLE (avatrombopag)	AKARX INC	N	First	10.0	AP	10.0	Y
VOSTALLY (ramipril)	ROSEMONT PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
ATMEKSI (methocarbamol)	ROSEMONT PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
ARYNTA (lisdexamphetamine dimesylate)	AZURITY PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
INZIRQO (hydrochlorothiazide)	NOVITIUM PHARMA LLC	N	First	10.1	AP	10.1	Y
EVRYSDI (risdiplam)	GENENTECH INC	N	First	10.1	AP	10.1	Y
IOMERVU (iomeprol)[6]	BRACCO DIAGNOSTICS INC	Y	First	11.5	AP	11.5	Y♦
DATROWAY (datopotamab deruxtecan-dlnk)	DAIICHI SANKYO, INC.	Y	First	11.6	AP	11.6	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
ENSACOVE (ensartinib)	XCOVERY HOLDINGS INC	Y	First	11.7	AP	11.7	Y
VIZZ (aceclidine)	LENZ THERAPEUTICS INC	Y	First	11.7	AP	11.7	Y♦
AUCATZYL (obecabtagene autoleucel)	AUTOLUS, INC.	Y	First	11.7	AP	11.7	Y♦
ATTRUBY (acoramidis)	BRIDGEBIO PHARMA INC	Y	First	11.8	AP	11.8	Y♦
IOMERVU (iomeprol)[6]	BRACCO DIAGNOSTICS INC	Y	First	11.9	AP	11.9	Y♦
TRYPTYR (acoltremon)	ALCON LABORATORIES INC	Y	First	11.9	AP	11.9	Y♦
PENMENVY (meningococcal groups a, b, c, w, and y vaccine)	GLAXOSMITHKLINE BIOLOGICALS	Y	First	12.0	AP	12.0	Y♦
QIVIGY (immune globulin intravenous, human-kthm, 10% solution)	KEDRION, S.P.A.	Y	First	12.0	AP	12.0	Y♦
HYMPAVZI (marsticimab-hncq)	PFIZER INC.	Y	First	12.0	AP	12.0	Y♦
NEMLUVIO (nemolizumab-ilto)	GALDERMA LABORATORIES, L.P.	Y	First	12.0	AP	12.0	Y♦
QFITLIA (fitusiran)	GENZYME CORP	Y	First	12.0	AP	12.0	Y♦
PALSONIFY (paltusotine)	CRINETICS PHARMACEUTICALS INC	Y	First	12.0	AP	12.0	Y♦
ANZUPGO (delgocitinib)	LEO PHARMA AS	Y	First	12.0	AP	12.0	Y♦
VANRAFIA (atrasentan)	NOVARTIS PHARMACEUTICALS CORP	Y	First	12.0	AP	12.0	Y♦
DAWNZERA (donidalorsen)	IONIS PHARMACEUTICALS INC	Y	First	12.0	AP	12.0	Y♦
SEPHIENCE (sepiapterin)	PTC THERAPEUTICS INC	Y	First	12.0	AP	12.0	Y♦
WAYRILZ (rilzabrutinib)	GENZYME CORP	Y	First	12.0	AP	12.0	Y♦
NILCEYA (nilotinib)	CIPLA LTD	N	First	12.3	AP	12.3	Y#
			First	10.0	CR	10.0	Y

[6] NDA reviewed under the PDUFA V program. At time of receipt, the active ingredient Iomeprol had never been approved in the United States, allowing for NME designation; however, at time of approval, iomeprol had already been approved for marketing in another application

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
BRYNOVIN (sitagliptin)	AZURITY PHARMACEUTICALS INC	N	Sponsor	0.5		10.5	
			Second	1.9	AP	12.4	Y▲
EKTERLY (sebetralstat)	KALVISTA PHARMACEUTICALS LTD	Y	First	12.5	AP	12.5	N♦
BEIZRAY (docetaxel)	ZHUHAI BEIHAI BIOTECH CO LTD	N	First	12.6	AP	12.6	Y#
KHINDIVI (hydrocortisone)	ETON PHARMACEUTICALS INC	N	First	12.9	AP	12.9	Y
MYINFLA (colchicine)	PHARMASCIENCE INC	N	First	13.0	TA	13.0	Y#
NUVAXOVID (covid-19 vaccine, adjuvanted)	NOVAVAX, INC.	Y	First	13.5	AP	13.5	N♦
ARBLI (losartan potassium)	SCIENTURE LLC	N	First	10.0	CR	10.0	Y
			Sponsor	1.0		11.0	
			Second	5.8	AP	16.8	YΔ
SUBVENITE (lamotrigine)	OWP PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
			Sponsor	2.4		12.4	
			Second	6.0	AP	18.4	YΔ
ANDEMBRY (garadacimab-gxii)	CSL BEHRING LLC	Y	First	11.8	CR	11.8	Y♦
			Sponsor	2.3		14.1	
			Second	5.9	AP	20.0	YΔ
Submitted in FY 2023							
epinephrine in sodium chloride	BAXTER HEALTHCARE CORP	N	First	10.0	CR	10.0	Y
			Sponsor	2.4		12.4	
			Second	4.6	AP	17.0	YΔ
diltiazem hydrochloride in sodium chloride	HQ SPECIALTY PHARMA CORP	N	First	9.9	CR	9.9	Y
			Sponsor	1.2		11.1	
			Second	6.0	AP	17.1	YΔ
ONTRALFY (tizanidine)	FIDELITY BIOPHARMA CO USA	N	First	10.0	CR	10.0	Y
			Sponsor	2.5		12.5	
			Second	6.0	AP	18.5	YΔ
			First	12.9	CR	12.9	Y#

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
HEMICLOR (chlorthalidone)	PRM PHARMA LLC	N	Sponsor	4.4		17.3	
			Second	1.9	AP	19.2	Y▲
bendamustine hydrochloride	DR REDDYS LABORATORIES LTD	N	First	13.0	CR	13.0	Y#
			Sponsor	2.6		15.6	
			Second	5.6	AP	21.2	YΔ
MIUDELLA (copper intrauterine system)	SEBELA WOMENS HEALTH INC	N	First	10.0	CR	10.0	Y
			Sponsor	3.8		13.8	
			Second	9.1	AP	22.9	YΔ#
UNLOXCYT (cosibelimab-ipdl)	CHECKPOINT THERAPEUTICS, INC.	Y	First	11.4	CR	11.4	Y♦
			Sponsor	6.4		17.8	
			Second	5.5	AP	23.3	YΔ
QAMZOVA (meloxicam)	NANJING DELOVA BIOTECH CO LTD	N	First	10.0	CR	10.0	Y
			Sponsor	8.0		18.0	
			Second	6.0	AP	24.0	YΔ
LOPRESSOR (metoprolol tartrate)	XTM CONSULTING LLC	N	First	9.9	CR	9.9	Y
			Sponsor	8.6		18.5	
			Second	5.9	AP	24.4	YΔ
ATZUMI (dihydroergotamine)	SATSUMA PHARMACEUTICALS INC	N	First	10.1	CR	10.1	Y
			Sponsor	9.4		19.5	
			Second	6.0	AP	25.5	YΔ
XIFYRM (meloxicam)	AZURITY PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
			Sponsor	10.8		20.8	
			Second	6.0	AP	26.8	YΔ
AUSUSVAR (rivaroxaban)	AUSON PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
			Sponsor	11.7		21.7	
			Second	6.0	TA	27.7	NΔ
LASIX ONYU (furosemide)	SQ INNOVATION INC	N	First	10.0	CR	10.0	Y
			Sponsor	3.2		13.2	
			Second	6.0	TA	19.2	YΔ
			Sponsor	9.6		28.8	
			Third	2.0	AP	30.8	Y▲
Submitted in FY 2022							
VYALEV (foscarbidopa and foslevodopa)	ABBVIE INC	N	First	9.9	CR	9.9	Y
			Sponsor	9.1		19.0	
			Second	6.0	CR	25.0	YΔ

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Sponsor	1.9		26.9	
			Third	2.0	AP	28.9	Y▲
RAPIBLYK (landiolol)	AOP ORPHAN PHARMACEUTICALS GMBH	Y	First	12.0	CR	12.0	Y♦
			Sponsor	12.0		24.0	
			Second	5.8	AP	29.8	YΔ
ONAPGO (apomorphine hydrochloride)	MDD US OPERATIONS LLC A SUB OF SUPERNUS PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
			Sponsor	11.9		21.9	
			Second	6.0	CR	27.9	YΔ
			Sponsor	3.9		31.8	
			Third	6.1	AP	37.9	NΔ
Submitted in FY 2021							
SYMBAVO (meloxicam and rizatriptan)	AXSOME THERAPEUTICS INC	N	First	10.0	CR	10.0	Y
			Sponsor	27.1		37.1	
			Second	6.0	AP	43.1	YΔ
penpulimab-kcqx	AKESO BIOPHARMA CO., LTD.	Y	First	30.1	CR	30.1	N♦#
			Sponsor	8.4		38.5	
			Second	6.7	AP	45.2	NΔ
BREKIYA (dihydroergotamine mesylate)	AMNEAL PHARMACEUTICALS LLC	N	First	10.0	CR	10.0	Y
			Sponsor	12.0		22.0	
			Second	5.9	CR	27.9	YΔ
			Sponsor	16.0		43.9	
			Third	5.9	AP	49.8	YΔ
epinephrine	FRESENIUS KABI USA LLC	N	First	9.9	CR	9.9	Y
			Sponsor	8.0		17.9	
			Second	5.7	CR	23.6	YΔ
			Sponsor	11.9		35.5	
			Third	6.0	CR	41.5	YΔ
			Sponsor	2.4		43.9	
			Fourth	2.0	TA	45.9	Y▲
			Sponsor	2.5		48.4	
			Fifth	1.9	AP	50.3	Y▲
Submitted in FY 2020							
GRAFAPEX (treosulfan)	MEDEXUS PHARMA INC	Y	First	11.6	CR	11.6	Y♦
			Sponsor	33.0		44.6	
			Second	8.7	AP	53.3	YΔ#
			First	9.8	CR	9.8	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	CIPLA LTD	N	Sponsor	3.9		13.7	
			Second	5.5	CR	19.2	Y∆◊
			Sponsor	0.6		19.8	
			Third	6.0	CR	25.8	Y∆◊
			Sponsor	1.4		27.2	
			Fourth	5.5	CR	32.7	Y∆◊
			Sponsor	4.1		36.8	
			Fifth	5.8	CR	42.6	Y∆◊
			Sponsor	7.6		50.2	
			Sixth	5.9	TA	56.1	Y∆◊
BONDLIDO (lidocaine)	MEDRX USA INC	N	First	10.1	CR	10.1	N
			Sponsor	20.9		31.0	
			Second	6.0	CR	37.0	Y∆
			Sponsor	3.4		40.4	
			Third	6.0	CR	46.4	Y∆
			Sponsor	8.4		54.8	
			Fourth	6.0	AP	60.8	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∆
			Sponsor	7.2		61.9	
			Fourth	2.0	AP	63.9	Y▲
MEZOFY (aripiprazole)	CMG PHARMACEUTICAL CO LTD	N	First	10.0	CR	10.0	Y
			Sponsor	49.9		59.9	
			Second	6.0	AP	65.9	Y∆
Submitted in FY 2018							
dolutegravir, lamivudine, and tenofovir disoproxil fumarate	CIPLA LTD	N	First	9.7	CR	9.7	Y◊
			Sponsor	2.0		11.7	
			Second	5.3	CR	17.0	Y∆◊
			Sponsor	6.2		23.2	
			Third	5.7	CR	28.9	Y∆◊
			Sponsor	2.8		31.7	
			Fourth	5.9	CR	37.6	Y∆◊
			Sponsor	1.7		39.3	

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			Fifth	5.7	CR	45.0	Y△◊
			Sponsor	0.3		45.3	
			Sixth	5.7	CR	51.0	Y△◊
			Sponsor	6.5		57.5	
			Seventh	5.9	CR	63.4	Y△◊
			Sponsor	2.4		65.8	
			Eighth	5.9	CR	71.7	Y△◊
			Sponsor	4.4		76.1	
			Nineth	1.9	TA	78.0	Y▲◊
OTEZLA (apremilast)	AMGEN INC	N	First	8.1	WD	8.1	Y
			Sponsor	74.4		82.5	
			Second	10.0	AP	92.5	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 2025 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 2025 by Review Division/Office.

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
CDER Review Divisions					
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	6	0	0	0
Division of Anti-Infectives	1	1	0	0	1
Division of Antivirals	2	6	2	0	1
Division of Cardiology and Nephrology	1	7	1	0	3
Division of Dermatology and Dentistry	1	1	0	1	1
Division of Diabetes, Lipid Disorders, and Obesity	0	2	0	1	1
Division of Gastroenterology	0	2	0	0	1
Division of General Endocrinology	1	3	0	0	0
Division of Hematologic Malignancies I	1	1	0	0	1
Division of Hematologic Malignancies II	1	2	0	1	0
Division of Hepatology and Nutrition	0	3	0	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Imaging and Radiation Medicine	0	7	1	0	0
Division of Neurology I	2	2	1	1	3
Division of Neurology II	1	2	0	0	0
Division of Non-Malignant Hematology	1	2	0	0	1
Division of Non-Prescription Drugs I	0	1	0	0	1
Division of Non-Prescription Drugs II	0	0	0	0	0
Division of Oncology I	2	8	0	1	3
Division of Oncology II	7	2	2	2	0
Division of Oncology III	0	3	0	0	0
Division of Ophthalmology	1	5	0	0	0
Division of Psychiatry	0	7	0	0	0
Division of Pulmonology, Allergy, and Critical Care	5	2	0	1	0
Division of Rare Diseases and Medical Genetics	3	0	1	0	0
Division of Rheumatology and Transplant Medicine	0	2	0	2	0
Division of Urology, Obstetrics, and Gynecology	1	1	0	0	2
CDER Totals	*31*	*78*	*8*	*10*	*19*
CBER Review Offices					
Office of Tissues and Advanced Therapies	0	0	8	2	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Office of Vaccines Research and Review	0	0	0	1	0
CBER Totals	*0*	*0*	*8*	*3*	*0*
FDA Totals	31	78	16	13	19

Table B-2. Efficacy Supplements Filed in FY 2025 by Review Division/Office.

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
CDER Review Divisions			
Division of Anesthesiology, Addiction Medicine, and Pain Medicine	0	3	0
Division of Anti-Infectives	2	8	1
Division of Antivirals	2	7	0
Division of Cardiology and Nephrology	5	11	0
Division of Dermatology and Dentistry	1	11	2
Division of Diabetes, Lipid Disorders, and Obesity	7	7	0
Division of Gastroenterology	1	10	0
Division of General Endocrinology	0	4	0
Division of Hematologic Malignancies I	3	7	0
Division of Hematologic Malignancies II	2	11	0
Division of Hepatology and Nutrition	1	1	0
Division of Imaging and Radiation Medicine	0	3	0
Division of Neurology I	1	7	0
Division of Neurology II	1	5	0
Division of Non-Malignant Hematology	4	2	0
Division of Non-Prescription Drugs I	0	1	0

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Non-Prescription Drugs II	0	0	0
Division of Oncology I	9	11	2
Division of Oncology II	11	8	2
Division of Oncology III	11	16	0
Division of Ophthalmology	1	2	0
Division of Psychiatry	3	5	0
Division of Pulmonology, Allergy, and Critical Care	6	7	2
Division of Rare Diseases and Medical Genetics	2	2	0
Division of Rheumatology and Transplant Medicine	1	10	0
Division of Urology, Obstetrics, and Gynecology	1	3	0
CDER Totals	*75*	*162*	*9*
CBER Review Divisions			
Office of Tissues and Advanced Therapies	8	6	0
Office of Vaccines Research and Review	3	17	0
CBER Totals	*11*	*23*	*0*
FDA Totals	86	185	9

Table B-3. Submissions with Special Designations Filed in FY 2025 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	1	0	1	97
Division of Anti-Infectives	0	2	0	0	27
Division of Antivirals	1	6	1	6	42
Division of Cardiology and Nephrology	0	0	0	1	109
Division of Dermatology and Dentistry	0	0	1	0	71
Division of Diabetes, Lipid Disorders, and Obesity	0	1	1	2	81
Division of Gastroenterology	0	0	0	0	54
Division of General Endocrinology	0	0	2	1	17
Division of Hematologic Malignancies I	0	1	3	1	78
Division of Hematologic Malignancies II	1	1	2	2	101
Division of Hepatology and Nutrition	0	0	1	1	27

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
Division of Imaging and Radiation Medicine	0	1	3	0	90
Division of Neurology I	0	3	5	5	102
Division of Neurology II	0	0	2	5	65
Division of Non-Malignant Hematology	0	0	1	5	42
Division of Non-Prescription Drugs I	0	0	0	0	1
Division of Non-Prescription Drugs II	0	0	0	0	1
Division of Oncology I	1	2	1	5	258
Division of Oncology II	5	4	7	12	244
Division of Oncology III	0	0	0	7	188
Division of Ophthalmology	0	0	2	3	38
Division of Psychiatry	0	0	0	1	88
Division of Pulmonology, Allergy, and Critical Care	0	1	2	2	58
Division of Rare Diseases and Medical Genetics	2	3	4	2	7
Division of Rheumatology and Transplant Medicine	0	1	0	3	61
Division of Urology, Obstetrics, and Gynecology	0	0	0	1	31

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
CDER Totals	*10*	*27*	*38*	*66*	*1,978*
CBER Review Divisions					
Office of Tissues and Advanced Therapies	0	2	6	1	12
Office of Vaccines Research and Review	0	0	0	0	0
CBER Totals	*0*	*2*	*6*	*1*	*12*
FDA Totals	10	29	44	67	1,990

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2025. 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 2025. Data represent all the original NDA and BLA approvals that occurred during FY 2025, 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 2025.[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 2025 Original Application Approval Cycle Summary.

Approval Cycle Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2025*	Approval in FY 2025†	On Time‡	Overdue‡	Percent On Time
First Cycle Priority NMEs & BLAs	6 months of filing date	39	33	32	1	**97%**
First Cycle Standard NMEs & BLAs	10 months of filing date	30	22	20	2	**91%**
First Cycle Priority Non-NME NDAs	6 months	8	8	8	0	**100%**
First Cycle Standard Non-NME NDAs	10 months	61	41	41	0	**100%**
First Cycle Priority Undesignated~	N/A	19	--	--	--	--
Class 1 Resubmissions	2 months	6	7	7	0	**100%**
Class 2 Resubmissions	6 months	50	29	26	3	**90%**
Total	**--**	**213**	**140**	**134**	**6**	--*

* For this reporting table, "Filed" counts include applications that have been filed, are in pending filing status, or have been accepted as a resubmission. Data do not reflect applications 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.

† This column represents applications approved in FY 2025, regardless of when the application or resubmission was received.

‡ The on time and overdue metrics are based on the cycle that received the approval action.

§ Performance is not calculated on combined goals.

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

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 2024 updated performance enhancement goals.

Table C-2. FY 2024 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 FY24	9/30/2024	N	--	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates

The table below represents FDA's FY 2025 performance enhancement goals.

Table C-3. FY 2025 Performance Enhancement Goals.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
ESG Website Update FY24	10/21/2024	Y	10/8/2024	https://www.fda.gov/industry/resources/submission-statistics
Quarterly Hiring Reporting Q4 FY24	10/21/2024	Y	10/8/2024	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Publish Data Standards Action Plan Q4 FY24	12/31/2024	Y	11/22/2024	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-

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

				program-strategic-plan-and-board
Quarterly Hiring Reporting Q1 FY25	1/21/2025	Y	1/14/2025	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Contribute Information on Sentinel to PDUFA Financial Report FY24	1/30/2025	Y	10/18/2024	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports
Provide Rare Diseases Information to PDUFA Annual Report FY24	1/30/2025	Y	9/27/2024	https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-prescription-drug-user-fee-act-pdufa-performance-reports
Provide Information on Appropriated User Fee Funds Financial Report FY24	3/31/2025	Y	11/4/2024	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports
Provide Information on CPA Fee Revenues to PDUFA Annual Financial Report FY24	3/31/2025	Y	10/31/2024	https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports
Publish Data Standards Action Plan Q1 FY25	3/31/2025	Y	3/27/2025	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board
Publish Financial Plan Updates FY25	3/31/2025	N	7/30/2025	https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans See corrective actions for additional information.
Publish Capacity Planning Implementation Plan Updates FY25	3/31/2025	Y	3/31/2025	https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting

Include Rare Diseases Information in Novel Drug Approvals Report CY24	3/31/2025	Y	1/1/2025	https://www.fda.gov/media/184967/download?attachment
Quarterly Hiring Reporting Q2 FY25	4/21/2025	N	6/26/2025	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates FDA sets the target goal date for these postings because the Commitment Letter does not specify a date. FDA achieved timely postings, so no corrective actions are needed.
Publish Final Guidance on Alternative Tools to Assess Manufacturing Facilities	5/21/2025	N	9/12/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications The Commitment Letter states that FDA should "work toward" the target date. Given that FDA did work toward the target date for publishing the final guidance, no corrective actions are needed.
Conduct Public Meeting Financial Plan FY25	6/30/2025	N	9/30/2025	https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and See corrective actions for additional information.

Publish CMC IR Assessment Report	6/30/2025	Y	6/2/2025	https://www.fda.gov/media/186729/download
Publish Data Standards Action Plan Q2 FY25	6/30/2025	N	8/5/2025	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board FDA sets the target goal date for these action plans because the Commitment Letter does not specify a date. FDA achieved timely publications, so no corrective actions are needed.
Publish Independent Assessment of Hiring Report	6/30/2025	N	8/25/2025	https://www.fda.gov/media/188083/download?attachment See corrective actions for additional information.
Report Real-World Evidence Submissions to CDER and CBER - FY24	6/30/2025	Y	6/10/2025	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 FY25	7/21/2025	Y	7/15/2025	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates
Conduct Public Workshop on CMC Development and Readiness Pilot	7/31/2025	N	9/10/2025	https://www.fda.gov/drugs/news-events-human-drugs/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-cdrp See corrective actions for additional information.

Finalize Innovative Manufacturing Strategy Document	8/12/2025	N	--	See corrective actions for additional information.
Annual FDA-Industry IT Leadership Meetings 3 FY25	9/30/2025	Y	6/3/2025	
Assess and Share Bioinformatics Capabilities FY25	9/30/2025	Y	9/30/2025	
CBER Roadmap Updates FY25	9/30/2025	N	--	See corrective actions for additional information.
Complete ESG Transition to Cloud	9/30/2025	Y	4/14/2025	
Conduct PFDD Methodology Workshop 2	9/30/2025	Y	9/19/2025	https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-workshop-2-discuss-methodologic-and-other-challenges-related
Conduct Public Meeting CGT Manufacturers	9/30/2025	Y	9/18/2025	https://www.fda.gov/news-events/otp-events-meetings-and-workshops/fda-cber-otp-public-listening-meeting-leveraging-knowledge-facilitating-development-and-review-cell
Conduct STAR Interim Assessment	9/30/2025	Y	8/1/2025	
Develop and Update Data and Tech Modernization Strategy FY25	9/30/2025	N	--	See corrective actions for additional information.
Hiring PDUFA Human Drug Review Program Staff FY25	9/30/2025	N	--	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates See corrective actions for additional information.
Hold Public Meeting for Independent Assessment of Hiring	9/30/2025	Y	9/24/2025	https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-

				user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment
Publish Data Standards Action Plan Q3 FY25	9/30/2025	Y	9/26/2025	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board
Publish Draft Guidance on CID	9/30/2025	N	--	See corrective actions for additional information.
Publish Draft Guidance on Evaluation of Efficacy in Small Patient Populations Using Novel Trial Designs	9/30/2025	Y	9/25/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/innovative-designs-clinical-trials-cellular-and-gene-therapy-products-small-populations
Publish Draft Guidance on Post Approval CGT	9/30/2025	Y	9/25/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postapproval-methods-capture-safety-and-efficacy-data-cell-and-gene-therapy-products
Publish Draft Guidance on Regenerative Medicine Therapies	9/30/2025	Y	9/25/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions-0
Publish Report on Use of Sentinel	9/30/2025	Y	9/30/2025	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-commitment-assessment-sentinel-system-2022-2024
Publish Resource Capacity Planning Assessment Report	9/30/2025	Y	9/26/2025	https://www.fda.gov/media/188791/download?attachment

Publish Update on Public and Sponsor Access on Sentinel Website	9/30/2025	Y	9/24/2025	https://www.fda.gov/media/188920/download?attachment
Quarterly PDUFA Standing Meetings with Industry FY25	9/30/2025	Y	9/30/2025	
RDEA Selection Committee Meetings FY25	9/30/2025	Y	8/21/2025	

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 OII, 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 2025 Performance Results.

Cause or Trend	Impact on FDA's Commitments
Loss of staff during the fiscal year.	The loss of staff during the fiscal year impacted FDA's ability to achieve some performance goals.

Appendix D: FY 2025 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 2024 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 2024, then the Agency fully reported on it in last year's report.[1]

Table D-1. FY 2024 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	While FDA reported missing the Class 1 and 2 resubmissions goal in the FY 2024 PDUFA Performance Report, once all reviews were ultimately completed, FDA achieved the performance standard for all review goal categories.	N/A

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

Procedural and Processing Goals	After the FY 2024 PDUFA Performance Report, when meetings were fully completed, data showed that FDA missed an additional procedural goal: Type B Written Response Only (WRO). Similar to other meeting goals missed in FY 2024 already reported on, there are several factors that may have contributed to the missed goal including other competing PDUFA goals, increased meeting volume, and complexity of questions requiring more disciplines and time to resolve.	FDA is continuing to explore ways to improve meeting performance and improve upon the upward performance trend.

Table D-2. FY 2025 Review and Procedural and Processing Goal Performance Results.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Review Goals	FDA experienced higher than normal attrition in FY 2025, resulting in above average staff departure rate and loss of some review capacity. While remaining staff tried to absorb the workload, not all reviews could be done on-time, and some review goals were missed.	FDA will continue to strive to meet our performance standards for review goals, and work toward addressing resource constraints caused by the high attrition in FY 2025.
Procedural and Processing Goals	While FDA missed several meetings goals, despite loss in staffing, FDA was still able to improve meetings related performance in FY 2025 compared to previous years. Similar to the trend affecting review goals, the loss of review staff had an impact on FDA's ability to meet the goal for reviewing some responses to clinical holds on time. As a result, FDA is currently missing that performance metric by only one percentage point but may meet the standard once all reviews are complete. For the missed goal Human Factors Validation Protocol Submissions to INDs, FDA experienced higher than normal attrition in FY 2025, resulting in above	For meetings FDA will continue to explore ways to build on the performance improvement trend. FDA will continue to strive to meet our performance standard for reviewing clinical hold responses and work toward addressing resource constraints caused by the high attrition in FY 2025. For the Human Factors Validation goal, FDA will continue to strive to iteratively improve performance similar to FY 2024.

	average staff departure rate and loss of some review capacity. While remaining staff tried to absorb the workload, not all reviews could be done on-time, and this procedural and processing goal was missed.	• FDA continues to assess ways to handle the large volume and increasing complexity of Human Factors Validation Protocol Submissions to INDs more effectively. • FDA will work toward addressing resource constraints caused by the high attrition in FY 2025 and focus on ongoing training of new staff and toward continued improvements to work processes to gain efficiencies and meet FDA's commitments.

Table D-3. FY 2025 Performance Enhancement Goal Performance Results.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Financial Transparency	FDA missed the goal to publish a PDUFA 5-year financial plan and the subsequent goal to hold a public meeting to present the financial plan. The financial plan, due by March 31, 2025, was published July 30, 2025. The public meeting, due by June 30, 2025, was held September 30, 2025. The delay in publishing the Five-Year Financial Plans reflects the Agency's commitment to providing accurate and meaningful financial projections.	FDA plans on meeting these commitments in FY 2026.
Hiring Assessment, Hiring, CMC Development and Readiness Pilot, Innovative Manufacturing	Due to the hiring pause implemented by E.O 14210 and extended in July 2025, the Agency has been unable to post announcements for positions to be filled by outside candidates.	FDA does not anticipate the replication of these unforeseen circumstances.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
IT Modernization & Bioinformatics IT Support	Driven by the Commissioner's mandate to eliminate siloes and implement enterprise approaches to technology solutions and AI, FDA is currently consolidating agency systems across centers and bringing each center to a shared, modernized platform which supersedes previous data and technology strategy and CBER IT modernization plans. Given the magnitude of the change and the pace of the consolidations, CDER and CBER are focused on achieving the results. Updates were provided quarterly to industry partners for the last two quarters of the fiscal year.	FDA will investigate how to continue meeting the spirit of these commitments through regular stakeholder meetings and other approaches.
Complex Innovative Trial Designs	The guidance required review coordination across multiple FDA offices and high-level clearance from the Department of Health and Human Services. This review process occurred while the Agency balanced many policy priorities that became particularly acute in the first half of 2025. This led to a delay in publication.	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 2025, 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 2025.

If a goal type is not listed for FY 2024, then the Agency fully reported on it in last year's report.

1. FY 2024 Updated Review and Procedural and Processing Goal Performance Results

Summary of Performance:

Review Goals
FDA achieved the performance standard for all review goal categories in FY 2024.

Procedural and Processing Goals
FDA missed an additional formal meetings goal for issuing Type B Written Response Only (WRO) in FY 2024, in addition to previous goals reported in the FY 2024 PDUFA Performance Report.

Justification:

Similar to other meeting goals missed in FY 2024 already reported on, there are several factors that may have contributed to the missed goal including other competing PDUFA goals, increased meeting volume, and complexity of questions requiring more disciplines and time to resolve.

Corrective Actions:

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

2. FY 2025 Review and Procedural and Processing Performance Results

Summary of Performance:

Review Goals
FDA is currently missing the review performance goal for Priority Non-NME NDAs & Class 1&2 Efficacy Supplement Resubmissions in FY 2025.

Procedural and Processing Goals

FDA is currently missing the performance standard for the following formal meetings related goals:

- Meeting scheduling for Type A, B, and C
- Final written response for Type B and C Meetings

FDA also is currently missing the performance standard for review of responses to Clinical Holds.

Lastly, FDA missed the performance standard for reviewing Human Factors Validation Protocol Submissions to INDs.

Justification:

Review Goals
While FDA experienced higher than normal attrition in FY 2025, resulting in above average staff departure rate and loss of some review capacity, FDA also received a small number of submissions in both review categories that FDA is currently under performing on. The result is that missing only a single review goal brings the performance below the 90% goal. FDA still strives to meet all review goals; however, because of the small cohort size, unless the FDA meets 100% of the reviews, the 90% goal will be missed, leaving no room for unexpected challenges. Nonetheless, there are still several pending submissions that could potentially be classified as a priority non-NME category once filed and if those are reviewed on time, FDA's performance may shift upwards for the final assessment in next year's report.

Procedural and Processing Goals
Similar to the trend effecting review goals, the loss of review staff had an impact on FDA's ability to meet the goal for reviewing some responses to clinical holds on time. As a result, FDA is currently missing that performance metric by only one percentage point, but may meet the standard once all reviews are complete.

While FDA missed several meetings goals, FDA was still able to improve meeting related performance in FY 2025 compared to previous years.

Loss of review staff/resourcing constraints had an impact on FDA's ability to meet the goal for evaluation of human factors validation study protocols. As a result, FDA is currently missing that performance metric.

Corrective Actions:

Review Goals
FDA will continue to strive to meet our performance standards for review goals, and work toward addressing resource constraints caused by the high attrition in FY 2025.

Procedural and Processing Goals
For meetings, FDA will continue to explore ways to build upon the performance improvement trend.

FDA will continue to strive to meet our performance standard for reviewing clinical hold responses and work toward addressing resource constraints caused by the high attrition in FY 2025.

FDA continues to assess ways to handle the large volume and increasing complexity of Human Factors Validation Protocol Submissions to INDs more effectively and work toward addressing resource constraints through increased hiring and training.

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 “Corrective Actions”).

This section presents non-review performance goals cited in the PDUFA VII Commitment Letter with required completion dates in FY 2025. 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 2026 will be covered in subsequent corrective action reports.

I. Financial Transparency

A. Summary of Performance:

FDA missed the goal to publish a PDUFA 5-year financial plan and the subsequent goal to hold a public meeting to present the financial plan. The financial plan, due by March 31, 2025, was published July 30, 2025. The public meeting, due by June 30, 2025, was held September 30, 2025.

B. Justification:

The delay in publishing the Five-Year Financial Plans reflects the Agency's commitment to providing accurate and meaningful financial projections.

C. Corrective Actions:

FDA plans on meeting these commitments in FY 2026.

II. Hiring Assessment

A. Summary of Performance:

FDA missed the PDUFA goal to publish a third-party assessment report on the hiring and retention of program staff. The commitment letter states the report should be published by June 30, 2025. FDA published the report on August 25, 2025.

B. Justification:

Delays occurred due to unanticipated staff departures.

C. Corrective Actions:

FDA does not anticipate the reoccurrence of these unforeseen circumstances.

III. Hiring

A. Summary of Performance:

FDA missed the PDUFA goal for hiring in FY 2025. As of September 30, 2025, 17 of 44 FTEs were hired.

B. Justification:

Due to the hiring pause implemented by E.O 14210 and extended in July 2025, the Agency has been unable to post announcements for positions to be filled by outside candidates.

C. Corrective Actions:

FDA will strive to meet hiring goals in future years.

IV. CMC Development and Readiness Pilot

A. Summary of Performance:

FDA missed the PDUFA goal to conduct a public workshop on the CMC Development and Readiness Pilot (CDRP) by July 31, 2025. FDA held the workshop on September 10, 2025.

B. Justification:

In April 2025, the CDRP workgroup postponed the meeting originally scheduled for May 20, 2025, due to resource constraints.
The original CBER/CDER speakers and policy staff were part of the Reduction in Force or left the agency.

C. Corrective Actions:

FDA will continue to strive to iteratively improve implementation of PDUFA Performance Enhancement Goals. FDA will also continue to evaluate and modernize its strategy for implementation of deliverables through resource constraints.

This delay is not expected to have any downstream impact on other commitments. FDA will continue work on the Strategy Document and expects no delays for the April 30, 2026 deliverable.

V. Innovative Manufacturing

A. Summary of Performance:

FDA missed the PDUFA goal to finalize the draft strategy document related to facilitating the utilization of innovative manufacturing technologies. The commitment letter states the strategy document should be finalized within 9 months after the close of the public comment period on the draft strategy document. The public comment period closed on November 12, 2024, and the final strategy document was due by August 12, 2025. As of September 30, 2025, the final strategy document had not been published.

B. Justification:

Due to resource constraints in Q2 through Q4 of FY 2025, the clearance and publication of the final Strategy Document was delayed.

Drafting of the final Strategy Document was completed June 2025.

C. Corrective Actions:

FDA will continue to strive to iteratively improve implementation of PDUFA Performance Enhancement Goals. FDA will also continue to evaluate and modernize its strategy document development processes to streamline the review and clearance process.

This delay is not expected to have any downstream impact on other commitments. At this point, no further corrective actions are planned.

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VI. IT Modernization & Bioinformatics IT Support

A. Summary of Performance:

FDA missed the PDUFA goal to develop and update FDA's data and technology modernization strategy for fiscal year 2025. FDA also did not provide updates on CBER's IT modernization roadmap.

B. Justification:

Driven by the Commissioner's mandate to eliminate siloes and implement enterprise approaches to technology solutions and AI, FDA is currently consolidating agency systems across centers and bringing each center to a shared, modernized platform which supersedes previous data and technology strategy and CBER IT modernization plans. Given the

magnitude of the change and the pace of the consolidations, CDER and CBER are focused on achieving the results. FDA provided quarterly updates to industry partners for the last two quarters of the fiscal year.

C. Corrective Actions:

FDA will investigate how to continue meeting the spirit of these commitments through regular stakeholder meetings and other approaches.

VII. Complex Innovative Trial Designs

A. Summary of Performance:

FDA missed the PDUFA goal to publish guidance on the Use of Bayesian Methodology in Clinical Trials of Drugs and Biologics by the end of FY2025.

B. Justification:

The guidance required review coordination across multiple FDA offices and high-level clearance from the Department of Health and Human Services. This review process occurred while the Agency balanced many policy priorities that became particularly acute in the first half of 2025. Unfortunately, this led to a delay in publication.

C. Corrective Actions:

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 since the guidance is being worked on and will be published as soon as possible

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 type of meeting other than Type A, B, B(EOP), D, or INTERACT.

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. Postmarketing 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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