Performance Report to Congress

Prescription Drug User Fee Act

FY 2023

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 2022 and FY 2023. Specifically, this report updates performance data for submissions received in FY 2022 (initially reported in the FY 2022 PDUFA performance report)[2] and presents preliminary data on FDA's progress in meeting FY 2023 goals. Updates on FDA's accomplishments related to additional PDUFA VII commitments for FY 2023 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 2023, the number and characteristics of applications filed by review division, and definitions of key terms used in this report. In addition, descriptions of the various submission types are included on page 4 of this report.

The estimated[3] median approval times for priority NDAs and BLAs received in FY 2022 are the same compared to the estimated median approval times for priority NDAs and BLAs received in FY 2021. The preliminary data show that the percentage of priority

[1] https://www.fda.gov/media/151712/download.
[2] http://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.
[3] The median approval time is estimated because an application can receive an approval after multiple review cycles, thus impacting the median approval time for all applications in a given receipt cohort. Some applications may be approved several years after their original receipt.

and standard applications filed in FY 2022 and approved during the first review cycle were 81 percent and 52 percent, respectively.

A. Achievements in FY 2023

In FY 2023, although the Agency continued to appropriately allocate resources to work focused on the pandemic, according to preliminary data, FDA met or exceeded 9 of the 10 review performance goals. For example, 100 percent of current performance goals were achieved for Original Standard new molecular entities (NMEs) and BLAs, Original Standard non-NME, Priority NDA and BLA Efficacy Supplements, and Class 1 and Class 2 Resubmitted NDA and BLA Efficacy Supplements.

B. Review Performance Results

The FY 2022 cohort had a workload of 3,131 goal closing actions. FDA met or exceeded the 90 percent performance level for 12 of the 12 review performance goals for FY 2022.

For the FY 2023 cohort, FDA had completed 1,940 actions as of September 30, 2023. FDA is currently meeting or exceeding nine of the 10 review performance goals for FY 2023. With 1,535 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed nine of the 10 review performance goals for FY 2023.

C. Procedural and Processing Performance Results

For the FY 2022 cohort, FDA's workload for activities related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) totaled 11,012 actions. FDA met or exceeded the performance level for seven of the 20 procedural and processing goals for FY 2022.

For the FY 2023 cohort, FDA is currently meeting or exceeding 15 of the 29 procedural and processing goals. There are 30 procedural and processing goals, but only 29 had applicable submissions. With 1,239 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 18 of the 28 applicable procedural and processing goal commitments for FY 2023.[4]

[4] 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.

D. Additional PDUFA VII Commitments

To highlight just a few achievements, there were several important PDUFA commitments completed in FY 2023, including the following:

- Establishing the Advancing Real-World Evidence Program and selection of initial meeting requests.

- Publishing a guidance and holding a public webinar related to patient-focused drug development.

- Modernizing and enhancing the assessments of Risk Evaluation and Mitigation Strategies by establishing review performance goals and developing new letter templates.

- Publishing a draft guidance on decentralized clinical trials that addresses the use of digital health technologies to capture clinical trial information directly from participants. These technologies are intended to improve trial access for patients, particularly those with difficulty getting to research sites.

- Performing enhancements related to product quality reviews; approaches to chemistry, manufacturing, and controls (CMC); and innovative manufacturing technologies through:

    - Promoting enhanced communications between FDA and Sponsors during application review
    - Issuing a MAPP and establishing pilot programs to facilitate CMC readiness for products with accelerated clinical development
    - Publishing a draft guidance on alternative tools to assess manufacturing facilities

- Enhancing FDA's financial transparency and efficiency by publishing updates to the FY 2023 PDUFA Five-Year Financial Plan

- Enhancing the recruitment and retention of review personnel

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Acronym List

BLA	Biologics License Application
BT	Breakthrough Therapy
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
DHT	Digital Health Technology
EOP	End of Phase
ETASU	Elements to Assure Safe Use
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDARA	FDA Reauthorization Act of 2017
FTE	Full-Time Equivalent
FUFRA	FDA User Fee Reauthorization Act of 2022
FY	Fiscal Year (October 1 to September 30)
IND	Investigational New Drug
IT	Information Technology
NDA	New Drug Application
NME	New Molecular Entity
OC	Office of the Commissioner
OND	Office of New Drugs
ORA	Office of Regulatory Affairs
PDUFA	Prescription Drug User Fee Act
PMR	Postmarketing Requirement
REMS	Risk Evaluation and Mitigation Strategy

I. Introduction

On September 30, 2022, the President signed the FDA Reauthorization Act of 2022 (FUFRA) into law, which included the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal year (FY) 2023 through FY 2027, known as PDUFA VII. PDUFA VII continues to provide the Food and Drug Administration (FDA or Agency) with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biological products. In commitments tied to this funding, FDA agreed to certain review performance goals, such as reviewing and acting on new drug application (NDA) and biologics license application (BLA) submissions within predictable time frames.

Since the enactment of PDUFA I in 1992, FDA has used PDUFA resources to significantly reduce the time needed to evaluate new drugs and biological products without compromising its rigorous standards for a demonstration of safety, efficacy, and quality of these products before approval. The efficiency gains under PDUFA have revolutionized the drug review process in the United States and enabled FDA to ensure more timely access to innovative and important new therapies for patients.

More information on the history of PDUFA is available on FDA's website.[1]

A. Information Presented in This Report

This report presents PDUFA performance and workload information for two different types of goals: (1) the review of applications and other submissions pertaining to human drugs and biological products and (2) meeting management and other procedural goals related to responses and notifications in the human drug review process. PDUFA workload information for these goals is included in the tables that follow. Significant components of the PDUFA workload (such as reviews of investigational new drug (IND) applications, labeling supplements, and annual reports, as well as the ongoing monitoring of drug safety in the postmarket setting) are not captured by PDUFA goals and are therefore not presented in this report.

PDUFA performance information related to achieving these two types of goals includes reviews of submissions pending from the previous fiscal year as well as reviews of submissions received during the current fiscal year. This report presents the final

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

performance results for the FY 2022 cohort of submissions based on actions completed in FY 2022 and FY 2023. In addition, this report includes the preliminary performance results for the FY 2023 cohort of submissions that had actions completed or due for completion in FY 2023. Final performance for the FY 2023 cohort will be presented in the FY 2024 PDUFA performance report and will include actions for submissions still pending within the PDUFA goal date as of September 30, 2023.

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

- The following terminology is used throughout this document:
  - *Application* means a new, original application.
  - *Supplement* means a request to approve a change in an application that has been approved.
  - *Resubmission* means a resubmitted application or supplement in response to a complete response, approvable, not approvable, or tentative approval letter.
  - *New molecular entities (NMEs)* refer only to NMEs that are submitted for approval under NDAs (not BLAs).
  - *Submission* applies to all the above.
  - *Action* refers to an FDA decision on any of the above, including an approval, a tentative approval, a complete response, or withdrawal of the submission by the sponsor.

- Under PDUFA 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 applications only that are sufficiently complete to permit a substantive review. The Agency makes a filing decision within 60 days of an original application's receipt by FDA. FDA's review of an application begins once the application is received. For NME NDAs and original BLAs reviewed under the

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

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 2022 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 2023 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2023, 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 shown.

- Filed applications and supplements include submissions that have been filed or are in pending filing status. Data do not include submissions that are

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

[4] There are four processing and procedural performance goals with performance thresholds at 50 percent and two goals at 60 percent. Therefore, a current performance result at these rates or higher will be shown as currently meeting the goal.

unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

- FY 2023 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, 2023.
- Definitions of key terms used throughout this report can be found in Appendix E.

Submission Types Included in This Report

- **NDA** – When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA an NDA. The application must contain data from specific technical viewpoints for review, including chemical, pharmacological, medical, biopharmaceutical, and statistical. If the NDA is approved, the product may be marketed in the United States.
- **NME** – An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or has been previously marketed as a drug in the United States.
- **BLA** – A BLA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the clinical effects of a biological product. If the information provided meets FDA requirements, the application is approved, and a license is issued allowing the firm to market the product.
- **Resubmission** – A resubmitted original application or supplement is a complete response to an FDA action letter that addresses all identified deficiencies.
- **Supplement** – A supplement is an application to allow a company to make changes in a product that already has an approved NDA or to seek FDA approval for new uses of an approved drug. The Center for Drug Evaluation and Research (CDER) must approve all major NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still being met.

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

II. PDUFA Review Goals

A. Review Workload: FY 2018 to FY 2023

In the table below, preliminary workload numbers from FY 2023 are compared to the previous 5-year averages for original NDAs and BLAs, resubmissions, and supplements, and the workload numbers for the previous 5 years are presented. FDA saw an increase between FY 2022 and FY 2023 in the numbers of original priority non-NME NDAs, original standard non-NME NDAs, Class 1 and Class 2 resubmitted NDAs and BLAs, NDA and BLA manufacturing supplements requiring prior approval, and NDA and BLA manufacturing supplements not requiring prior approval.

Definitions of Class 1 and Class 2 resubmissions and other terms are found in Appendix E. The data presented in this section represent receipts by FDA of the submission types listed in Table 1.

Table 1. Workload for Applications and Submissions

Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22*	FY 23	FY 18 to FY 22 5-Year Average	FY 23 Compared to 5-Year Average
Original Priority NMEs and BLAs	48	44	54	52	43	39**	48	-19%
Original Standard NMEs and BLAs	22	35	29	29	33	25	30	-17%
Original Priority Non-NME NDAs	16	16	14	22	11	32**	16	100%
Original Standard Non-NME NDAs	69	68	59	72	44	60	62	-3%
Class 1 Resubmitted NDAs and BLAs	9	8	5	5	8	9	7	29%
Class 2 Resubmitted NDAs and BLAs	50	41	57	51	59	64	52	23%
Priority NDA and BLA Efficacy Supplements	97	81	112	100	77	71**	93	-24%
Standard NDA and BLA EfficacySupplements	177	197	195	173	171	164	183	-10%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	3	4	3	3	1	1	3	-67%

Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22*	FY 23	FY 18 to FY 22 5-Year Average	FY 23 Compared to 5-Year Average
Class 2 Resubmitted NDA and BLA Efficacy Supplements	11	2	20	10	11	3	11	-73%
NDA and BLA Manufacturing Supplements Requiring Prior Approval	992	973	1,168	1,243	1,155	1,349	1,106	22%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	1,610	1,450	1,717	1,779	1,518	1,658	1,615	3%

* FY 2022 numbers were changed to reflect updates to the data presented in the FY 2022 PDUFA performance report.
** Some applications have not yet received a review priority designation. There were four undesignated NMEs and BLAs counted as Priority NMEs and BLAs, 15 undesignated non-NME NDAs counted as Priority non-NME NDAs, and 11 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 2024 PDUFA performance report.

B. Final FY 2022 Review Goal Performance Results

The final FY 2022 review goal performance results are presented in Table 2. The final performance results for submission types that met or exceeded the goal (i.e., 90 percent or more actions were completed by the goal date) are shown in bold text. FDA met or exceeded the 90-percent performance level for 12 review performance goals in FY 2022.

Table 2. FY 2022 Final Review Goal Performance Results

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2022 Performance
Original Priority NMEs and BLAs	6 months of filing date	43 of 43 on time	**100%**
Original Standard NMEs and BLAs	10 months of filing date	31 of 31 on time	**100%**
Original Priority Non-NME NDAs	6 months	10 of 11 on time	**91%**
Original Standard Non-NME NDAs	10 months	42 of 43 on time	**98%**
Class 1 Resubmitted NDAs and BLAs	2 months	8 of 8 on time	**100%**

Submission Type	Goal: Act on 90 Percent Within	Total	FY 2022 Performance
Class 2 Resubmitted NDAs and BLAs	6 months	57 of 59 on time	**97%**
Priority NDA and BLA Efficacy Supplements	6 months	71 of 77 on time	**92%**
Standard NDA and BLA Efficacy Supplements	10 months	162 of 170 on time	**95%**
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2 months	1 of 1 on time	**100%**
Class 2 Resubmitted NDA and BLA Efficacy Supplements	6 months	11 of 11 on time	**100%**
NDA and BLA Manufacturing Supplements Requiring Prior Approval	4 months	1,105 of 1,155 on time	**96%**
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	6 months	1,496 of 1,518 on time	**99%**

C. Final FY 2022 Review Goal Performance Details

Tables 3 to 7 detail the final performance data for the FY 2022 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 2022 PDUFA performance report.

Table 3. FY 2022 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	43	43	0	100%
Standard NMEs & BLAs	10 months of filing date	33	31	0	100%*
Priority Non-NME NDAs	6 months	11	10	1	91%
Standard Non-NME NDAs	10 months	44	42	1	98%†

* Two standard NMEs and BLAs are pending within goal as of September 30, 2023. Regardless of the action, the final performance result will remain above 90 percent.

† One standard non-NME NDA is pending within goal as of September 30, 2023. Regardless of the action, the final performance result will remain above 90 percent.

Table 4. FY 2022 Resubmitted Original Applications

ResubmittedApplication Type	Goal: Act on 90 Percent Within	Received	On Time	Overdue	Percent on Time
Class 1	2 months	8	8	0	100%
Class 2	6 months	59	57	2	97%

Table 5. FY 2022 Efficacy Supplements

Efficacy Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Priority	6 months	77	71	6	92%
Standard	10 months	171	162	8	95%††

†† One standard efficacy supplement is pending within goal as of September 30, 2023. Regardless of the action, the final performance result will remain above 90 percent.

Table 6. FY 2022 Resubmitted Efficacy Supplements

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

Table 7. FY 2022 Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Percent on Time
Prior Approval Required	4 months	1,155	1,105	50	96%
Prior Approval Not Required	6 months	1,518	1,496	22	99%

D. Preliminary FY 2023 Review Goal Performance Results

The preliminary FY 2023 review goal performance results are presented in Table 8.

- The *progress* (i.e., the number of reviews completed) and the total number of submissions received for each submission type are shown in the second column. *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, 2023, are shown in bold text. FDA is currently meeting or exceeding the 90-percent performance level for nine 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 nine review performance goals.

Table 8. FY 2023 Preliminary Review Goal Performance Results

Submission Type	Progress*	Goal: Act on 90 Percent Within	FY 2023 Current Performance	Highest Possible Final Performance
Original Priority NMEs and BLAs	11 of 35 complete	6 months of filing date	**91%**	97%
Original Standard NMEs and BLAs	1 of 25 complete	10 months of filing date	**100%**	100%
Original Priority Non-NME NDAs	12 of 17 complete	6 months	83%	88%
Original Standard Non-NME NDAs	8 of 60 complete	10 months	**100%**	100%
Class 1 Resubmitted NDAs and BLAs	9 of 9 complete	2 months	**93%**	96%
Class 2 Resubmitted NDAs and BLAs	37 of 64 complete	6 months		
Priority NDA and BLA Efficacy Supplements	37 of 60 complete	6 months	**100%**	100%
Standard NDA and BLA Efficacy Supplements	49 of 164 complete	10 months	**98%**	99%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	1 of 1 complete	2 months	**100%**	100%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	2 of 3 complete	6 months		
NDA and BLA Manufacturing Supplements Requiring Prior Approval	869 of 1,349 complete	4 months	**97%**	98%
NDA and BLA Manufacturing Supplements Not Requiring Prior Approval	904 of 1,658 complete	6 months	**97%**	98%

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

E. Preliminary FY 2023 Review Goal Performance Details

The following detailed performance information for the FY 2023 cohort submissions includes the number of submissions filed, reviewed on time (i.e., acted on by the PDUFA goal date), and overdue (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the PDUFA goal date (pending within goal) is also provided, along with the highest possible percent of reviews that may be completed on time (highest possible percent on time).

Table 9. FY 2023 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	35	10	1	24	91%	97%
Standard NMEs & BLAs	10 months of filing date	25	1	0	24	100%	100%
Priority Non-NME NDAs	6 months	17	10	2	5	83%	88%
Standard Non-NME NDAs	10 months	60	8	0	52	100%	100%
Review Priority Undesignated*	N/A	19	--	--	--	--	--
Total		156	29	3	105	--	--

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

Table 10. FY 2023 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	9	9	0	0	93%	96%
Class 2	6 months	64	34	3	27		

Table 11. FY 2023 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	60	37	0	23	100%	100%
Standard	10 months	164	48	1	115	98%	99%
Review Priority Undesignated*	N/A	11	--	--	--	--	--

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

Table 12. FY 2023 Resubmitted Efficacy Supplements

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

Table 13. FY 2023 Manufacturing Supplements

Manufacturing Supplement Type	Goal: Act on 90 Percent Within	Filed	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Prior Approval Required	4 months	1,349	840	29	480	97%	98%
Prior Approval Not Required	6 months	1,658	878	26	754	97%	98%
Review Priority Undesignated*	N/A	0	--	--	--	--	--

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

III. PDUFA Procedural and Processing Goals and Commitments

A. Procedural and Processing Workload: FY 2018 to FY 2023

The FY 2023 procedural and processing workload, which includes activities related to meeting management, procedural responses, and procedural notifications, is compared to the previous 5-year averages in Table 14. The upward trend of meeting management workload continued into FY 2023.

New categories of Type D meeting and Type INTERACT meeting, were created under PDUFA VII. These new categories also included new meeting metrics for Type D and Type INTERACT Meetings: Scheduled, Written Response, and Preliminary Response. Meeting type definitions and other terms can be found in Appendix E. The table shows updated final FY 2022 performance and presents new reporting required under PDUFA VII.

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

Submission/Request Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022*	FY 2023	FY 2018 to FY 2022 5-Year Average	FY 2023 Compared to 5-Year Average
Type A Meeting Requests±	146	153	182	178	211	268**	174	54%
Type B Meeting Requests±	1,609	1,725	2,438	2,332	2,174	1,895	2,056	-8%
Type B(EOP) Meeting Requests±	343	343	350	347	304	297	337	-12%
Type C Meeting Requests±	1,403	1,550	1,716	1,706	1,699	1,461	1,615	-10%
Type D Meeting Requests±	--	--	--	--	--	371	--	--
Type INTERACT Requests±	--	--	--	--	--	111	--	--
Type A Meetings Scheduled	127	130	147	143	157	233**	141	65%
Type B Meetings Scheduled	945	936	869	741	714	636	841	-24%
Type B(EOP) Meetings Scheduled	324	325	322	282	259	258	302	-15%

Submission/Request Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022*	FY 2023	FY 2018 to FY 2022 5-Year Average	FY 2023 Compared to 5-Year Average
Type C Meetings Scheduled	640	732	699	648	619	574	668	-14%
Type D Meetings Scheduled	--	--	--	--	--	84	--†	--†
Type INTERACT Meetings Scheduled	--	--	--	--	--	20	--†	--†
Type A Written Response	6	6	13	11	19	11	11	0%
Type B Written Response	578	719	1,430	1,451	1,341	1,158	1,104	5%
Type B(EOP) Written Response	14	11	23	49	38	28	27	4%
Type C Written Response	686	728	905	918	974	793	842	-6%
Type D Meeting Written Response	--	--	--	--	--	261	--†	--†
Type INTERACT Written Response	--	--	--	--	--	28	--†	--†
Preliminary Response for Type B(EOP) Meetings	303	305	309	271	246	253	287	-12%
Preliminary Response for Type D Meetings	--	--	--	--	--	88	--†	--†
Preliminary Response for Type INTERACT Meetings	--	--	--	--	--	30	--†	--†
Meeting Minutes	1,541	1,638	1,515	1,363	1,281	1,239	1,468	-16%
Responses to Clinical Holds	199	197	261	275	344	278	255	9%
Major Dispute Resolutions	23	28	35	14	12	15	22	-32%
Special Protocol Assessments	160	158	148	150	167	138	157	-12%
Review of Proprietary Names Submitted During IND Phase	159	212	224	211	188	150	199	-25%
Review of Proprietary Names Submitted During NDA/BLA Phase	228	230	255	223	206	235	228	3%
Human Factors Protocol Submissions to NDAs, BLAs, or INDs	--	70	79	79	59	--	--†	--†
Human Factors Protocol Submissions to INDs	--	--	--	--	--	63	--†	--†

* FY 2022 numbers were changed to reflect updates to the data presented in the FY 2022 PDUFA performance report.
** Some meeting requests and the subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 96 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 2024 PDUFA performance report.
† Because of changing reporting requirements, no past average is presented for this area.
± Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

B. Final FY 2022 Procedural and Processing Performance Results

Table 15 presents the final performance results for FY 2022 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 seven of the 20 procedural and processing goals in FY 2022.

Table 15. FY 2022 Final Procedural and Processing Performance Results

Submission/Request Type	Goal: 90 Percent	Total	FY 2022 Performance
Type A Meeting Requests*	Respond within 14 days	195 of 211 on time	**92%**
Type B Meeting Requests*	Respond within 21 days	1,976 of 2,174 on time	**91%**
Type B(EOP) Meeting Requests*	Respond within 14 days	269 of 304 on time	88%
Type C Meeting Requests*	Respond within 21 days	1,534 of 1,699 on time	**90%**
Type A Meetings Scheduled	Schedule within 30 days	114 of 157 on time	73%
Type B Meetings Scheduled	Schedule within 60 days	573 of 714 on time	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	219 of 259 on time	85%
Type C Meetings Scheduled	Schedule within 75 days	520 of 619 on time	84%
Type A Written Response	Respond within 30 days	16 of 19 on time	84%
Type B Written Response	Respond within 60 days	877 of 1,341 on time	65%
Type B(EOP) Written Response	Respond within 70 days	29 of 38 on time	76%
Type C Written Response	Respond within 75 days	736 of 974 on time	76%

Submission/Request Type	Goal: 90 Percent	Total	FY 2022 Performance
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	222 of 246 on time	**90%**
Meeting Minutes	Issue within 30 days after meeting date	1,203 of 1,281 on time	**94%**
Responses to Clinical Holds	Respond within 30 days	304 of 344 on time	88%
Major Dispute Resolutions	Respond within 30 days	9 of 12 on time	75%
Special Protocol Assessments	Respond within 45 days	159 of 167 on time	**95%**
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	69 of 188 on time	37%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	199 of 206 on time	**97%**
Human Factors Protocol Submissions to NDAs, BLAs, or INDs	Respond within 60 days	33 of 59 on time	56%

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

C. Final FY 2022 Procedural and Processing Performance Details

Tables 16 to 22 detail the final performance data for the FY 2022 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 2022 PDUFA performance report.

Table 16. FY 2022 Meeting Management

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type A Meeting Requests^	Respond within 14 days	211	195	16	**92%**
Type B Meeting Requests^	Respond within 21 days	2,174	1,976	198	**91%**
Type B(EOP) Meeting Requests^	Respond within 14 days	304	269	35	88%

Type	Goal: 90 Percent	Received*	On Time	Overdue	Percent on Time
Type C Meeting Requests^	Respond within 21 days	1,699	1,534	165	**90%**
Type A Meetings Scheduled	Schedule within 30 days	157	114	43	73%
Type B Meetings Scheduled	Schedule within 60 days	714	573	141	80%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	259	219	40	85%
Type C Meetings Scheduled	Schedule within 75 days	619	520	99	84%
Type A Written Response	Respond within 30 days	19	16	3	84%
Type B Written Response	Respond within 60 days	1,341	877	464	65%
Type B(EOP) Written Response	Respond within 70 days	38	29	9	76%
Type C Written Response	Respond within 75 days	974	736	238	76%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	246	222	24	**90%**
Meeting Minutes	Issue within 30 days after meeting date	1,281	1,203	78	**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.

Table 17. FY 2022 Responses to Clinical Holds

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	344	304	40	88%

Table 18. FY 2022 Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	12	9	3	75%

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

Table 19. FY 2022 Special Protocol Assessments

Goal	Received	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	167	159	8	95%

Table 20. FY 2022 Special Protocol Assessments Resubmissions

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
15	14	1	0	0	16

Table 21. FY 2022 Drug/Biological Product Proprietary Names

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	188	69	119	37%
Proprietary Name Submitted During NDA/BLA Phase	Review and respond within 90 days	206	199	7	97%

Table 22. FY 2022 Human Factors Protocol Submissions

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Percent on Time
Human Factors Protocol Submissions to NDAs, BLAs, or INDs	Respond within 60 days	59	33	26	56%

D. Preliminary FY 2023 Procedural and Processing Performance Results

Table 23 presents preliminary performance results for FY 2023 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, 2023, are shown in bold text. FDA is currently meeting or exceeding the performance level for 15 of the 29[5] applicable procedural and processing goals (e.g., 90 percent or more reviews were completed by the goal date). If all pending submissions are reviewed on time, FDA has the potential to meet 18 of the 28 applicable goals, as seen in the Highest Possible Final Performance column.[6]

Table 23. FY 2023 Preliminary Procedural and Processing Performance Results

Submission/Request Type	Progress	Goal: 90 Percent	FY 2023 Current Performance	Highest Possible Final Performance
Type A Meeting Requests*†	186 of 268 complete	Respond within 14 days	87%	91%
Type B Meeting Requests*	1,864 of 1,895 complete	Respond within 21 days	**92%**	92%
Type B(EOP) Meeting Requests*	293 of 297 complete	Respond within 14 days	87%	87%
Type C Meeting Requests*	1,439 of 1,461 complete	Respond within 21 days	**95%**	95%

[5] There are 30 procedural and processing goals, but only 29 had applicable submissions.
[6] The highest potential performance is not calculated for the two PMR goals as is it not possible to accurately predict the number of pending submissions that will be approved with PMRs.

Submission/Request Type	Progress	Goal: 90 Percent	FY 2023 Current Performance	Highest Possible Final Performance
Type D Meeting Requests*	367 of 371 complete	Respond within 14 days	89%	89%
Type INTERACT Requests*	106 of 111 complete	Respond within 21 days	**94%**	95%
Type A Meetings Scheduled†	139 of 233 complete	Schedule within 30 days	71%	82%
Type B Meetings Scheduled	591 of 636 complete	Schedule within 60 days	78%	79%
Type B(EOP) Meetings Scheduled	246 of 258 complete	Schedule within 70 days	78%	79%
Type C Meetings Scheduled	537 of 574 complete	Schedule within 75 days	82%	83%
Type A Written Response	11 of 11 complete	Respond within 30 days	**91%**	91%
Type B Written Response	1,013 of 1,158 complete	Respond within 60 days	74%	77%
Type B(EOP) Written Response	25 of 28 complete	Respond within 70 days	**96%**	96%
Type C Written Response	653 of 793 complete	Respond within 75 days	83%	86%
Preliminary Response for Type B(EOP) Meetings	198 of 253 complete	Issue no later than 5 days prior to meeting date	89%	92%
Preliminary Response for Type D Meetings	73 of 88 complete	Issue no later than 5 days prior to meeting date	89%	91%
Preliminary Response for Type INTERACT Meetings	20 of 30 complete	Issue no later than 5 days prior to meeting date	75%	83%
Meeting Minutes	915 of 1,239 complete	Issue within 30 days after meeting date	**94%**	95%
Responses to Clinical Holds	261 of 278 complete	Respond within 30 days	89%	90%
Major Dispute Resolutions	13 of 15 complete	Respond within 30 days	**92%**	93%
Special Protocol Assessments	127 of 138 complete	Respond within 45 days	**95%**	96%
Proprietary Name Submitted During IND Phase	85 of 150 complete	Review and respond within 180 days	**94%**	97%

Submission/Request Type	Progress	Goal: 90 Percent	FY 2023 Current Performance	Highest Possible Final Performance
Proprietary Name Submitted During NDA/BLA Phase	186 of 235 complete	Review and respond within 90 days	**93%**	94%
Human Factors Protocol Submissions to INDs	53 of 63 complete	Respond within 60 days	26%	38%

* Excludes meetings withdrawn prior to the meeting granted/denied response goal date.
† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined.
There were 96 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 2024 PDUFA performance report.

Submission/Request Type	Progress	Goal: 50 Percent	FY 2023 Current Performance	Highest Possible Final Performance
Type D Meetings Scheduled	81 of 84 complete	Schedule within 50 days	**84%**	85%
Type INTERACT Scheduled	20 of 20 complete	Schedule within 75 days	**85%**	85%
Type D Meeting Written Response	212 of 261 complete	Respond within 50 days	**87%**	90%
Type INTERACT Written Response	23 of 28 complete	Respond within 75 days	**91%**	93%

E. Preliminary FY 2023 Procedural and Processing Performance Details

The following detailed performance information for FY 2023 cohort submissions includes the number of submissions *received*, reviewed *on time* (i.e., acted on by the PDUFA goal date), and *overdue* (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the PDUFA goal date (*Pending Within Goal*) is also provided, along with the highest possible percent of reviews that may be completed on time (*Highest Possible Percent on Time*).

Table 24. FY 2023 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	268	162	24	82	87%	91%
Type B Meeting Requests±	Respond within 21 days	1,895	1,721	143	31	92%	92%
Type B(EOP) Meeting Requests±	Respond within 14 days	297	255	38	4	87%	87%
Type C Meeting Requests±	Respond within 21 days	1,461	1,360	79	22	95%	95%
Type D Meeting Requests±	Respond within 14 days	371	328	39	4	89%	89%
Type INTERACT Meeting Requests±	Respond within 21 days	111	100	6	5	94%	95%
Type A Meetings Scheduled†	Schedule within 30 days	233	98	41	94	71%	82%
Type B Meetings Scheduled	Schedule within 60 days	636	459	132	45	78%	79%
Type B(EOP) Meetings Scheduled	Schedule within 70 days	258	193	53	12	78%	79%
Type C Meetings Scheduled	Schedule within 75 days	574	442	95	37	82%	83%
Type A Written Response	Respond within 30 days	11	10	1	0	91%	91%
Type B Written Response	Respond within 60 days	1,158	749	264	145	74%	77%
Type B(EOP) Written Response	Respond within 70 days	28	24	1	3	96%	96%
Type C Written Response	Respond within 75 days	793	540	113	140	83%	86%
Preliminary Response for Type B(EOP) Meetings	Issue no later than 5 days prior to meeting date	253	177	21	55	89%	92%
Preliminary Response for Type D Meetings	Issue no later than 5 days prior to meeting date	88	65	8	15	89%	91%
Preliminary Response for Type INTERACT Meetings	Issue no later than 5 days prior to meeting date	30	15	5	10	75%	83%
Meeting Minutes	Issue within 30 days after meeting date	1,239	856	59	324	94%	95%

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.
† Some meeting requests and subsequent scheduling of meetings are for requests where the type cannot be initially determined. There were 96 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 2024 PDUFA performance report.
± Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Type	Goal: 50 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	84	68	13	3	84%	85%
Type INTERACT Scheduled	Schedule within 75 days	20	17	3	0	85%	85%
Type D Written Response	Respond within 50 days	261	185	27	49	87%	90%
Type INTERACT Written Response	Respond within 75 days	28	21	2	5	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 25. FY 2023 Responses to Clinical Holds

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 30 days	278	232	29	17	89%	90%

Table 26. FY 2023 Major Dispute Resolutions

Goal	Responses*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 30 days	15	12	1	2	92%	93%

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

Table 27. FY 2023 Special Protocol Assessments

Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Respond to 90 percent within 45 days	138	121	6	11	95%	96%

Table 28. FY 2023 Special Protocol Assessments Resubmissions

SPAs with Resubmissions	Applications with1 Resubmission	Applications with2 Resubmissions	Applications with3 Resubmissions	Applications with4 Resubmissions	Total Resubmissions
24	22	2	0	0	26

Table 29. FY 2023 Drug/Biological Product Proprietary Names

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Proprietary Name Submitted During IND Phase	Review and respond within 180 days	150	80	5	65	94%	97%

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 NDA/BLA Phase	Review and respond within 90 days	235	173	13	49	93%	94%

Table 30. FY 2023 Human Factors Protocol Submissions

Submission Type	Goal: 90 Percent	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Human Factors Protocol Submissions to INDs	Respond within 60 days	63	14	39	10	26%	38%

Under PDUFA VII, FDA committed to communicating details on anticipated Postmarketing Requirements (PMRs) for NME NDAs and BLAs required under Section 505(o)(3), PREA, Accelerated Approval, and the Animal Rule to the Applicant prior to the PDUFA action goal date. These communications summarize FDA's preliminary evaluation of required post marketing studies, including the study purpose, critical study design elements including type of study and study population, timelines for discussions and engagement on the PMR for the remainder of the review cycle, and for 505(o)(3) PMRs the specific serious risk.

Below is the performance for communication of anticipated PMRs for NME NDAs and BLAs that were received in FY 2023 and approved with PMRs, regardless of approval date.

Table 31. FY 2023 Communication of Anticipated Postmarketing Requirements

Application Type	Goal: 60 Percent	Approved Applications with PMRs	On Time[1]	Overdue[2]	Current Percent on Time
Priority NME NDAs and original BLAs	Communicate PMRs 6 weeks prior to action goal date	5	5	0	100%

Standard NME NDAs and original BLAs	Communicate PMRs 8 weeks prior to action goal	0	0	0	--

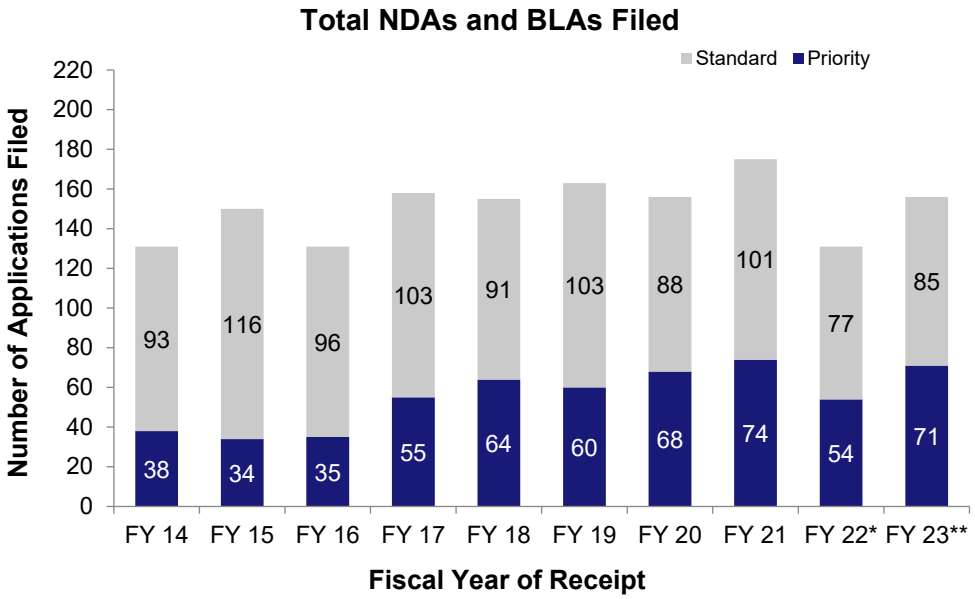
[1] On time refers to the number of approved applications with PMRs where the PMRs required at approval were communicated by the 6- or 8-week goal date.

[2] 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.

IV. PDUFA Trend Graphs

The number of NDAs and BLAs filed from FY 2014 to FY 2023 is presented in Figure 1. The total number of all original applications (NDAs and BLAs) filed in FY 2023 increased from the number filed in FY 2022.

Figure 1. Total NDAs and BLAs Filed

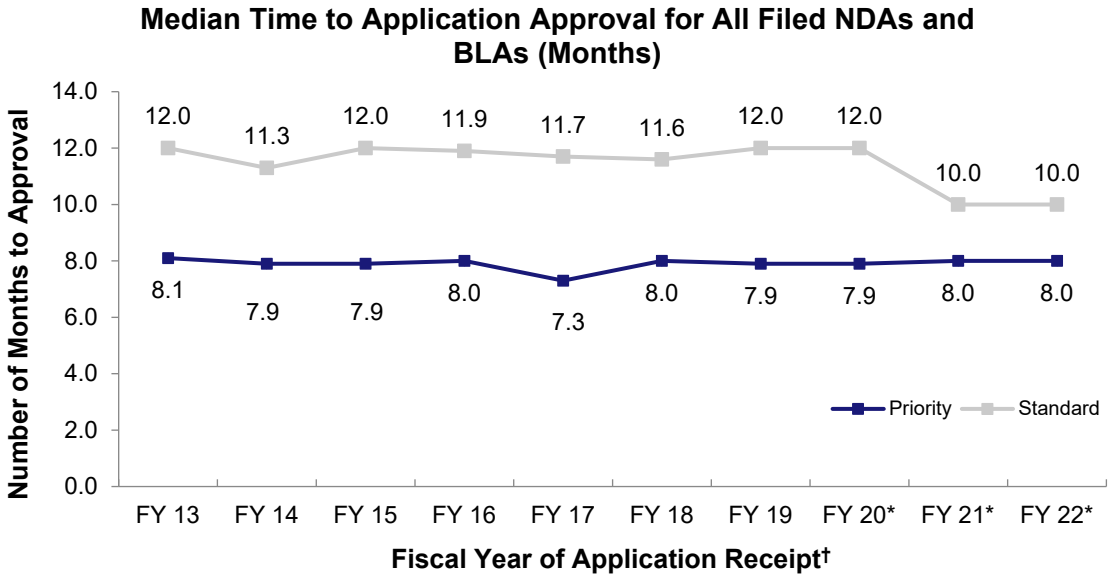


* FY 2022 numbers were changed to reflect updates to the data presented in the FY 2022 PDUFA performance report.

** Some applications filed in FY 2023 have not yet received a review priority designation. The undesignated NDAs and BLAs are counted as Priority NDAs and BLAs. Designation may change and the table will then be updated accordingly, as appropriate, in the FY 2024 PDUFA performance report.

The median total times to approval for priority and standard applications received from FY 2013 through FY 2022 are presented in the graph below.[7] The data represented in Figure 2 are updated based on the approvals reported in Appendix A. FY 2023 data are too preliminary to estimate the median approval time.

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

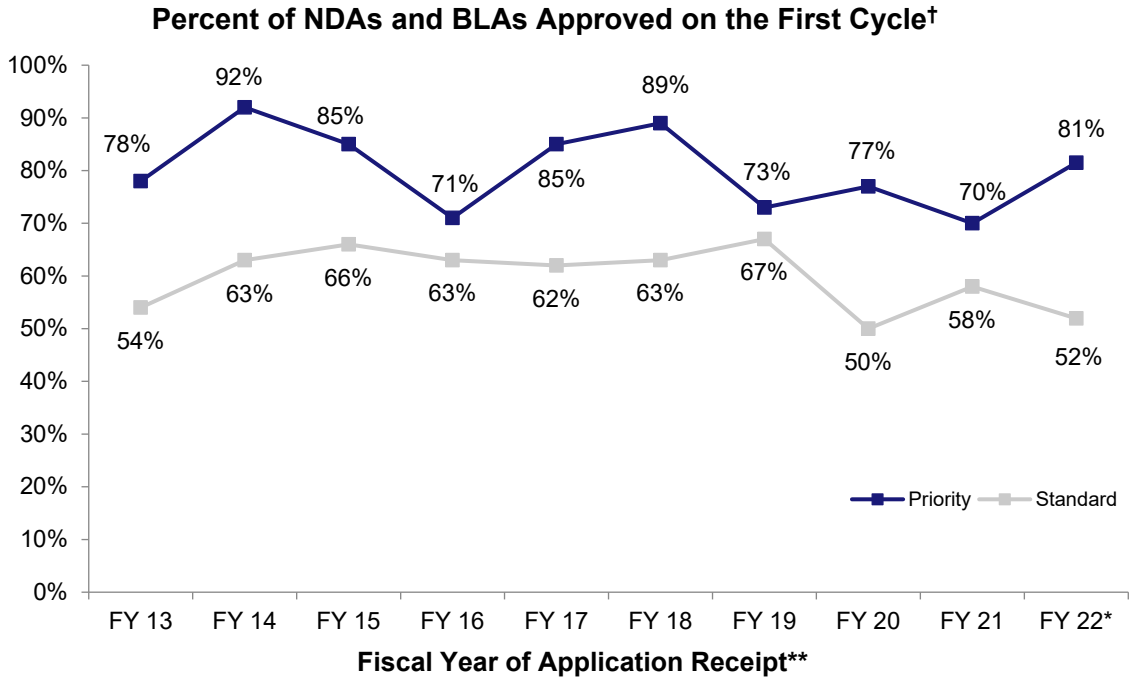


* The median approval times for the 3 most recent years are estimated.
† The data represented in this figure are based on the approvals reported in Appendix A.

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

Figure 3 depicts the percentages of priority and standard NDAs and BLAs approved in the first review cycle for the receipt cohorts from FY 2012 to FY 2022. These percentages are based on the approvals reported in Appendix A. The percentage of standard applications in first-cycle approvals decreased in FY 2022. For the FY 2022 cohort, which is still preliminary, 52 percent of standard applications were approved on the first cycle. First-cycle approvals for approved priority applications increased in FY 2022, with 81 percent of approved priority applications being approved on the first cycle. The FY 2023 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 2022 standard applications, so the data are preliminary.
† The data were changed to reflect updates to the data presented in the FY 2022 PDUFA performance report.
** The data represented in this graph are based on the approvals reported in Appendix A.

V. Additional PDUFA VII Commitments

Under Section VI ("Progress reporting for PDUFA VII and Continuing PDUFA VI initiatives") of the PDUFA VII Commitment Letter, FDA committed to report its progress on the specific commitments identified in the following sections of the Commitment Letter:[8]

- 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.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
- 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

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

Further, section 736B(a) of the FD&C Act, as amended by section 103 of FDARA, requires FDA to report on the Agency's performance under PDUFA 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 2023 with updates on commitments in respective sections of the Commitment Letter cited above in the list. In addition, this report includes updates on FDA's accomplishments under Section II: Continued Enhancing Management of User Fee Resources, Section III: Improving FDA Hiring and Retention of Review Staff, and Section IV: Information Technology and Bioinformatics Goals. The Section II progress reports are duplicated in the FY 2023 PDUFA VII Financial Report. Each accomplishment includes a reference to a specific section of the Commitment Letter. External references are also provided to published guidances, meeting summaries, and other pertinent public information.

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

Table 32. FDA's Overall FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
I.A Review Performance Goals	• None
I.B Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs	• None
I.C New Molecular Entity (NME) Milestones and Postmarketing Requirements (PMRs)	• Conduct training for Pre-Approval Review of PMRs. • Implement Post Approval Review of PMRs. • Implement Pre-Approval Review of PMRs. • Conducted training for external and internal stakeholders related to new PMR commitments. • Created and implemented new processes in DARRTS for communicating anticipated PMRs, which include two new templates and communication codes and updating and revising several other pre-existing templates. • Created and implemented new processes in DARRTS for responding to postapproval release requests of PMRs, which included developing several

	new letter and memo templates, and their communication and supporting document codes, and revising several pre-existing letters templates and documents. • Collaborated on the development and dissemination of reports that track preapproval PMR communication goals and postapproval PMR release request notification goals. • Started reviewing and updating MAPPs related to PMR commitments as appropriate. • Continue to monitor the effectiveness of these new processes and templates making revisions as needed. • Implemented Commitments for Pre-Approval Review of PMRs ○ Conducted Training for Pre-Approval Review of PMRs. ○ Created and implemented new processes in DARRTS for communicating anticipated PMRs, which include two new templates and communication codes and updating and revising several other pre-existing templates. • Implemented Commitments for Post Approval Review of PMRs ○ Created and implemented new processes in DARRTS for responding to postapproval release requests of PMRs. ○ Developed several new letter and memo templates, and their communication and supporting document codes, and revising several pre-existing letters templates and documents.
I.D Split Real Time Application Review (STAR) Pilot Program	• Implement STAR Pilot Program ○ The STAR Pilot Program became available for qualifying efficacy supplements beginning on October 1, 2022. ○ Business processes, tools, and templates were developed to facilitate the program. • Develop STAR Web Page ○ A public-facing web page (https://www.fda.gov/drugs/development-resources/split-real-time-application-review-star) was created on FDA.gov to provide further information for the STAR program. • Conduct STAR Employee Training ○ An internal STAR program resource page was made available in October 2022. ○ Internal training related to STAR processes was provided beginning in October 2022. STAR training was recorded for future use.

I.E Expedited Reviews	• None
I.F Review of Proprietary Names to Reduce Medication Errors	• None
I.G Major Dispute Resolution	• None
I.H Clinical Holds	• None
I.I Special Protocol Assessment and Agreement	• None
I.J Meeting Management Goals	• FDA updated IT systems with new timelines and definitions to accommodate the following new PDUFA VII meeting types/interactions: ○ INTERACT Meetings ○ Type D Meetings ○ Written Response for Clarification • FDA also published a revised draft *Guidance on Formal Meetings Between FDA and Sponsors* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products). • Additionally, FDA is planning for internal assessments of meetings to prepare for and support a public workshop to discuss meeting best practices by July 30, 2024.

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

Table 33. Section I.K's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
I.K.1 Promoting Innovation Through Enhanced Communication Between FDA and	• FDA is actively planning and preparing for the public workshop to discuss meeting best practices, to be held by no later than July 30, 2024.

Sponsors During Drug Development	
I.K.2 Ensuring Sustained Success of Breakthrough Therapy Program	• None
I.K.3 Early Consultation on the Use of New Surrogate Endpoints	• None
I.K.4 Advancing Drug Development of Drugs for Rare Diseases	**OVERALL** Advancing drug development for rare diseases is a cross-Agency collaborative effort. In FY 2023, CDER's Rare Diseases Team (RDT) and the Center for Biologics Evaluation and Research (CBER) engaged in critical rare disease drug development enhancement activities. In FY 2023, CDER's Accelerating Rare disease Cures Program (CDER ARC Program), which was launched in May 2022, worked 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 managed by the RDT and 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 (OTS). CBER collaborates with CDER on specific cross-cutting efforts under the CDER ARC Program. **EXPERTISE IN REVIEW** • In FY 2023, the RDT continued to consult on or contribute to the approval of rare disease drug applications across the review divisions in OND regarding the design of trials, the assessment of substantial evidence of effectiveness, the selection of endpoints and the labeling of rare disease products. • CBER continued to ensure that its review offices considered flexible and feasible approaches in the review of biologics for rare diseases through sharing of expert review practices and case study presentations during CBER Rare Disease Coordinating Committee meetings. • CDER's Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), in conjunction with the RDT, continued to facilitate CDER's Rare Disease Drug Development Council meetings. Members of CDER's Division of Rare Diseases and Medical Genetics (DRDMG) and RDT serve on the council. The council meetings are a forum (1) to discuss cross-cutting rare disease issues with leaders in rare disease drug development across OND and OTS and (2) to solicit input from OND and OTS on rare disease applications.

- The RDT is the CDER program lead for the development and implementation of the PDUFA VII Rare Disease Endpoint Advancement (RDEA) Pilot Program. This joint CDER/CBER pilot program supports novel efficacy endpoint development for rare disease treatments. FDA began receiving RDEA proposal submissions for quarter 4 of 2023 on July 1, 2023, with a submission deadline of September 30, 2023. One submission will be selected for quarter 4 of 2023. The program will continue receiving quarterly submissions through June 2027, with the goal of admitting up to three proposals per year into the program.

- The RDT worked closely with other offices within CDER to continue to provide expertise for the rare disease pediatric voucher program.

- In July 2023, DRDMG and CBER's Office of Therapeutic Products launched an informal forum for quarterly internal reviewer discussion of rare disease products and indications. This informal forum serves as an opportunity for CBER and CDER medical officers to interact and work more closely together on rare disease specific issues that are relevant to both centers.

- In September 2023, CBER and CDER jointly announced the Support for clinical Trials Advancing Rare Disease Therapeutics (START) pilot program. The goal of the START pilot program is to further accelerate the pace of development of certain CBER- and CDER- novel drug and biological products that are intended to treat a rare disease by addressing issues related to the development of individual products through more rapid communication mechanisms. In CDER, the START pilot program is being implemented by RDT and in CBER, it is being implemented by the Office of Therapeutic Products.

EDUCATION AND TRAINING

- In FY 2023, the RDT and CBER continued to train CDER and CBER review staff, as well as other FDA staff, in areas of rare disease drug development.

- In September 2023, the RDT, in collaboration with CBER and other FDA offices, held a 2-day annual reviewer training event titled *The Role of Translational Science and Confirmatory Evidence in Rare Disease Product Development*. This training focused on presentations, discussion, successful rare disease case examples from CDER and CBER, and RDT regulatory research projects related to the newly released guidance *Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence*. Over 500 staff attended the program.

- The RDT hosts a rare diseases seminar series. During these seminars, which host internal and external speakers for all FDA staff, timely and innovative topics pertaining to rare diseases are presented, such as

	information on model informed drug development in rare diseases or the complexities of disease agnostic platform trials for rare diseases. CBER staff were integral contributors of topic ideas to this series. • The RDT, in conjunction with DRDMG and ORPURM, distributed an internal FDA rare disease newsletter, Zebragram. The newsletter, for FDA staff, provided not only news relating to rare disease science, regulations, and policies within OND, across the Agency, and with key stakeholders, but also on information about rare disease drug and biological product applications from across CDER and CBER. CBER's rare disease program staff routinely contributed content to this newsletter on CBER rare disease activities and ensured a wide distribution of it within its Center. **EXTERNAL OUTREACH** • In FY 2023, the RDT, in collaboration with CBER, continued its outreach activities with external stakeholders to advance rare disease drug development by engaging and presenting at multiple meetings, poster presentations, and speaking engagements, and by publishing on regulatory rare disease topics. • In FY 2023, CDER, in conjunction with the RDT, enhanced the CDER ARC Program website[9] with rare disease information and resources to create a "one-stop site" for external stakeholders and FDA staff. CDER also launched its quarterly CDER ARC Program newsletter in November 2022 to provide external stakeholders and FDA staff with highlights of rare disease drug development news. • The RDT and CBER rare disease program staff interacted with FDA's Office of Orphan Products Development (OOPD) on rare disease activities, such as bimonthly planning meetings for and participation in FDA Rare Disease Day 2023, which was a public meeting, titled *Intersections with Rare Diseases: A Patient-Focused Event*, on February 27, 2023. The RDT and CBER staff also contributes to the review of extramural grants on natural history studies for the OOPD's Rare Neurodegenerative Disease Grant Program. • CDER-RDT, CBER, the Center for Devices and Radiological Health, and the Office of the Commissioner's rare disease subject-matter experts participated in the October 2022 NORD Summit by coordinating an FDA plenary session on real-world data and real-world evidence. The RDT also facilitated FDA participation in other sessions and presented two posters at the Summit, one on novel drug approvals and the other on the International Rare Disease Cluster. The RDT and CBER also reviewed abstracts for selection of Summit poster presentations.

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

	• In May 2023, the RDT, along with CDER's Office of Biostatistics and the Johns Hopkins University Center of Excellence in Regulatory Science and Innovation (CERSI), co-sponsored a 2-day workshop called *Addressing Challenges in the Design and Analysis of Rare Disease Clinical Trials: Considerations and Tools*.[10] The workshop provided information on collection and use of fit-for-purpose data for rare disease drug development, and adaptive design and analysis methods in small population clinical trials. This workshop targeted academic investigators, patient groups, and small or emerging pharmaceutical or biotechnology companies that are often the sponsors for rare disease drug development but may lack regulatory experience. • In May 2023, CDER, in collaboration with the University of Maryland CERSI, co-sponsored a 1-day workshop titled *Creating a Roadmap to Quantitative Systems Pharmacology-informed Rare Disease Drug Development.*[11] This workshop included presentations on the potential utility and challenges of quantitative systems pharmacology in rare disease drug development. • In June 2023, CDER and CBER in collaboration with the Duke-Margolis Center for Health Policy held the first public workshop, *Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development*, of the RDEA Pilot Program.[12] Topics included case study presentations on different types of endpoints and RDEA program overview, process, and requirements. The RDEA Pilot Program external web page[13] was significantly expanded in early June 2023. • 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 accessible educational materials for Rare Disease Drug Development (RDDD) stakeholders. Internal FDA and external outreach was conducted via interviews and public docket comments seeking input to identify knowledge gaps for stakeholders about regulatory process of rare disease drug development. The information gathered from stakeholders was divided into six relevant topics of interest (1) nonclinical, (2) dose-finding, (3) natural history studies and registries, (4) novel endpoints and biomarkers, (5) clinical trial design and analysis, and (6) RDDD regulatory considerations. An analysis of the information gathered will be used to inform the development and dissemination of educational materials specific to RDDD.

[10] https://www.fda.gov/drugs/news-events-human-drugs/fda-cder-jhu-cersi-workshop-addressing-challenges-design-and-analysis-rare-disease-clinical-trials.
[11] https://cersi.umd.edu/event/17946/creating-a-roadmap-to-quantitative-systems-pharmacology-informed-rare--disease-drug-development.
[12] https://www.fda.gov/drugs/news-events-human-drugs/fda-cder-and-cber-duke-margolis-center-health-policy-rare-disease-endpoint-advancement-pilot-program.
[13] https://www.fda.gov/drugs/development-resources/rare-disease-endpoint-advancement-pilot-program.

	• In June 2023, the RDT and CDER's OTS presented a poster, *Confirmatory Evidence of Effectiveness Used to Support Non-Oncologic Rare Disease Novel Drug Marketing Application Approvals, CY 2020 – 2022,* at the 2023 FDA Science Forum. • In August 2023, RDT presented a poster, *Rare Disease Patient Experience Use in Clinical Trial Design and Endpoint Selection for Novel Orphan Drug Development*, at the FDA Annual Student Scientific Research Day. • The RDT led and facilitated the International Rare Diseases Cluster for FDA. In addition to including CDER and CBER at the FDA, this cluster includes two other regulatory agencies—namely, the European Medicines Agency and Health Canada. These cluster meetings include exchange of information on the development and scientific evaluation of medicines for rare diseases, such as conducting clinical trials in small populations, obtaining preclinical evidence to support development programs, risk management strategies for long-term safety issues and the design of post-marketing studies. In FY 2023, there were 9 cluster meetings discussing 20 topics. CBER staff gave presentations at four of the nine Cluster meetings held with the European Medicines Agency and Health Canada. • The RDT and CBER rare disease program staff participate on the International Rare Diseases Research Consortium's (IRDiRC'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. In March 2023, the RDT and CBER rare disease program staff presented at the RE(ACT) Congress and IRDiRC conference in Berlin, Germany. • CDER and CBER rare disease experts collaboratively ensured the relevance of rare diseases for four guidance documents for industry to facilitate rare disease drug development. Two of these were draft guidances —one titled *Considerations for the Design and Conduct of Externally Controlled Trials for Drugs and Biological Products*[14] and one titled *Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence*.[15] The third guidance, *Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products*,[16] and the fourth guidance, *Rare Diseases: Considerations for the*

[14] https://www.fda.gov/media/164960/download.
[15] https://www.fda.gov/media/172166/download.
[16] https://www.fda.gov/media/171667/download.

	Development of Drugs and Biological Products[17] finalized a draft guidance on this topic. In addition, DRDMG issued the revised draft guidance *Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development.*[18] • In February 2023, the CDER ARC Program announced the addition of "Original Rare Disease Application Approval" and "Novel Rare Disease Drugs Approval" filters to CDER's Drugs and Biologics Dashboard on FDA-TRACK.[19] FDA-TRACK is an agency-wide performance management program that reports on performance measures and key projects for various FDA Centers and Programs. With this new filter, visitors can toggle-view the history of CDER's cumulative drug approvals to view those which were approved for the treatment of rare diseases. This information, curated by the RDT, provides a more accessible view to the rare disease community about the development and approval of safe and effective drugs to treat rare diseases. Current rare disease approval information is provided for September 1, 2022, to June 30, 2023. The FDA-TRACK will be updated quarterly with additional rare disease information. • ORPURM, DRDMG, and the RDT made over 30 presentations to the public on various rare disease topics. • CDER staff and reviewers in DRDMG published an FDA approval summary for Lonafarib, a drug treatment for two rare conditions, Hutchinson-Gilford progeria syndrome and processing-deficient progeroid laminopathies.[1] In addition, the RDT and other CDER staff contributed to various chapters of the book *Drug Development for Rare Diseases*.[2] • In the first three quarters of FY 2023, CBER staff participated in a minimum of 132 outreach activities intended to support the development of biological products for rare diseases. These activities included presentations (72%), publications (20%), and posters/abstracts (8%) internal to FDA and diverse external rare disease stakeholders. • The RDT and CBER staff attended multiple Patient-Focused Drug Development (PFDD) and Patient Listening Sessions for rare diseases. The PFDD meetings, some of which were hosted by patient organizations, provided a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation. These listening sessions enabled FDA medical product centers to

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rare-diseases-considerations-development-drugs-and-biological-products.
[18] https://www.fda.gov/media/114764/download.
[19] 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.

	engage informally with patients and caregivers, including those belonging to under-represented communities, allowing them to share with the Agency their experiences living with a disease/condition. Similar to PFDD meetings, the listening sessions help the Agency inform medical product development, clinical trial design, patient preferences, and shape regulatory thinking. • In FY 2023, CBER held the following rare disease-relevant workshops and webinars on cell and gene therapy topics for industry and patient stakeholders, including: ○ OTP Town Hall: *Nonclinical Assessment of Cell and Gene Therapy Products*[20] ○ *Methods and Approaches for Capturing Post-Approval Safety and Efficacy Data on Cell and Gene Therapy Products*[21] ○ OTP Town Hall: *Gene Therapy Chemistry, Manufacturing, and Controls* – April 2023[22] ○ *Clinical Trials: The Patient Experience*[23] ○ OTAT Town Hall: *Clinical Development of Gene Therapy Products for Rare Diseases*[24] In August 2023, CBER launched the web page CBER Rare Disease Program,[25] a new, publicly available, rare disease resource. This page includes highlights of CBER Rare Disease Program activities including collaborative efforts with partners at FDA and beyond. The page also provides annual listings of CBER's recent orphan approvals starting from 2022 and CBER Rare Disease Program Frequently Asked Questions | FDA.[26]
Would I.K.5 Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER	• Establish review of Human Factors Validation Study protocols ○ Updated human factors validation study protocol review templates and best practice documents to facilitate review and provide sponsor with written comments for 90% of human factors validation protocol submissions within 60 days of receipt of protocol submission. • Establish review of use-related risk analysis

[20] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/otp-town-hall-nonclinical-assessment-cell-and-gene-therapy-products-08302023.
[21] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/methods-and-approaches-capturing-post-approval-safety-and-efficacy-data-cell-and-gene-therapy.
[22] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/otp-town-hall-gene-therapy-chemistry-manufacturing-and-controls-april-2023-04252023.
[23] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/clinical-trials-patient-experience-04132023.
[24] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/otat-town-hall-clinical-development-gene-therapy-products-rare-diseases-02072023.
[25] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program.
[26] https://www.fda.gov/vaccines-blood-biologics/cber-rare-disease-program-frequently-asked-questions.

	○ Updated use-related risk analysis review templates and best practice documents to facilitate review and provide sponsor with written comments for 50% of filed submissions, within 60 days of receipt of submission for FY 2024.
I.K.6 Enhancing Use of Real-World Evidence for Use in Regulatory Decision-Making	• Announced establishment of the Advancing Real-World Evidence Program in a *Federal Register* notice (FRN) (https://www.federalregister.gov/documents/2022/10/20/2022-22795/advancing-real-world-evidence-program) and provided additional program details on the Advancing Real-World Evidence web page (https://www.fda.gov/drugs/development-resources/advancing-real-world-evidence-program) (I.K.6.a & I.K.6.b). • Completed evaluation and selection of initial meeting requests received for first semi-annual submission cycle ending March 31, 2023 (I.K.6.b).

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

Table 34. Section I.L's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
I.L.1 Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making	• In April 2023, FDA published the draft guidance document *Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision-Making* (PFDD Guidance 4).[27] The comments will be reviewed and considered as part of the process to finalize this guidance document. • In May 2023, FDA conducted a public webinar to provide an overview of PFDD Guidance 4 and to answer stakeholder questions. • In May 2023, FDA issued a public docket to collect comments on methodological challenges related to patient experience data.[28] The comments will be summarized, will help FDA (1) plan two public workshops focused on methodological issues and (2) identify priorities for future work. • FDA staff members continued to interact with patient stakeholders to systematically obtain the patient perspective on specific diseases and their treatments. These interactions included conducting one FDA-led PFDD meeting on Long COVID, participating in 18 Patient Listening Sessions, and

[27] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory.
[28] https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments.

	participating in 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 *International Rett Syndrome Foundation Annual Meeting*, and many others. • FDA continued the Standard Core Clinical Endpoints and Grant Program that (1) funds the development of core outcome sets in a variety of clinical divisions and (2) increases the familiarity and understanding of the development of Clinical Outcome Assessments within review divisions and other areas. • FDA 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. o FDA provided staff trainings on Patient-Focused methodologies. These trainings included a training on PFDD Guidance 4 which was provided to the CDER Office of Biostatistics in November 2022 and a widely attended training for reviewers from across the Agency on the *Patient-Focused Drug Development Guidance* series, that was hosted by the FDA Statistical Association in September 2023. In addition, FDA staff provided ongoing just-in-time in-service trainings to review divisions throughout the fiscal year. o FDA conducted targeted outreach to industry and methodological consulting organizations to provide a variety of presentations, sessions, and resources. Selected examples include participation in multiple FDA public webinars as well as participating as moderators, presenters and panelists in meetings hosted by the Professional Society for Health Economics and Outcomes Research (ISPOR), the Drug Information Association (DIA) Annual Global Meeting, the Biotechnology Innovation Organization (BIO) International Convention, the Duke-Industry Statistics Symposium, and the NHLBI Biostatistics Workshop on Clinical Trial Designs. In addition, FDA continued to engage an external expert through the Intergovernmental Personnel Act to support the review of patient experience data.
I.L.2 Enhancing the Benefit-Risk Assessment in Regulatory Decision-Making	• None
I.L.3 Advancing Model-Informed	• On Jan. 11, 2023, an FRN was published (https://www.fda.gov/media/151712/download) announcing the continuation of the MIDD Paired Meeting Program.

Drug Development	• FDA continued to select proposals on a quarterly basis for the Model-Informed Drug Development Paired Meeting Program. A cross-center internal review committee convened every quarter to review and provide recommendations on prioritization and selection of proposals. Industry meetings were led by the Office of Clinical Pharmacology and consisted of a multidisciplinary team to ensure alignment across disciplines. • The Office of Clinical Pharmacology granted six MIDD meeting requests out of eight meeting requests received from October 2022 to September 2023. • A working group was created to develop a Request for Information (RFI) to gather public input on priority focus areas for future policy development and stakeholder engagement.
I.L.4 Enhancing Capacity to Review Complex Innovative Designs	• Published an FRN on October 20, 2022 (https://www.federalregister.gov/documents/2022/10/20/2022-22794/complex-innovative-design-paired-meeting-program) for the Paired Meeting Program.
I.L.5 Enhancing Capacity to Support Analysis Data Standards for Product Development and Review	• None
I.L.6 Enhancing Drug Development Tools Qualification Pathway for Biomarkers	• None

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

Table 35. Section I.M's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
I.M.1 Modernization and Improvement of REMS Assessments	• Establish Review Performance Goals for Risk Evaluation and Mitigation Strategy (REMS) methodological approaches and study protocols

	○ Created and implemented goal dates in DARRTS for REMS Methodology submissions ○ Created new communication and supporting document codes in DARRTS to support the REMS methodology review process ○ Developed and cleared new letter templates to support the REMS methodology review process. The letter templates are available in the CDER Standard Templates SharePoint site ○ Updated the 356h form and instructions to include REMS methodology submissions ○ Developed a report to track REMS methodology goal dates
I.M.2 Optimization of the Sentinel Initiative	• Conduct Public Workshop on Negative Controls FDA satisfied the commitment to complete a public workshop on use of negative controls by September 30, 2023. ○ FDA hosted a virtual public workshop titled *Understanding the Use of Negative Controls to Assess the Validity of Non-Interventional Studies of Treatment Using Real-World Evidence* on March 8, 2023. ○ Subject matter experts provided their perspectives on basic concepts for use of negative controls and presented examples of specific analytic approaches. ○ Scientists from CBER and CDER described their proposed methods development projects and requested feedback from the public through comments submitted to the FRN and comments provided on the day of the workshop. • Conduct Public Workshop on Post Market Pregnancy Data FDA satisfied the commitment to complete a public workshop on pregnancy safety studies by September 30, 2023. ○ FDA hosted a 2-day, hybrid public workshop titled *Optimizing the Use of Postapproval Pregnancy Safety Studies* on September 18 and 19, 2023. ○ The workshop discussed considerations for further development of a framework that describes how data from different types of postapproval pregnancy safety studies might optimally be used when it has been determined that these data should be collected.

D. Section I.N: Enhancements Related to Product Quality Reviews, Chemistry, Manufacturing, and Control Approaches, and

Advancing the Utilization of Innovative Manufacturing Technologies

Table 36. Section I.N's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
I. N.1 Enhancing Communication Between FDA and Sponsors During Application Review	• CDER/OPQ updated NDA Integrated Quality Assessment (IQA) SOP (OPQ-ALL-SOP-0006), the NDA IQA Assessment Guide, and the NDA IQA Template. CDER/OPQ also conducted a chemistry, manufacturing, and control (CMC) assessment training via the Quality Management Information System, which is due for completion on September 20, 2023. • CDER/OPQ updated and externally published the MAPP 5016.8, Rev. 1 (Four-Part Harmony MAPP) (https://www.fda.gov/media/171613/download?attachment) on August 25, 2023, with an effective date of September 22, 2023. • CDER/OPQ conducted live training for the revised Four Part Harmony MAPP on September 15, 2023. The recorded training was posted in LMS on September 20, 2023. • CBER updated SOPP 8401.1 to include requirements for information requests to be written in Four-Part Harmony with an effective date of October 1, 2022: https://www.fda.gov/media/85301/download. CBER conducted two live trainings on Four-Part Harmony on May 31, 2023, and July 21, 2023. The recorded training was posted internally on July 31, 2023.
I. N.2 Enhancing Inspection Communication for Applications, not Including Supplements	• Enhance Inspection Communication for Applications ○ Enhanced communications inspection language has been included in the revised compliance program for Pre-Approval inspection (PAI) and Pre-License inspection (PLI).
I.N.3 Alternative Tools to Assess Manufacturing Facilities Named in Pending Applications	• Publish Draft Guidance on Alternative Tools to Assess Manufacturing Facilities ○ The draft guidance published on September 22, 2023, and can be found on FDA's public website (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications).
I.N.4 Facilitating Chemistry, Manufacturing, and Controls Readiness for Products with	• Implemented the CMC Development and Readiness Pilot Program on April 1, 2023. • Published the FRN announcing the CMC Development and Readiness Pilot Program on October 31, 2022.

Accelerated Clinical Development	• On September 11, 2023, the Year 2 FRN was published (https://www.federalregister.gov/documents/2023/09/11/2023-19502/chemistry-manufacturing-and-controls-development-and-readiness-pilot-program-program-announcement • Published CDER's MAPP 5015.13, Quality Assessment for Products in Expedited Programs (effective December 7, 2022) (https://www.fda.gov/media/162786/download). • Created the CMC Development and Readiness Pilot website on March 16, 2023 (https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program). • CDER accepted one applicant's request to participate in the pilot program and has proceeded to disclosure agreement discussions. • CBER described the CDRP program in several conferences and OTP CGT Town Hall meetings, to make sponsors aware of this new initiative. • CBER developed various job aids, letter templates, review templates and a tracker to follow the status of these applications. • CBER received three applications with two in OTP and one in OVRR. Of these three applications, two applications did not qualify as they did not meet specific pre-requisites for enrollment in the program such as not having either BT or RMAT designations. • One application was eligible and has been selected for further evaluation and has proceeded to disclosure agreement discussions.
I.N.5 Advancing Utilization and Implementation of Innovative Manufacturing	• *The Innovative Manufacturing Public Workshop* was held on June 8, 2023 (https://healthpolicy.duke.edu/events/advancing-utilization-and-supporting-implementation-innovative-manufacturing-approaches). The FRN was posted on April 26, 2023. (https://www.federalregister.gov/documents/2023/04/24/2023-08545/advancing-the-utilization-and-supporting-the-implementation-of-innovative-manufacturing-approaches)

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

Table 37. Section I.O's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments

I.O.1 Patient-Focused Drug Development	• FDA conducted a PFDD public meeting on gene therapy products.
	  ○ FDA hosted a virtual patient-focused drug development listening meeting titled *FDA CBER OTAT Patient-Focused Drug Development Listening Meeting — Patient Perspectives on Gene Therapy Products* on November 15, 2022.
	  ○ This virtual listening meeting was an opportunity for patients, caregivers, patient advocates, and other important stakeholders to share their understanding and expectations regarding gene therapy risks and benefits and involvement in clinical study design and execution for these products.

I.O.2 Novel Approaches to Development of Cell and Gene Therapy	• None
I.L.3 Advancing Model-Informed Drug Development	• None
I. O.4 Leveraging Knowledge	• None

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

Table 38. Section I.P's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments

I.P.1 Allergenic Extract Products Licensed After October 1, 2022	• Incorporate Review of Allergenic Extract Products
	  ○ CBER updated all relevant SOPPs, process documents, and templates to reflect allergenic extracts covered under PDUFA VII and posted the updates internally and externally on September 30, 2022.
	  ○ CBER trained staff on September 16, 2022, and September 19, 2022, on allergenic extract products and posted the recording internally.

I.P.2 Allergenic Extract Products Licensed Before October 1, 2022	• None

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

Table 39. Section II's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
II.A Resource Capacity Planning and Modernized Time Reporting	• The Resource Capacity Planning Implementation Plan (https://www.fda.gov/media/166677/download?attachment) was published in March 2023.
II.B Financial Transparency and Efficiency	• FDA published the FY 2023 PDUFA Five-Year Financial Plan update (see https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) in April 2023 (II.B.2). • FDA held a public meeting on the FY 2023 financial plan on June 8, 2023 (see https://www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act) (II.B.3).

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

Table 40. Section III's FY 2023 Commitments and Accomplishments

Commitment Title	FY 2023 Accomplishments
III.A Set Clear Goals for Human Drug Review Program Hiring	• FDA has provided updated hiring data for FY 2023 PDUFA VII hires by posting the information on the public website within 2 weeks past the end date of the quarter. The numbers can be found on the website at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates. • In August, FDA has also began providing updated net hiring data on the public website. The hiring data can be found here at https://www.fda.gov/industry/fda-user-fee-programs/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data-fy-2023
III.B Assessment of Hiring and Retention	• None

I. Section IV: Information Technology and Bioinformatics Goals

Table 41. Section IV's FY 2023 Commitments and Accomplishments

Goal	FY 2023 Accomplishments

IV.A Enhancing Transparency and Leveraging Modern Technology	• FDA conducted the annual PDUFA VII FDA-Industry IT Leadership meeting kickoff on March 9, 2023.
	• FDA Published Data Standards Action Plan FY 2023
	  ○ Quarter 1 (version 1.0) on March 2, 2023,
	  ○ Q2 (v1.1) on May 10, 2023, and
	  ○ Q3 (v1.2) on August 18, 2023
	• FDA published the Data Standards Catalog
	  ○ Version 9.0 on January 25, 2023, and
	  ○ Version 9.1 on April 19, 2023
	• FDA held quarterly PDUFA standing meetings with industry on November 15, 2022; February 7, 2023; June 6, 2023; and September 12, 2023.
	• FDA's Data and IT Modernization Strategy was completed early on September 19, 2023, and posted to the *Federal Register* (https://www.federalregister.gov/d/2023-20136) for public comments (to close on October 30, 2023)
	• CBER drafted its Modernization Roadmap and ensured its alignment with FDA's overall strategy
	  ○ CBER's IT Modernization Roadmap was published on May 26, 2022. The Roadmap was shared with public stakeholders at conferences, such as RAPS convergence in September 2022 and the PDUFA annual meeting with industry in September 2023.
	  ○ Updates to the roadmap, performance metrics, and accomplishments and challenges were shared at the annual leadership meeting held on March 9, 2023.
	  ○ Updates to the roadmap were also presented at the PDUFA annual meeting with industry in September 2023.
	• FDA completed an assessment on challenges and barriers to cloud technologies. A summary of the assessment's findings will be publicly available within 6-months of the assessment completion.
	• FDA completed the enhancement of internal systems to support the review and tracking of Digital Health Technology (DHT)-related submissions

	• FDA launched the first cloud-based demonstration project focused on the receipt, validation, cleansing, and analysis of DHT data on a third-party platform.
	  ○ FDA held a listening session with industry on September 12, 2023, to identify potential additional demonstration projects.
	  ○ CBER assessed PDUFA bioinformatics capabilities as part of the PDUFA VII Agreement to assure support for bioinformatic activities and computational biology used in the review of human drugs and biologics. A summary will be shared at the Leadership meeting.

IV.B Expanding and Enhancing Bioinformatics Support	• None

IV.C Enhancing Use of Digital Health Technologies to Support Drug Development and Review	• FDA satisfied the following end of FY 2023's quarter 2 commitments that support the use of DHTs in drug development.
	  ○ Published the Framework for the Use of Digital Health Technologies in Drug and Biological Product Development (https://www.fda.gov/media/166396/download?attachment) (IV.C.1).
	  ○ Established a DHT committee and made its purpose publicly available on the newly developed DHT for Drug Development web page (https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development) (IV.C.2).
	  ○ On March 28-29, 2023, convened the first of a series of five public meetings with key stakeholders titled *Understanding Priorities for the Use of DHTs to Support Clinical Trials for Drug Development and Review* (see https://healthpolicy.duke.edu/events/digitalhealthtechnologies) (IV.C.3).
	• FDA published, in December 2021, the draft guidance *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations). FDA is working toward finalizing the draft guidance (IV.C.5).
	• FDA published, on September 19, 2023, the draft guidance *Regulatory Considerations for Prescription Drug Use-Related Software* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-prescription-drug-use-related-software), which satisfies the Agency's commitment to publish it by the end of FY 2023 (IV.C.6).
	• Enhance Internal Systems to Support DHT Review

	○ On March 20, 2023, FDA completed the enhancement of its internal systems to support the review and tracking of DHT-related submissions • Establish DHT Secure Cloud Technology ○ FDA has already established a secure cloud technology, which interacts with over 30 cloud-service providers and hosts over 100 cloud-based systems. ○ FDA's IT modernization strategy and objectives are outlined in Technology, Data, Enterprise, Cybersecurity, and Leadership Modernization Action Plans (TMAP, DMAP, EMAP, CMAP, and LMAP, respectively). Central to these efforts is FDA's data and IT strategy, which began its journey in February 2023 and has an expected completion date of September 30, 2023. ○ As part of this strategy, FDA set the vision for its "NexGen ESG," which will fully transition FDA's Electronic Submission Gateway into the Agency's secure cloud environment by 2025. ○ FDA continues this journey by enhancing its infrastructure and analytical environment, which will enable the seamless exchange and processing of continuously expanding and evolving data, such as DHT ○ Using established systems, FDA launched the first cloud-based demonstration project focused on the receipt, validation, cleansing, and analysis of DHT data on a third-party platform.

[1] https://pubmed.ncbi.nlm.nih.gov/36507973/.
[2] https://www.taylorfrancis.com/books/edit/10.1201/9781003080954/drug-development-rare-diseases-bo-yang-yang-song-yijie-zhou.

J. 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[29]. 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.

[29] https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm604305.htm.

VI. Rationale for PDUFA Program Changes

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

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

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

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

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

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

The information below fulfills these reporting requirements.

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

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

FDA is committed to hiring 352 FTEs from FY 2023 to FY 2027 as agreed upon in the PDUFA VII Commitment Letter. FDA has successfully hired 151 FTEs of the 352 FTEs (43 percent) as of September 30, 2023. The data in the following table show the total number of FTEs hired towards the FY 2022 and FY 2023 hiring targets as agreed upon in the PDUFA VII Commitment Letter and the change in the number of FTE hires from FY 2022 to FY 2023.

Table 42. Number of Individuals Hired as Agreed Upon in the PDUFA VII Commitment Letter and Remaining Vacancies

Center	Number Hired in FY 2022*	Number Hired in FY 2023	Change in Number Hired	Remaining Vacancies in FY 2022*	Remaining Vacancies in FY 2023	Change in Number of Remaining Vacancies
CDER	0	41	41	0	36	36
CBER	0	109	109	0	23	23
ORA	0	1	1	0	0	0
OC	0	0	0	0	0	0
Total	0	151	151	0	59	59

* PDUFA VII became effective in FY 2023; therefore, there are neither PDUFA VII hires nor remaining vacancies in FY 2022. A *hire* is defined as someone who has been confirmed as on board by the date indicated in a full-time position at the noted Center. Although some hires are recruited from outside the Center/FDA, a hire can also be a current Center/FDA employee who is changing positions within the Agency.

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

The data in the table below show the number of User Fee and Budget Authority funded FTEs at FDA by each division within CDER, CBER, ORA and OC. This table reflects the number of FTEs funded by User Fee and Budget Authority for the PDUFA VII program. For this table, "budget authority" refers to FDA's non-user fee annual appropriations. To address the requirement that information on the number of FTEs funded by budget authority be presented "by each division," the information in this table is broken down to the office level for the Centers, ORA, and OC. FDA uses a 2080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2023 represent the number of FTEs committed to PDUFA work. The number of FTEs funded by User Fee and budget authority for FY 2023 are those FTEs as of September 30, 2023.

Table 43. Number of FTEs Funded by Budget Authority and Number of FTEs funded byFees by Division Within CDER, CBER, ORA, and OC

Center and Office	Number of FTEs Funded by Budget Authority		Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2022	FY 2023		FY 2022	FY 2023	
CDER						
Office of Communications	7.39	7.51	0.12	36.10	39.38	3.28
Office of Compliance	20.79	14.95	-5.84	64.72	77.98	13.26
Office of the Center Director	7.37	2.06	-5.31	33.61	36.84	3.23
Office of Executive Programs	2.09	3.65	1.56	65.46	65.91	0.45
Office of Generic Drugs	4.38	3.76	-0.62	1.54	3.40	1.86
Office of Management	15.09	9.00	-6.09	100.82	79.18	-21.64
Office of Medical Policy	11.61	7.12	-4.49	79.32	107.52	28.20
Office of New Drugs	57.57	132.16	74.59	1146.55	1162.77	16.22
Office of Pharmaceutical Quality	25.09	58.59	33.50	395.18	387.35	-7.83
Office of Regulatory Policy	18.44	15.49	-2.95	38.93	46.08	7.15
Office of Surveillance and Epidemiology	32.88	13.37	-19.51	185.49	213.49	28.00
Office of Strategic Programs	13.43	5.12	-8.31	75.20	76.81	1.61
Office of Information Management and Technology	0.00	0.12	0.12	0.00	4.90	4.90

Office of Translational Sciences	11.42	34.37	22.95	526.73	518.08	-8.65
Other Offices	0.15	0.66	0.51	5.48		-5.48
Working Capital Fund (WCF)	51.70	56.62	4.92	161.46	156.41	-5.05
CDRH						
Office of Product Evaluation and Quality	2.10	1.06	-1.04	15.20	12.60	-2.60
Office of Management	0.00	0.50	0.50	0.20	0.58	0.38
Office of Science and Engineering Laboratories	0.30	0.22	-0.08	0.10	0.00	-0.10
Office of Communication and Education	0.00	0.36	0.36		0.38	0.38
Office of Policy	0.00	0.05	0.05	0.20	0.15	-0.05
Office of Strategic Partnership and Technology Innovation	0.10	0.05	-0.05	0.00	0.00	0.00
Office of the Center Director	0.00	0.15	0.15	0.00	0.09	0.09
Office of Information Management and Technology	0.10	0.05	-0.05	0.00	0.00	0.00
WCF	0.80	0.59	-0.21	1.75	0.78	-0.97
CBER			0.00			
Office of Biostatistics and Epidemiology / Office of Biostatistics and Pharmacovigilance[†]	13.71	25.59	11.88	64.53	68.37	3.83
Office of Blood Research and Review	5.26	6.83	1.57	6.80	7.26	0.46
Office of Compliance and Biologics Quality	21.97	23.04	1.07	72.42	82.37	9.95
Office of Tissues and Advanced Therapies / Office of Therapeutic Products[‡]	57.44	60.53	3.10	180.06	187.99	7.93
Office of Vaccines Research and Review	96.30	97.06	0.76	118.49	126.99	8.49
Office of Communication Outreach and Development	9.74	7.67	-2.07	34.06	38.04	3.98
Office of the Center Director	13.95	8.20	-5.75	35.00	22.46	-12.54
Office of Regulatory Operations[§]	5.38	9.18	3.80	20.44	38.66	18.22
Office of Management	21.53	13.52	-8.01	55.53	62.29	6.76
Office of Information Management and Technology	1.78	1.54	-0.24	3.97	3.91	-0.06
WCF	33.37	36.11	2.74	46.12	49.27	3.15

OC						
OC Immediate Office	2.70	6.09	3.39	12.33	15.08	2.75
Office of the Chief Counsel	7.20	12.94	5.74	33.06	32.07	-0.99
Office of the Chief Scientist	4.60	7.84	3.24	21.05	19.42	-1.63
Office of Clinical Policy and Programs	11.60	20.56	8.96	53.19	50.95	-2.24
Office of Digital Transformation	0.00	0.64	0.64	3.09	1.59	-1.50
Office of Enterprise Management Services	0.00	3.59	3.59	10.55	8.89	-1.66
Office of External Affairs	3.20	6.34	3.14	14.51	15.72	1.21
Office of Global Policy and Strategy	0.00	0.40	0.40	2.00	0.99	-1.01
Office of International Programs	0.00	0.00	0.00	0.00	0.00	0.00
Office of Operations	10.90	12.66	1.76	36.32	31.37	-4.95
Office of Policy, Legislation, and International Affairs	6.50	9.67	3.17	29.89	23.97	-5.92
WCF	12.70	6.34	-6.36	13.78	18.42	4.64
ORA						
Office of Pharmaceutical Quality Operations	99.10	106.80	7.70	47.40	45.59	-1.81
Office of Global Partnerships and Strategy	0.40		-0.40			
WCF	8.70	9.53	0.83	3.37	3.01	-0.36

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

† CBER's Office of Biostatistics and Epidemiology was reorganized to the Office of Biostatistics and Pharmacovigilance in FY 2023.

‡ CBER's Office of Tissues and Advanced Therapies was reorganized to the Office of Therapeutic Products in FY 2023.

§ The FY 2023 reorganization of CBER created a new office – the Office of Regulatory Operations. Prior to the reorganization, this office was under the Office the Center Director.

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 2022 and FY 2023, as well as the changes in these amounts from FY 2022 to FY 2023. As amended by FDORA section 3206, 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 2023) and the prior fiscal year (FY 2022). Although FDARA does not explicitly require this data, they do provide relevant context necessary to interpret the required information.

In FY 2022, FDA had net collections of $1,159,139,951.00 in prescription drug user fees, spent $1,129,727,665 in user fees for the human drug review process, and carried a cumulative balance of $287,669,825 forward for future fiscal years. Detailed financial information for the PDUFA user fee program can be found in the FY 2023 PDUFA financial report.[30]

The process for setting the annual target revenue is set forth in the statute. For FY 2023, the base revenue amount is $1,151,522,958. The FY 2023 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional FTE positions to support PDUFA VII initiatives. The FY 2023 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 $1,310,319,000 (rounded to the nearest thousand dollars).

In FY 2023, PDUFA review process costs increased from FY 2022.

Table 44. Changes in the Average Total Cost Per FTE in the Prescription Drug Review Program

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

Revenue/Cost	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Fee Revenue Amounts (Net Collections)	$1,159,139,951	$1,222,888,088	+5%
Process Cost (Cost of Activities)	$1,480,601,875	$1,686,733,841	+14%
Average total cost per FTE	$206,123	$216,474	+5%

C. Number of Employees for Whom Time Reporting Is Required

Section 736B(a)(4) of the FD&C Act requires FDA to provide—for CDER, CBER, ORA, and OCthe number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, the table below provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2023.

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

Table 45. Time Reporting Requirement for FY 2023

Center	FTEs for Whom Time Reporting Is Required	FTEs for Which Time Reporting Is Not Required
CDER	5,739	0
CBER	1,260	8
ORA	4,592	0
OC	61	2,606
Total	**11,652**	**2,614**

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 the 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 46. 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 Application Reviews in FY 2022	Average FTE Hours Required to Complete Application Reviews inFY 2023	Change from FY 2022 to FY 2023
PDUFA NME and BLA Applications	6,256	7,386	1,130
PDUFA Non-NME Applications	2,651	2,434	-217
Total	**8,907**	**9,820**	**913**

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 2022 to the 3-year average ending in FY 2023. 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 2023. 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 2023 can be found in the appendices of the earlier PDUFA performance reports.[1]

When determining total time, FDA calculates the number of months and rounds to the nearest tenth. Therefore, when cycle times are added, rounding discrepancies may occur.

Because months consist of varying numbers of days, FDA uses the average number of days in a month for the average year length, which takes into account leap years, to calculate review time in months. Prior to FY 2022, FDA did not take into account leap years in our calculations, which may have caused a submission to appear overdue even though it was approved on the goal date.

Terms and Coding Used in Tables in This Appendix

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

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

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

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

Table A-1. FY 2023 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 2023							
AKEEGA (niraparib and abiraterone acetate)	JANSSEN BIOTECH Inc.	N	FIRST	5.4	AP	5.4	Y♦
abacavir, dolutegravir and lamivudine tablet for oral suspension	AUROBINDO PHARMA Ltd.	N	FIRST	5.9	TA	5.9	Y
abacavir, dolutegravir and lamivudine	MYLAN LABORATORIES Ltd.	N	FIRST	5.9	TA	5.9	Y
BOSULIF (bosutinib)	PF PRISM CV	N	FIRST	5.9	AP	5.9	Y
OPVEE (nalmefene hydrochloride)	INDIVIOR Inc.	N	FIRST	5.9	AP	5.9	Y
TRIKAFTA (elexacaftor/ tezacaftor/ ivacaftor)	VERTEX PHARMACEUTICALS Inc.	N	FIRST	5.9	AP	5.9	Y
dolutegravir	LAURUS GENERICS Inc.	N	FIRST	6.0	TA	6.0	Y
COLUMVI (glofitamab-gxbm)	GENENTECH, Inc.	Y	FIRST	7.4	AP	7.4	Y♦
EYLEA HD (aflibercept)	REGENERON PHARMACEUTICALS, Inc.	N	FIRST	6.0	CR	6.0	Y
			Sponsor	0.2		6.2	
			SECOND	1.5	AP	7.5	Y△
IZERVAY (avacincaptad pegol)	IVERIC BIO Inc.	Y	FIRST	7.5	AP	7.5	Y♦
ELREXFIO (elranatamab-bcmm)	PFIZER Inc.	Y	FIRST	7.8	AP	7.8	Y♦

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

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
VEOPOZ (pozelimab-bbfg)	REGENERON PHARMACEUTICALS, Inc.	Y	FIRST	7.9	AP	7.9	Y♦
Respiratory Syncytial Virus Vaccine	Pfizer Inc.	Y	FIRST	8.0	AP	8.0	Y♦
RYSTIGGO (rozanolixizumab-noli)	UCB, Inc.	Y	FIRST	8.0	AP	8.0	N♦
TALVEY (talquetamab-tgvs)	JANSSEN BIOTECH, Inc.	Y	FIRST	8.0	AP	8.0	Y♦
ZURZUVAE (zuranolone)	SAGE THERAPEUTICS Inc.	Y	FIRST	8.0	AP	8.0	Y♦
RIVIVE (naloxone hydrochloride)	HARM REDUCTION THERAPEUTICS Inc.	N	FIRST	9.0	AP	9.0	Y#
Submitted in FY 2022							
MEKINIST (trametinib)	NOVARTIS PHARMACEUTICALS Corp.	N	FIRST	6.9	AP	6.9	Y#
TAFINLAR (dabrafenib)	NOVARTIS PHARMACEUTICALS Corp.	N	FIRST	6.9	AP	6.9	Y#
ORSERDU (elacestrant)	STEMLINE THERAPEUTICS Inc.	Y	FIRST	7.4	AP	7.4	Y♦
ZYNYZ (retifanlimab-dlwr)	INCYTE CORPORATION	Y	FIRST	7.4	AP	7.4	Y♦
ELAHERE (mirvetuximab soravtansine-gynx)	IMMUNOGEN, Inc.	Y	FIRST	7.6	AP	7.6	Y♦
ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	Bioverativ Therapeutics, Inc.	Y	FIRST	7.7	AP	7.7	Y♦
JOENJA (leniolisib phosphate)	PHARMING TECHNOLOGIES BV	Y	FIRST	7.8	AP	7.8	Y♦
LUNSUMIO (mosunetuzumab-axgb)	GENENTECH, Inc.	Y	FIRST	7.8	AP	7.8	Y♦
XACDURO (sulbactam for	ENTASIS THERAPEUTICS Inc.	Y	FIRST	7.8	AP	7.8	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
injection; durlobactam for injection)							
DAYBUE (trofinetide)	ACADIA PHARMACEUTICALS Inc.	Y	FIRST	7.9	AP	7.9	Y♦
EPKINLY (epcoritamab-bysp)	GENMAB US, Inc.	Y	FIRST	7.9	AP	7.9	Y♦
HEMGENIX (etranacogene dezaparvovec-drlb)	CSL Behring LLC	Y	FIRST	7.9	AP	7.9	Y♦
IMJUDO (tremelimumab)	ASTRAZENECA AB	Y	FIRST	7.9	AP	7.9	Y♦
ABRYSVO (Respiratory Syncytial Virus Vaccine)	Pfizer Inc.	Y	FIRST	8.0	AP	8.0	Y♦
AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)	GlaxoSmithKline Biologicals	Y	FIRST	8.0	AP	8.0	Y♦
JAYPIRCA (pirtobrutinib)	LOXO ONCOLOGY Inc.	Y	FIRST	8.0	AP	8.0	Y♦
LAMZEDE (velmanase alfa-tycv)	CHIESI FARMACEUTICI S.P.A.	Y	FIRST	8.0	AP	8.0	Y♦
LEQEMBI (lecanemab-irmb)	EISAI, INCORPORATED	Y	FIRST	8.0	AP	8.0	Y♦
REZZAYO (rezafungin)	CIDARA THERAPEUTICS Inc.	Y	FIRST	8.0	AP	8.0	Y♦
VOWST (Fecal Microbiota Spores)	Seres Therapeutics, Inc.	Y	FIRST	8.0	AP	8.0	Y♦
ELEVIDYS (delandistrogene moxeparvovec-rokl)	Sarepta Therapeutics, Inc.	Y	FIRST	8.8	AP	8.8	N♦
LODOCO (colchicine)	AGEPHA PHARMA FZ LLC	N	FIRST	8.8	AP	8.8	Y#
SYFOVRE (pegcetacoplan)	APELLIS PHARMACEUTICALS Inc.	N	FIRST	8.8	AP	8.8	Y#
SEZABY (phenobarbital)	SUN PHARMACEUTICAL INDUSTRIES Inc.	N	FIRST	9.0	AP	9.0	Y#

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc)	ARGENX BV	N	FIRST	9.0	AP	9.0	Y#
TECVAYLI (teclistamab-cqyv)	JANSSEN BIOTECH, Inc.	Y	FIRST	9.9	AP	9.9	Y#♦
OMISIRGE (omidubicel-onlv)	Gamida Cell Ltd.	Y	FIRST	10.5	AP	10.5	Y#♦
VEOZAH (fezolinetant)	ASTELLAS PHARMA US Inc.	Y	FIRST	10.6	AP	10.6	Y#♦
PAXLOVID (nirmatrelvir and ritonavir)	PFIZER Inc.	Y	FIRST	10.8	AP	10.8	Y#♦
Vanflyta	DAIICHI SANKYO Inc.	Y	FIRST	10.8	AP	10.8	Y#♦
QALSODY (tofersen)	BIOGEN MA Inc.	Y	FIRST	11.0	AP	11.0	Y#♦
SKYCLARYS (omaveloxolone)	REATA PHARMACEUTICALS Inc.	Y	FIRST	11.0	AP	11.0	Y#♦
VYJUVEK (beremagene geperpavec-svdt)	Krystal Biotech, Inc.	Y	FIRST	11.0	AP	11.0	Y#♦
FILSPARI (sparsentan)	TRAVERE THERAPEUTICS Inc.	Y	FIRST	11.1	AP	11.1	Y#♦
SOHONOS (palovarotene)	IPSEN BIOPHARMACEUTICALS Inc.	Y	FIRST	7.8	CR	7.8	Y♦
			Sponsor	1.8		9.6	
			SECOND	5.9	AP	15.5	Y△
Submitted in FY 2021							
SUNLENCA (lenacapavir)	GILEAD SCIENCES Inc.	Y	FIRST	8.0	AP	8.0	Y♦
SUNLENCA (lenacapavir)	GILEAD SCIENCES Inc.	N[3]	FIRST	8.0	AP	8.0	Y♦
TZIELD (teplizumab-mzwv)	PROVENTION BIO, Inc.	Y	FIRST	8.0	CR	8.0	Y♦
			Sponsor	7.6		15.6	

[3] The applicant submitted two NDAs for the same moiety but different dosage forms (i.e., tablet versus injection), and only one retains the NME designation upon approval; in this case, the NDA for the tablet 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
			SECOND	9.0	AP	24.6	Y#△
Submitted in FY 2020							
ELFABRIO (pegunigalsidase alfa-iwxj)	CHIESI FARMACEUTICI S.P.A.	Y	FIRST	11.0	CR	11.0	Y#♦
			Sponsor	18.4		29.4	
			SECOND	5.9	AP	35.3	Y
ROCTAVIAN (valoctocogene roxaparvovec-rvox)	Biomarin Pharmaceutical Inc.	Y	FIRST	7.8	CR	7.8	Y#
			Sponsor	26.2		34.0	
			SECOND	9.0	AP	43.0	Y△
Submitted in FY 2018							
ADSTILADRIN (nadofaragene firadenovec-vncg)	Ferring Pharmaceuticals A/S	Y	FIRST	7.7	CR	7.7	Y♦
			Sponsor	26.2		33.9	
			SECOND	5.6	AP	39.5	Y△
Submitted in FY 2017							
sincalide	MAIA PHARMACEUTICALS Inc.	N	FIRST	6.0	TA	6.0	Y
			Sponsor	55.1		61.1	
			SECOND	1.9	AP	63.0	Y▲
BRIXADI (buprenorphine hydrochloride)	BRAEBURN Inc.	N	FIRST	6.0	CR	6.0	Y
			Sponsor	5.2		11.2	
			SECOND	5.8	TA	17.0	Y
			Sponsor	17.3		34.3	
			THIRD	6.0	CR	40.3	Y
			Sponsor	6.4		46.7	
			FOURTH	6.0	CR	52.7	Y
			Sponsor	11.3		64.0	
			FIFTH	5.9	AP	69.9	Y△

Table A-2. FY 2023 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 2023							
XALKORI (crizotinib)	PF PRISM CV	N	FIRST	9.3	AP	9.3	Y
melphalan hydrochloride injection	APOTEX Inc.	N	FIRST	9.9	AP	9.9	Y
RYZUMVI (phentolamine)	OCUPHIRE PHARMA Inc.	N	FIRST	9.9	AP	9.9	Y
LIKMEZ (metronidazole)	SAPTALIS PHARMACEUTICALS LLC	N	FIRST	10.0	AP	10.0	Y
micafungin in 0.9% sodium chloride	BAXTER HEALTHCARE Corp.	N	FIRST	10.0	AP	10.0	Y
vasopressin in 0.9% sodium chloride injection	BAXTER HEALTHCARE Corp.	N	FIRST	10.0	AP	10.0	Y
Submitted in FY 2022							
BEYFORTUS (nirsevimab-alip)	ASTRAZENECA AB	Y	FIRST	9.7	AP	9.7	Y♦
Docetaxel	INGENUS PHARMACEUTICALS LLC	N	FIRST	9.7	AP	9.7	Y
VEVYE (cyclosporine)	HARROW EYE LLC	N	FIRST	9.7	AP	9.7	Y
cyclophosphamide	NEVAKAR INJECTABLES Inc.	N	FIRST	9.8	AP	9.8	Y
IYUZEH (latanoprost)	THEA PHARMA Inc.	N	FIRST	9.8	AP	9.8	Y
AUSTEDO XR (deutetrabenazine)	TEVA NEUROSCIENCE Inc.	N	FIRST	9.9	AP	9.9	Y
dolutegravir, lamivudine and tenofovir alafenamide	LUPIN Ltd.	N	FIRST	9.9	TA	9.9	Y
MOTPOLY XR (lacosamide)	AUCTA PHARMACEUTICALS Inc.	N	FIRST	9.9	AP	9.9	Y
ABILIFY ASIMTUFII (aripiprazole)	OTSUKA PHARMACEUTICAL Co. Ltd.	N	FIRST	10.0	AP	10.0	Y
ADRENALIN (epinephrine in sodium chloride)	PAR STERILE PRODUCTS LLC	N	FIRST	10.0	AP	10.0	Y
ALVAIZ (eltrombopag choline)	TEVA PHARMACEUTICALS Inc.	N	FIRST	10.0	TA	10.0	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
cefazolin for injection	HIKMA PHARMACEUTICALS USA Inc.	N	FIRST	10.0	AP	10.0	Y
daptomycin for injection, 350mg/vial and 500 mg/vial	XELLIA PHARMACEUTICALS APS	N	FIRST	10.0	AP	10.0	Y
SYMBICORT AEROSPHERE (budesonide and formeterol fumarate)	ASTRAZENECA PHARMACEUTICALS LP	N	FIRST	10.0	AP	10.0	Y
kit for the preparation of technetium tc 99m mertiatide	JUBILANT DRAXIMAGE Inc.	N	FIRST	10.1	AP	10.1	Y
PREVDUO (neostigmine methylsulfate and glycopyrrolate)	SLAYBACK PHARMA LLC	N	FIRST	10.0	AP	10.0	Y
AIRSUPRA (albuterol and budesonide)	ASTRAZENECA PHARMACEUTICALS LP	N	FIRST	10.1	AP	10.1	Y
fentanyl citrate	EXELA PHARMA SCIENCES LLC	N	FIRST	10.1	AP	10.1	Y
MIEBO (perfluorohexyloctane)	BAUSCH AND LOMB Inc.	Y	FIRST	10.6	AP	10.6	Y♦
XDEMVY (lotilaner)	TARSUS PHARMACEUTICALS Inc.	Y	FIRST	10.9	AP	10.9	Y♦
BALFAXAR (Prothrombin complex concentrate, human-lans)	Octapharma Pharmazeutika Produktionsges.m.b.H.	Y	FIRST	11.8	AP	11.8	Y♦
KRAZATI (adagrasib)	MIRATI THERAPEUTICS Inc.	Y	FIRST	11.9	AP	11.9	Y♦
APHEXDA (motixafortide)	BIOLINERX Ltd.	Y	FIRST	12.0	AP	12.0	Y♦
INPEFA (sotagliflozin)	LEXICON PHARMACEUTICALS Inc.	Y	FIRST	12.0	AP	12.0	Y♦
JESDUVROQ (daprodustat)	GLAXOSMITHKLINE INTELLECTUAL PROPERTY NO 2 Ltd. ENGLAND	Y	FIRST	12.0	AP	12.0	Y♦
LITFULO (ritlecitinib)	PFIZER Inc.	Y	FIRST	12.0	AP	12.0	Y♦
POSLUMA (flotufolastat f 18)	BLUE EARTH DIAGNOSTICS Ltd.	Y	FIRST	12.0	AP	12.0	Y♦

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
REBYOTA (Microbiota Transplantation, Frozen Preparation)	Ferring Pharmaceuticals Inc.	Y	FIRST	12.0	AP	12.0	Y#♦
REZLIDHIA (olutasidenib)	RIGEL PHARMACEUTICALS Inc.	Y	FIRST	12.0	AP	12.0	Y♦
RIVFLOZA (nedosiran)	NOVO NORDISK Inc.	Y	FIRST	12.0	AP	12.0	Y♦
ZAVZPRET (zavegepant)	PFIZER Inc.	Y	FIRST	12.0	AP	12.0	Y♦
cyclophosphamide injection	SANDOZ Inc.	N	FIRST	13.0	AP	13.0	Y#
zolpidem tartrate	ALMATICA PHARMA Inc.	N	FIRST	10.0	CR	10.0	Y
			Sponsor	11.8		11.8	
			SECOND	2.0	AP	13.8	Y▲
BRENZAVVY (bexagliflozin)	THERACOSBIO LLC	Y	FIRST	14.9	AP	14.9	Y#♦
CYFENDUS (Anthrax Vaccine Adsorbed, Adjuvanted)	Emergent Product Development Gaithersburg, Inc.	Y	FIRST	15.0	AP	15.0	Y#♦
OJJAARA (momelotinib)	GLAXOSMITHKLINE LLC	Y	FIRST	15.0	AP	15.0	Y#♦
PHYRAGO (dasatinib)	NANOCOPOEIA LLC	N	FIRST	9.7	CR	9.7	Y
			Sponsor	0.2		9.9	
			SECOND	5.8	TA	15.7	Y△
dolutegravir, emtricitabine and tenofovir alafenamide	AUROBINDO PHARMA Ltd.	N	FIRST	9.5	CR	9.5	Y
			Sponsor	1.5		11	
			SECOND	5.9	TA	16.9	Y△
dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets, 50 mg/300 mg/300 mg	STRIDES PHARMA GLOBAL PTE Ltd.	N	FIRST	10.0	CR	10.0	Y
			Sponsor	1.7		11.7	
			SECOND	6.0	TA	17.7	Y△
FOCINVEZ (fosaprepitant injection)	SPES PHARMACEUTICALS Inc.	N	FIRST	9.9	CR	9.9	Y
			Sponsor	4.3		14.2	
			SECOND	5.7	AP	19.9	Y△

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
XENOVIEW (hyperpolarized 129-xe)	POLAREAN Inc.	Y	FIRST	12.0	CR	12.0	Y
			Sponsor	5.8		17.8	
			SECOND	8.8	AP	26.6	Y#△
Submitted in FY 2021							
ZEJULA (niraparib)	GLAXOSMITHKLINE LLC	N	FIRST	9.9	AP	9.9	Y
BRIUMVI (ublituximab-xiiy)	TG THERAPEUTICS, Inc.	Y	FIRST	15.0	AP	15.0	Y#♦
bendamustine hydrochloride	BAXTER HEALTHCARE Corp.	N	FIRST	10.0	TA	10.0	Y
			Sponsor	3.6		13.6	
			SECOND	1.5	AP	15.1	Y▲
OLPRUVA (sodium phenylbutyrate)	ACER THERAPEUTICS Inc.	N	FIRST	10.3	CR	10.3	N
			Sponsor	1.0		11.3	
			SECOND	5.3	AP	16.6	Y△
bendamustine hydrochloride	APOTEX Inc.	N	FIRST	10.0	TA	10.0	Y
			Sponsor	6.0		16.0	
			SECOND	2.0	AP	18.0	Y▲
paclitaxel	TEVA PHARMACEUTICALS Inc.	N	FIRST	9.5	TA	9.5	Y
			Sponsor	4.8		14.3	
			SECOND	2.0	TA	16.3	Y▲
			Sponsor	1.2		17.5	
			THIRD	1.9	AP	19.4	Y▲
JYLAMVO (methotrexate)	THERAKIND Ltd.	N	FIRST	9.7	CR	9.7	Y
			Sponsor	5.3		15.0	
			SECOND	6.0	AP	21.0	Y△
SUFLAVE (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride)	BRAINTREE LABORATORIES Inc.	N	FIRST	10.0	CR	10.0	Y
			Sponsor	8.6		18.6	
			SECOND	3.7	AP	22.3	Y△
UZEDY (risperidone)	TEVA NEUROSCIENCE Inc.	N	FIRST	9.9	CR	9.9	Y
			Sponsor	6.4		16.3	
			SECOND	6.0	AP	22.3	Y△
OPFOLDA (miglustat)	AMICUS THERAPEUTICS US LLC	N	FIRST	26.0	AP	26.0	N#

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
POMBILITI (cipaglucosidase alfa-atga)	AMICUS THERAPEUTICS US, LLC	Y	FIRST	26.0	AP	26.0	N#♦
XENOVIEW (hyperpolarized 129-xe)	POLAREAN Inc.	Y	FIRST	12.0	CR	12.0	Y
			Sponsor	5.8		17.8	
			SECOND	8.8	AP	26.6	Y#△
MYDCOMBI (tropicamide and phenylephrine)	EYENOVIA Inc.	N	FIRST	9.8	CR	9.8	Y
			Sponsor	12.6		22.4	
			SECOND	5.8	AP	28.2	Y△
LUMRYZ (sodium oxybate)	AVADEL CNS PHARMACEUTICALS LLC	N	FIRST	19.1	TA	19.1	N
			Sponsor	7.4		26.5	
			SECOND	2.0	AP	28.5	Y▲
LIQREV (sildenafil)	CMP DEVELOPMENT LLC	N	FIRST	10.0	CR	10.0	Y
			Sponsor	2.8		12.8	
			SECOND	5.9	CR	18.7	Y△
			Sponsor	4.0		22.7	
			THIRD	8.0	AP	30.7	N△
NGENLA (somatrogon-ghla)	PFIZER IRELAND PHARMACEUTICALS	Y	FIRST	15.0	CR	15.0	Y#♦
			Sponsor	10.0		25.0	
			SECOND	7.1	AP	32.1	N
meropenem	HQ SPECIALTY PHARMA Corp.	N	FIRST	9.9	CR	9.9	Y
			Sponsor	16.4		26.3	
			SECOND	5.9	AP	32.2	Y△
Submitted in FY 2020							
norepinephrine in 0.9% sodium chloride	LONG GROVE PHARMACEUTICALS LLC	N	FIRST	9.9	CR	9.9	Y
			Sponsor	9.8		19.7	
			SECOND	5.9	AP	25.6	Y△
dolutegravir, emtricitabine and tenofovir alafenamide	LUPIN Ltd.	N	FIRST	12.4	CR	12.4	N
			Sponsor	10.1		22.5	
			SECOND	6.0	AP	28.5	Y△
LANTIDRA (donislecel-jujn)	CellTrans Inc.	Y	FIRST	15.0	CR	15.0	Y#♦
			Sponsor	16.4		31.4	
			SECOND	5.9	AP	37.3	Y△
NEXOBRID (anacaulase-bcdb)	MEDIWOUND, Ltd..	Y	FIRST	11.9	CR	11.9	Y♦
			Sponsor	12.2		24.1	
			SECOND	5.9	AP	30.0	Y
pemetrexed		N	FIRST	9.9	CR	9.9	Y

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
	SHILPA MEDICARE Ltd.		Sponsor	3.7		13.6	
			SECOND	6.0	CR	19.6	Y△
			Sponsor	4.3		23.9	
			THIRD	8.9	AP	32.8	Y#△
ATORVALIQ (atorvastatin)	CMP DEVELOPMENT LLC	N	FIRST	9.1	CR	9.1	Y
			Sponsor	21.5		30.6	
			SECOND	6.0	AP	36.6	Y△
TECHNEGAS (technetium tc 99m carbon)	CYCLOMEDICA AUSTRALIA PTY Ltd.	N	FIRST	15.0	CR	15.0	Y#♦
			Sponsor	21.1		36.1	
			SECOND	6.1	AP	42.1	Y△
Submitted in FY 2019							
RYKINDO (risperidone)	SHANDONG LUYE PHARMACEUTICAL Co. Ltd.	N	FIRST	10.1	CR	10.1	Y
			Sponsor	18.7		28.8	
			SECOND	6.0	CR	34.8	Y△
			Sponsor	4.8		39.6	
			THIRD	6.0	AP	45.6	Y△
YCANTH (cantharidin)	VERRICA PHARMACEUTICALS Inc.	N	FIRST	10.0	CR	10.0	Y
			Sponsor	5.4		15.4	
			SECOND	8.8	CR	24.2	Y#△
			Sponsor	2.3		26.5	
			THIRD	5.9	CR	32.4	Y△
			Sponsor	8.0		40.4	
			FOURTH	5.9	AP	46.3	Y△
RIZAFILM (rizatriptan)	INTELGENX Corp.	N	FIRST	5.8	CR	5.8	Y△
			Sponsor	6.0		11.8	
			SECOND	5.9	CR	17.7	Y△
			Sponsor	30.8		48.5	
			THIRD	5.9	AP	54.4	Y△
ENTYVIO (vedolizumab)	TAKEDA PHARMACEUTICALS U.S.A., Inc.	N	FIRST	9.4	CR	9.4	Y
			Sponsor	39.3		48.7	
			SECOND	6.0	AP	54.7	Y△
Submitted in FY 2018							
VIVIMUSTA (bendamustine hydrochloride)	SLAYBACK PHARMA LLC	N	FIRST	9.5	CR	9.5	Y
			Sponsor	0.5		10.0	
			SECOND	2.5	CR	12.5	Y△
			Sponsor	5.0		17.5	

Proprietary Name (Established Name)	Applicant	NME (Y/N)	Review Cycle	Cycle Time (Mos.)	Cycle Result	Total Time (Mos.)	Goal Met
			THIRD	4.6	TA	22.1	Y#△
			Sponsor	11.5		33.6	
			FOURTH	9.0	TA	42.6	Y△
			Sponsor	3.4		46.0	
			FIFTH	2.0	TA	48.0	Y▲
			Sponsor	1.4		49.4	
			SIXTH	2.0	AP	51.4	Y▲
bendamustine	HOSPIRA Inc.	N	FIRST	10.1	TA	10.1	Y
			Sponsor	41.0		51.1	
			SECOND	5.5	AP	56.6	Y△
dolutegravir, lamivudine, and tenofovir disoproxil fumarate	EMCURE PHARMACEUTICALS Ltd.	N	FIRST	9.6	CR	9.6	Y
			Sponsor	18.1		27.7	
			SECOND	11.6	CR	39.3	N△
			Sponsor	15.9		55.2	
			THIRD	5.9	TA	61.1	Y△
cefazolin	HQ SPECIALTY PHARMA Corp.	N	FIRST	9.9	CR	9.9	Y
			Sponsor	8.4		18.3	
			SECOND	5.8	CR	24.1	Y△
			Sponsor	6.4		30.5	
			THIRD	6.0	CR	36.5	Y△
			Sponsor	22.0		58.5	
			FOURTH	5.9	AP	64.4	Y△
Submitted in FY 2017							
FUROSCIX INFUSOR (furosemide)	SCPHARMACEUTICALS Inc.	N	FIRST	9.6	CR	9.6	Y
			Sponsor	24.6		34.2	
			SECOND	5.1	CR	39.3	Y△
			Sponsor	16.1		55.4	
			THIRD	6.0	AP	61.4	Y△
vancomycin hydrochloride for injection	ZHEJIANG NOVUS PHARMACEUTICALS Co. Ltd.	N	FIRST	9.9	CR	9.9	Y
			Sponsor	23.5		33.4	
			SECOND	6.0	CR	39.4	Y△
			Sponsor	3.0		42.4	
			THIRD	5.9	CR	48.3	Y△
			Sponsor	10.8		59.1	
			FOURTH	6.0	AP	65.1	Y△
cyclophosphamide		N	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
	DR REDDYS LABORATORIES Ltd.		Sponsor	3.4		13.2	
			SECOND	5.9	CR	19.1	Y△
			Sponsor	0.6		19.7	
			THIRD	6	CR	25.7	Y△
			Sponsor	0.5		26.2	
			FOURTH	5.6	CR	31.8	Y△
			Sponsor	0.9		32.7	
			FIFTH	4.6	CR	37.3	Y△
			Sponsor	11.9		49.2	
			SIXTH	5.5	CR	54.7	Y△
			Sponsor	8		62.7	
			SEVENTH	5.7	AP	68.4	Y△
COMBOGESIC (acetaminophen and ibuprofen)	AFT PHARMACEUTICALS Ltd.	N	FIRST	9.7	CR	9.7	Y
			Sponsor	28.5		38.2	
			SECOND	6.0	CR	44.2	Y△
			Sponsor	8.6		52.8	
			THIRD	19.1	AP	71.9	N△
Submitted in FY 2016							
cabazitaxel	SANDOZ Inc.	N	FIRST	10.0	TA	10.0	Y
			Sponsor	64.2		74.2	
			SECOND	5.9	AP	80.1	Y△
REXTOVY (naloxone hydrochloride)	AMPHASTAR PHARMACEUTICALS Inc.	N	FIRST	10.0	CR	10.0	Y
			Sponsor	66.6		76.6	
			SECOND	5.9	AP	82.5	Y△
Submitted in FY 2012							
HEPZATO (melphalan hydrochloride)	DELCATH SYSTEMS Inc.	N	FIRST	12.9	CR	12.9	Y#
			Sponsor	113.1		126	
			SECOND	5.9	AP	131.9	Y△
Submitted in FY 2001							
EXXUA (gepirone)	FABRE KRAMER PHARMACEUTICALS Inc.	Y	FIRST	9.9	NA	9.9	Y
			Sponsor	21.3		31.2	
			SECOND	6.0	NA	37.2	Y△
			Sponsor	34.3		71.5	
			THREE	6.0	NA	77.5	Y△
			Sponsor	181.7		259.2	
			FOUR	9.0	AP	268.2	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 2023 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 2023 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	1	8	0	0	2
Division of Anti-Infectives	5	2	0	0	0
Division of Antivirals	4	0	0	0	0
Division of Cardiology and Nephrology	1	13	1	0	1
Division of Dermatology and Dentistry	1	5	0	0	1
Division of Diabetes, Lipid Disorders, and Obesity	2	1	0	1	1
Division of Gastroenterology	1	1	1	2	4
Division of General Endocrinology	0	2	0	0	0
Division of Hematologic Malignancies I	1	2	0	0	1
Division of Hematologic Malignancies II	0	2	5	0	1
Division of Hepatology and Nutrition	1	0	0	0	1
Division of Imaging and Radiation Medicine	1	0	0	0	1
Division of Neurology I	1	5	1	0	0

Review Division/Office	Priority NDAs	Standard NDAs	Priority BLAs	Standard BLAs	Undesignated Original Applications
Division of Neurology II	0	4	0	0	0
Division of Non-Malignant Hematology	2	2	0	1	0
Division of Non-Prescription Drugs I	1	0	0	0	2
Division of Non-Prescription Drugs II	0	1	0	0	0
Division of Oncology I	2	2	0	0	0
Division of Oncology II	3	3	0	1	2
Division of Oncology III	2	1	1	3	0
Division of Ophthalmology	2	7	1	0	0
Division of Psychiatry	1	7	0	0	0
Division of Pulmonology, Allergy, and Critical Care	1	1	0	0	0
Division of Rare Diseases and Medical Genetics	0	0	0	0	0
Division of Rheumatology and Transplant Medicine	0	1	0	1	0
Division of Urology, Obstetrics, and Gynecology	0	2	0	0	2
CDER Totals	*33*	*72*	*10*	*9*	*19*
CBER Review Offices					
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	0	0	6	3	0
Office of Vaccines Research and Review	0	0	3	1	0
CBER Totals	*0*	*0*	*9*	*4*	*0*
FDA Totals	**33**	**72**	**19**	**13**	**19**

Table B-2. Efficacy Supplements Filed in FY 2023 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	2	2	0
Division of Anti-Infectives	4	2	3
Division of Antivirals	8	8	1
Division of Cardiology and Nephrology	1	9	0
Division of Dermatology and Dentistry	1	10	1
Division of Diabetes, Lipid Disorders, and Obesity	6	12	1
Division of Gastroenterology	1	1	0
Division of General Endocrinology	0	3	0
Division of Hematologic Malignancies I	5	0	1
Division of Hematologic Malignancies II	1	7	0
Division of Hepatology and Nutrition	1	2	0
Division of Imaging and Radiation Medicine	0	1	0
Division of Neurology I	1	4	0
Division of Neurology II	0	3	0
Division of Non-Malignant Hematology	2	3	0
Division of Non-Prescription Drugs I	0	0	0
Division of Non-Prescription Drugs II	0	0	0
Division of Oncology I	13	22	0
Division of Oncology II	1	20	3

Review Division/Office	Priority Efficacy Supplements	Standard Efficacy Supplements	Undesignated Efficacy Supplements
Division of Oncology III	3	8	0
Division of Ophthalmology	0	3	0
Division of Psychiatry	3	5	0
Division of Pulmonology, Allergy, and Critical Care	4	7	0
Division of Rare Diseases and Medical Genetics	0	1	0
Division of Rheumatology and Transplant Medicine	0	10	1
Division of Urology, Obstetrics, and Gynecology	0	3	0
CDER Totals	*57*	*146*	*11*
Office of Blood Research and Review	0	0	0
Office of Tissues and Advanced Therapies	2	11	0
Office of Vaccines Research and Review	1	7	0
CBER Totals	*3*	*18*	*0*
FDA Totals	**60**	**164**	**11**

Table B-3. Submissions with Special Designations Filed in FY 2023 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	88
Division of Anti-Infectives	0	4	2	0	27
Division of Antivirals	0	2	0	0	52

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
Division of Cardiology and Nephrology	0	0	3	2	117
Division of Dermatology and Dentistry	0	1	1	1	75
Division of Diabetes, Lipid Disorders, and Obesity	0	1	1	1	50
Division of Gastroenterology	0	2	1	0	43
Division of General Endocrinology	0	1	0	0	16
Division of Hematologic Malignancies I	0	0	2	2	71
Division of Hematologic Malignancies II	4	4	4	2	98
Division of Hepatology and Nutrition	1	1	0	4	29
Division of Imaging and Radiation Medicine	0	1	0	2	75
Division of Neurology I	0	1	4	1	59
Division of Neurology II	0	1	2	1	46
Division of Non-Malignant Hematology	0	1	4	0	49
Division of Non-Prescription Drugs I	0	1	0	0	0
Division of Non-Prescription Drugs II	0	0	0	0	2
Division of Oncology I	0	1	0	2	239
Division of Oncology II	0	1	7	5	205
Division of Oncology III	0	3	5	6	135
Division of Ophthalmology	0	1	1	1	60

Review Division/Office	Accelerated Approval	Fast Track Products	Orphan Designations	Breakthrough Designations*	IND Applications Submitted
Division of Psychiatry	0	1	0	0	81
Division of Pulmonology, Allergy, and Critical Care	0	1	1	1	64
Division of Rare Diseases and Medical Genetics	0	0	0	0	11
Division of Rheumatology and Transplant Medicine	0	0	0	0	44
Division of Urology, Obstetrics, and Gynecology	0	0	0	0	21
CDER Totals	*5*	*30*	*38*	*32*	*1,757*
Office of Blood Research and Review	0	0	0	0	0
Office of Tissues and Advanced Therapies	0	6	7	1	12
Office of Vaccines Research and Review	0	3	0	2	1
CBER Totals	*0*	*9*	*7*	*3*	*13*
FDA Totals	**5**	**39**	**45**	**35**	**1,770**

* This column does not represent filed figures; rather it shows the number of BT designations granted on INDs, NDAs, and BLAs during FY 2023. 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 2023. Data represent all the original NDA and BLA approvals that occurred during FY 2023, regardless of when the application was received. Data are presented by the type of application and performance goal, as well as whether the approval occurred on time or was overdue on the performance goal.

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

Figures provided in the table below are indicated in detail in Appendix A of this report, which provides a detailed review history of the NDAs and BLAs approved under PDUFA during FY 2023.[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 2023 Original Application Approval Cycle Summary

Approval Cycle Type	Performance Goal: Act on 90 Percent Within	Approval Count	On Time	Overdue	Percent On Time
First Cycle Priority NMEs & BLAs	6 months of filing date	36	34	2	**94%**
First Cycle Standard NMEs & BLAs	10 months of filing date	19	18	1	**95%**
First Cycle Priority Non-NME NDAs	6 months	14	14	0	**100%**
First Cycle Standard Non-NME NDAs	10 months	26	25	1	**96%**
Class 1 Resubmissions	2 months	8	8	0	**100%**
Class 2 Resubmissions	6 months	43	38	4	**88%**
Total		**146**	**138**	**8**	**--***

* Performance is not calculated on combined goals.

B. Performance Enhancement Goals

Section 736B(a)(5)(B) of the FD&C Act, which requires FDA to include relevant data to determine whether CDER and CBER have met performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the applicable fiscal year. A link to each performance enhancement goal completed under PDUFA VI can be found on FDA's website.[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 2022 updated performance enhancement goals.

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

Table C-2. FY 2022 Performance Enhancement Goals (Updated)

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Final Guidance on Bridging Studies, Including the Bridging of Data from Combination Products	9/30/2022	N	N/A	A draft guidance document on this topic was published in December 2019 (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bridging-drug-device-and-biologic-device-combination-products), and the final guidance document is in progress.
FY 2022 PDUFA Hiring Goals	9/30/2022	N	9/24/2023	
Publish Summary Topics Discussed in MIDD Workshop on Disease Progression Model Development	N/A	N/A	N/A	The summary is currently in progress. For information about the workshop, see https://www.fda.gov/drugs/news-eventshuman-drugs/best-practicesdevelopment-and-application-diseaseprogression-models-11192021.
Focused Guidance on Specific Biomarker Uses and Contexts to Supplement Draft Guidance on General Evidentiary Standards	N/A	N/A	N/A	After the guidance document on evidentiary framework for biomarker qualification is published, FDA will continue to evaluate the potential need for a supplemental focused guidance and publish such guidance accordingly.

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

Table C-3. FY 2023 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Update PDUFA Program	10/1/2022	Y	10/1/2022	
Conduct Training for Pre-Approval Review of PMRs	10/1/2022	Y	10/1/2022	
Implement Post Approval Review of PMRs	10/1/2022	Y	10/1/2022	
Implement Pre-Approval Review of PMRs	10/1/2022	Y	10/1/2022	

Implement STAR Pilot Program	10/1/2022	Y	10/1/2022	
Develop STAR Web Page	10/1/2022	Y	10/1/2022	https://www.fda.gov/drugs/development-resources/split-real-time-application-review-star
Implement INTERACT Meeting Management	10/1/2022	Y	9/30/2022	
Implement Type D Meetings	10/1/2022	Y	9/30/2022	
Implement WRO for Clarification	10/1/2022	Y	9/30/2022	
Publish Revised Draft Guidance on Formal Meetings Between FDA and Sponsors	9/30/2023	Y	9/22/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products
Launch Rare Disease Endpoint Advancement Pilot Program	10/1/2022	Y	9/30/2022	https://www.fda.gov/drugs/development-resources/rare-disease-endpoint-advancement-pilot-program#:~:text=The%20RDEA%20Pilot%20Program%20is,the%20efficacy%20endpoint%20development%20process
Establish Human Factors Validation Study Review Protocols	10/1/2022	Y	10/1/2022	
Implement Use-Related Risk Analysis Review	10/1/2022	Y	03/08/2023	
Implement Advancing Real-World Evidence Program	12/31/2022	Y	10/22/2022	
Issue RFI for PFDD	6/30/2023	Y	5/2/2023	https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments
Implement MIDD program	10/1/2022	Y	9/30/2022	
Publish FRN on Continuation of MIDD	12/31/2022	N	1/11/2023	https://www.federalregister.gov/documents/2023/01/11/2023-00389/prescription-drug-user-fee-act-of-2023-vii-meetings-program-for-model-informed-drug-development See corrective actions.
Publish FRN for Paired Meeting Program	12/31/2022	Y	10/20/2022	https://www.federalregister.gov/documents/2022/10/20/2022-22794/complex-innovative-design-paired-meeting-program

Establish Review Performance Goals for REMS methodological approaches and study protocols	10/1/2023	Y	8/18/2023	
Conduct Public Workshop on Negative Controls	9/30/2023	Y	3/8/2023	https://healthpolicy.duke.edu/events/understanding-use-negative-controls-assess-validity-non-interventional-studies-treatment
Conduct Public Workshop on Post Market Pregnancy Data	9/30/2023	Y	9/18/2023	https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies
Conduct Four Part Harmony MAPP/SOPP Training	9/30/2023	Y	9/15/2023	
Update and Conduct CMC Assessment Training	9/30/2023	Y	9/15/2023	
Update Four Part Harmony MAPP & SOPP	9/30/2023	Y	8/25/2023	https://www.fda.gov/media/171613/download?attachment
Enhance Inspection Communication for Applications	10/1/2022	Y	9/16/2022	
Publish Draft Guidance on Alternative Tools to Assess Manufacturing Facilities	9/30/2023	Y	9/22/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications
Implement CMC Development and Readiness Pilot	9/30/2023	Y	4/1/2023	
Publish FRN Announcing CMC Development and Readiness Pilot	12/31/2022	Y	10/31/2022	https://www.federalregister.gov/documents/2022/10/31/2022-23575/chemistry-manufacturing-and-controls-development-and-readiness-pilot-program-program-announcement
Publish MAPP on Approaches to Address CMC Challenges	12/31/2022	Y	11/1/2022	https://www.fda.gov/media/162786/download
Conduct Innovative Manufacturing Public Workshop	9/30/2023	Y	6/8/2023	https://healthpolicy.duke.edu/events/advancing-utilization-and-supporting-implementation-innovative-manufacturing-approaches
Conduct PFDD Public Meeting on Gene Therapy Products	9/30/2023	Y	11/15/2022	https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-cber-otat-patient-focused-drug-development-listening-meeting-patient-perspectives-gene-therapy

Incorporate Review of Allergenic Extract Products	10/1/2022	Y	10/1/2022	
Publish Capacity Planning Implementation Plan	3/31/2023	Y	3/29/2023	https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting
Publish Five-Year Financial Plan	3/31/2023	Y	3/31/2023	https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans
Conduct Public Meeting Financial Plan FY23	6/30/2023	Y	6/8/2023	https://www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act
Hiring PDUFA Human Drug Review Program Staff FY23	9/30/2023	N	N/A	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates See corrective actions.
Quarterly Hiring Reporting Q1 FY23	1/21/2023	N	1/26/2023	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.
Quarterly Hiring Reporting Q2 FY23	4/21/2023	Y	4/10/2023	
Quarterly Hiring Reporting Q3 FY23	7/21/2023	Y	7/12/2023	
Annual PDUFA VII FDA-Industry IT Leadership Meeting Kickoff	9/30/2023	Y	3/9/2023	
Publish Data Standards Action Plan Q1 FY23	12/31/2022	Y	11/9/2022	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board
Publish Data Standards Action Plan Q2 FY23	3/31/2023	Y	3/1/2023	
Publish Data Standards Action Plan Q3 FY23	6/30/2023	Y	5/9/2023	
Publish Data Standards Action Plan Q4 FY23	9/30/2023	Y	8/14/2023	

Quarterly PDUFA Standing Meetings with Industry FY23	9/30/2023	Y	9/12/2023	Meetings were held on 11/15/2022, 2/7/2023, 6/6/2023, and 9/12/2023.
Develop and Update Data and Tech Modernization Strategy FY23	9/30/2023	Y	9/19/2023	https://www.fda.gov/about-fda/office-digital-transformation/fda-information-technology-strategy-fy-2024-fy-2027
Establish CBER Modernization Roadmap	9/30/2022	Y	5/26/2022	
CBER Roadmap Updates FY23	9/30/2023	Y	3/31/2023	
Complete Assessment on Challenges and Barriers to Cloud Technologies	6/30/2023	Y	6/30/2023	
Initiate Demonstration Project (1) on Cloud Based Technologies	9/30/2023	Y	9/28/2023	
Assess and Share Bioinformatics Capabilities FY23	9/30/2023	Y	9/27/2023	
Establish DHT Framework Document	3/31/2023	Y	3/23/2023	https://www.fda.gov/media/166396/download?attachment
Establish DHT Steering Committee	3/31/2023	Y	2/28/2023	
Publish Website of DHT Committee	3/31/2023	Y	2/28/2023	https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development
Conduct DHT Public Meeting 1	3/31/2023	Y	1/31/2023	https://healthpolicy.duke.edu/events/digitalhealthtechnologies
Publish Draft, Revised, or Final Guidance on DHTs	12/31/2022	Y	12/23/2021	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations
Publish Draft, Revised, or Final Guidance on Drug Use Related Software	9/30/2023	Y	9/19/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-prescription-drug-use-related-software
Enhance Internal Systems to Support DHT Review	3/31/2023	Y	3/20/2023	
Establish DHT Secure Cloud Technology	9/30/2023	Y	6/5/2023	

C. Common Causes and Trends Impacting Ability to Meet Goals

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

Table C-4. FY 2023 Performance Results

Cause or Trend	Impact on FDA's Commitments
High Volume of Meeting Requests	• In FY 2023, FDA continued to receive an increased volume of meeting requests as compared to the pre-pandemic levels. While new staff have been hired, resulting in a net increase in staff, the relative inexperience of new staff continued to impact the Agency's ability to meet the high demand of the review and formal meeting workload.
Specialty Candidates	• The federal hiring process (e.g., security and ethics clearances) delayed the onboarding process. In addition to last minute declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.

Appendix D: FY 2023 Corrective Action Report

Section 736B(a)(4) 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 2022 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 2022, then the Agency fully reported on it in last year's report.[1]

Table D-1. FY 2022 Review and Procedural and Process Goal Performance Results (Updated)

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Procedural and Process Goals	• Response to Clinical Hold ○ In FY 2022, FDA received 344 responses to clinical holds that were subject to PDUFA goal dates. This represents a 35% increase over the 5-year average. FDA completed 88% of these reviews on time.	• FDA will continue to strive to meet PDUFA goals related to Response to Clinical Holds and re-evaluate resource allocation to ensure that adequate resources are allotted.

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

	Missing the goal for only five responses to clinical holds resulted in the missed goal. ○ An increasing workload, combined with under-staffing, impacted performance on Response to Clinical Hold.	

Table D-2. FY 2023 Review and Procedural and Process Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Review Goals	• Original Priority non-NME NDAs ○ In FY 2023, FDA received 17 original priority non-NME NDAs subject to the PDUFA goal dates.	• Review Goals ○ FDA continues to hire new staff and to assess ways to handle the large volume of review and other regulatory work more effectively.
Procedural and Processing Goals	• Meeting Management Goals: ○ There were 4,403 meeting requests in FY 2023. The volume of formal PDUFA meeting requests continued to be high compared to pre-pandemic levels. ○ A sustained high workload, including marketing applications, Emergency Use Authorizations, and meeting requests, continue to constrain FDA's resources.	• Meeting Management Goals: ○ FDA continues to assess ways to handle the large volume of formal meeting requests received each year more effectively in addition to completing other regulatory and review work.
Procedural and Processing Goals	• Human Factors Protocol Submissions to INDs ○ In FY 2023, FDA received 63 Human Factors Protocol Submissions to INDs that were subject to PDUFA goal dates ○ Staffing levels for work related to these submissions is inadequate due to the volume of workload and loss of staff. ○ Due to the technical and specialized nature of the work, staff with appropriate training and background are needed, and the use of non-specialized staff to support the work requires a larger learning curve before such staff can achieve the same capacity and efficiency as an experienced employee.	• FDA will continue to strive to meet PDUFA goals related to Human Factors Protocol Submissions and re-evaluate resource allocation to ensure that adequate resources are allotted to support the high workload of the human factors program. • FDA has recruited, onboarded, and begun to train new staff to conduct this specialized work. • FDA will continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring.

		• Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work.
	• Response to Clinical Holds ○ In FY 2023, FDA received 278 responses to clinical holds that were subject to PDUFA goal dates. ○ FDA continues to receive and higher than average number of Response to Clinical Holds, particularly when compared to pre-pandemic levels ○ Although preliminary data reflect a missed goal in FY 2023, FDA has the potential to successfully meet this goal when the final response rate is reported in FY 2024. ○ An increasing workload, combined with under-staffing, impacted FDA's performance on Response to Clinical Hold.	• Response to Clinical Holds ○ FDA will continue to strive to meet PDUFA goals related to Response to Clinical Holds and re-evaluate resource allocation to ensure that adequate resources are allotted.

Table D-3. FY 2023 Performance Enhancement Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Federal Register Notice	• The preparation and clearance of the FRN required extensive internal discussion prior to finalization and submission. It was important to ensure that the shared information would continue to advance Model-Informed Drug Development. Final clearance also involved multiple offices and regulatory authorities across FDA and an extensive effort was needed to ensure that the FRN aligned with, and did not undermine, important regulatory frameworks.	• The FRN was published on January 11, 2023. FDA will continue to streamline internal processes to speed publishing and mitigate the risk of missing timelines.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Hiring	• CDER's FY 23 PDUFA VII hiring goals were not met; however, constant recruitment efforts and sourcing strategies were used on all vacancies throughout the year consistent with the corrective actions outlined in the FY 2022 PDUFA report to Congress. Of the remaining vacancies, nine had candidates set to enter on duty during FY 2024, and 24 had candidates identified who were pending final offers. In addition to declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.	• FDA plans to continue to advance the corrective actions outlined in the FY 2022 report to Congress and pursue new strategies to support hiring. FDA will fill the remaining PDUFA VII positions allocated for FY 2023 and will continue to track hiring progress until all 210 are on board.

B. PDUFA Review Goals

The following section addresses section 904(a)(2)(B) of FDARA (section 736B(c)(2)(A) of the FD&C Act), which requires FDA to provide a justification for the determination of review goals missed during FY 2023, 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 2023.

If a goal type is not listed for FY 2022, then the Agency fully reported on it in last year's report.

I. FY 2022 Updated Review and Procedural and Processing Goal Performance Results

A. Summary of Performance:

FDA did not miss any review goals in FY 2022.

FDA missed the following procedural and processing goal:

- Response to Clinical Holds

B. Justification:

Response to Clinical Holds

In FY 2022, FDA received 344 responses to clinical holds that were subject to PDUFA goal dates. Eighty-eight percent of response to clinical holds were achieved on time. A delay in only five responses to clinical hold resulted in a missed goal. FDA continues to receive a higher-than-average number of responses to clinical holds, particularly when compared to pre-pandemic levels. The sustained increase in workload, combined with under-staffing, impacted performance on the Response to Clinical Hold goal.

C. FY 2023 Corrective Actions:

Response to Clinical Holds

FDA will continue to strive to meet PDUFA goals related to Response to Clinical Holds and re-evaluate resource allocation to ensure that adequate resources are allotted.

II. FY 2023 Review and Procedural and Processing Performance Results

A. Summary of Performance:

FDA missed the following review goal:

- Original Priority Non-NME NDAs

FDA missed the following procedural and processing goals:

- Meeting request for Type A, B(EOP), and D
- Meeting scheduling for Type A, B, B(EOP), and C
- Final written response for Type B, and C
- Meeting preliminary response for Type B(EOP), D, and INTERACT
- Response to Clinical Holds
- Human Factors Protocol Submissions to INDs

B. Justification:

Review Goal: Original Priority Non-NME NDAs

In FY 2023, FDA received 17 original priority non-NME NDAs subject to the PDUFA goal dates. FDA saw an increase of 19% in original marketing application submissions between FY 2022 and FY 2023, with a 67-percent increase in the number of non-NME NDAs. This review work, in addition to other regulatory work, contributed to a sustained high workload that impacted performance.

Procedural and Processing Goal: Meeting Management Goals

In FY 2023, in addition to FDA's application review workload, FDA held or provided written responses to over 4,403 formal PDUFA meetings. Prior to the public health emergency, formal meetings were steadily increasing each year at a rate that ranged between two percent and 24 percent. Although the number of FY 2023 formal meetings held or written responses issued decreased slightly (-7%) when compared to FY 2022, the FY 2023 formal meetings still represented a 24-percent increase in meetings when compared to 3-year (FY 2017 to FY 2019) pre-pandemic average numbers. Although the Agency was able to hire additional staff, difficulties related to the hiring process resulted in net gains that were not sufficient to handle the increased meeting workload seen.

Procedural and Processing Goal: Response to Clinical Holds

In FY 2023, FDA received 278 responses to clinical holds that were subject to PDUFA goal dates. FDA continues to receive a higher-than-average number of Response to Clinical Holds, particularly when compared to pre-pandemic levels. An increasing workload impacted FDA's performance on Response to Clinical Hold. Although preliminary data reflect a missed goal in FY 2023, FDA has the potential to successfully meet this goal when the final response rate is reported in FY 2024.

Procedural and Processing Goal: Human Factors Protocol Submission to INDs

In FY 2023, FDA received 63 human factors protocol submissions that were subject to PDUFA goal dates. The continued high workload, insufficient staffing, and difficulty hiring new staff with the background and experience to conduct this specialized work resulted in difficulty achieving the human factors validation study protocol submission goal.

C. FY 2024 Corrective Actions:

Review Goal and Meeting Management Goals

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

Response to Clinical Holds

FDA will continue to strive to meet PDUFA goals related to Response to Clinical Holds and re-evaluate resource allocation to ensure that adequate resources are allotted.

Human Factors Protocol Submissions

FDA will continue to strive to meet PDUFA goals related the Human Factors Protocol Submissions and re-evaluate resource allocation to ensure that adequate resources are allotted to support the high workload in the human factors program.

FDA has recruited, onboarded, and begun to train new staff to conduct this specialized work and will also continue to use the hiring authority granted under the 21st Century Cures Act to advance hiring. Hiring managers will continue to increase their use of innovative recruitment tools to identify candidates with the specialized training and background needed for the technical work.

C. PDUFA Performance Enhancement Goals

The following section addresses section 904(a)(2) of FDARA (section 736B(c)(2) of the FD&C Act), which requires FDA to provide a justification for missed performance enhancement goals and a description of the efforts FDA has put in place to improve the

ability of the Agency to meet each goal in the coming fiscal year (included here under the heading “FY 2024 Corrective Actions”).

This section presents non-review performance goals cited in the PDUFA VII Commitment Letter with required completion dates in FY 2023. 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 2024 will be covered in subsequent corrective action reports.

I. *Federal Register* Notice

A. Summary of Performance:

FDA missed the PDUFA goal date to publish an FRN on continuation of the Model-Informed Drug Development program. The FRN, due by December 31, 2022, was published on January 12, 2023.

B. Justification:

The preparation and clearance of the FRN required extensive internal discussion prior to finalization and submission. It was important to ensure that the shared information would continue to advance Model-Informed Drug Development. Final clearance also involved multiple offices and regulatory authorities across FDA, and an extensive effort was needed to ensure that the FRN aligned with, and did not undermine, important regulatory frameworks.

C. FY 2023 Corrective Actions:

The FRN was published on January 11, 2023. FDA will continue to streamline internal processes to speed publishing and mitigate the risk of missing timelines.

II. Hiring

A. Summary of Performance:

FDA missed the PDUFA VII goal for hiring in FY 2023. As of September 29, 2023, 151 of 210 FTEs were hired.

B. Justification:

FDA's FY 2023 PDUFA VII hiring goals were not met; however, constant recruitment efforts and sourcing strategies were used on all vacancies throughout the year consistent with the corrective actions outlined in the FY 2022 PDUFA report to Congress. Of the remaining vacancies, nine had candidates set to enter on duty during FY 2024, and 24 had candidates identified who were pending final offers. In addition to declinations from candidates, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.

C. FY 2024 Corrective Actions:

FDA plans to continue to advance the corrective actions outlined in the FY 2022 report to Congress and pursue new strategies to support hiring. FDA will fill the remaining PDUFA VII positions allocated for FY 2023 and will continue to track hiring progress until all 210 are on board.

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 where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

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

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

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

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

        i. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by 3 months.
        ii. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by 2 months.

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

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

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences not previously reported with the product, are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform postmarketing studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval

8. A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry

E. *Class 2 resubmissions* are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. Meeting requests commit FDA to notify the requestor of a formal meeting in writing within 14 days of request for Type A, Type B(EOP), and Type D meetings or within 21 days of request for Type B, Type C, and Type INTERACT meetings.

G. Scheduled meetings should be made within 30 days of receipt of request for Type A meetings, 60 days for Type B meetings, 70 days for Type B(EOP) meetings, 75 days for Type C and Type INTERACT meetings, and 50 days for Type D meetings. If the requested date for any of these types of meetings is greater than 30, 50, 60, 70, or 75 days, as appropriate, from the date the request is received by FDA, the meeting date should be within 14 days of the requested date.

H. Preliminary responses to sponsor questions contained in the background package for Type B(EOP), D, and INTERACT meetings should be sent to the sponsor no later than 5 calendar days prior to the meeting date.

I. Meeting minutes are to be prepared by FDA clearly outlining agreements, disagreements, issues for further discussion, and action items. They will be available to the sponsor within 30 days of the meeting.

J. A Type A meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (a “critical path” meeting) or to address an important safety issue.

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

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

M. A Type D meeting is focused on a narrow set of issues (e.g., often one, but typically not

more than two issues and associated questions).

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

O. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

P. IT-specific definitions:

1. *Program* refers to the organizational resources, procedures, and activities assigned to conduct "the process for the review of human drug applications," as defined in PDUFA.
2. *Standards-base* means compliant with published specifications that address terminology or information exchange between FDA and regulated parties or external stakeholders, as adopted by FDA or other agencies of the federal government, and often based on the publications of national or international Standards Development Organizations.
3. *FDA Standards* means technical specifications that have been adopted and published by FDA through the appropriate governance process. FDA standards may apply to terminology, information exchange, engineering or technology specifications, or other technical matters related to information systems. FDA standards often are based on the publications of other federal agencies or the publications of national or international Standards Development Organizations.
4. *Product life cycle* means the sequential stages of human drug development, regulatory review and approval, postmarket surveillance and risk management, and where applicable, withdrawal of an approved drug from the market. In the context of the process for the review of human drug applications, the product life cycle begins with the earliest regulatory submissions in the IND phase, continues through the NDA or BLA review phase, and includes postmarket surveillance and risk management activities as covered under the process for the review of human drug applications.

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.

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