Performance Report to Congress

Generic Drug User Fee Amendments

FY 2024

Executive Summary

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act,[1] which included the authorization of the Generic Drug User Fee Amendments of 2012 (GDUFA I). GDUFA I authorized the Food and Drug Administration (FDA or Agency) to collect user fees for human generic drug activities and enabled FDA to advance a more efficient human generic drug review program, which helped to increase the availability of more affordable generic drugs.

On August 18, 2017, the President signed into law the FDA Reauthorization Act of 2017,[2] which included the Generic Drug User Fee Amendments of 2017 (GDUFA II). FDA worked closely with the generic drug industry during the development of GDUFA II to enhance the success started under GDUFA I with two main areas of focus: (1) reducing the number of review cycles to approval and (2) increasing the number of approvals of safe, effective, high-quality, and lower-cost generic drugs.

The second reauthorization of GDUFA was enacted on September 30, 2022, when the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180),[3] of which Division F is titled the FDA User Fee Reauthorization Act of 2022. The FDA User Fee Reauthorization Act of 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize the GDUFA program for an additional 5 years. This iteration of the GDUFA program is referred to as GDUFA III and is effective from fiscal year (FY) 2023 through FY 2027.

GDUFA III continues to build on previous iterations of the program. The GDUFA III Commitment Letter, agreed to by FDA and industry, includes performance goals intended to enhance the transparency and efficiency of the generic drug review process and to update terminology and negotiated timelines for responding to controlled correspondence. As described in this report, these commitments, and many other elements of the GDUFA III program have produced success for the generic drug program and, more importantly, for the American people.

This annual report presents both preliminary data on FDA's FY 2024 review performance goals and commitments under GDUFA III and updated data for FY 2023.

[1] http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.

[2] http://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf.

[3] https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf.

Highlighted Achievements – FY 2024

Highlights of FDA's FY 2024 activities are provided below.

Generic Drug Assessment and Approval Activity Highlights

In FY 2024, FDA approved 694 abbreviated new drug applications (ANDAs) and tentatively approved (TAs) 162 ANDAs.

A critically important subset of these generic drug approvals is the category of first generics, as first generics provide access to needed therapies that treat a wide range of medical conditions and for which no generic competition had previously existed. Significant first generic approvals for FY 2024 are displayed on Table 1.

Table 1. Significant First Generic Approvals for FY 2024

Generic Name	Brand Name	Indication	Approval Date
Pazopanib Tablets	Votrient	Advanced renal cell carcinoma; advanced soft tissue sarcoma	October 2023
Teriparatide Injection	Forteo	Osteoporosis	November 2023
Fidaxomicin Tablets	Dificid	C. difficile-associated diarrhea	January 2024
Dronedarone Tablets	Multaq	Atrial fibrillation	January 2024
Deflazacort Oral Suspension	Emflaza	Duchenne muscular dystrophy	April 2024
Edaravone Injection	Radicava	Amyotrophic lateral sclerosis (ALS)	May 2024
Emtricitabine and Tenofovir Alafenamide Tablets	Descovy	HIV-1 infection	May 2024
Bupivacaine Liposome Injectable Suspension	Exparel	Postsurgical local analgesia; regional analgesia	July 2024

GDUFA Regulatory Science and Research Highlights

The GDUFA Regulatory Science and Research Program has consistently fostered early engagement between FDA and the generic drug industry, supported collaboration with generic industry representatives to determine the GDUFA Regulatory Science and

Research Priority Initiatives for each future year,[4] facilitated continued engagement with prospective ANDA applicants through Pre-ANDA meetings during product development to discuss how insights from GDUFA research could be leveraged, and provided opportunities for better informed engagement following ANDA submission in meetings between FDA and ANDA applicants to discuss scientific matters.

During FY 2024, the GDUFA Regulatory Science and Research Program generated 77 peer-reviewed scholarly articles, 106 external posters related to generic drugs, and 165 external talks presented at national and international scientific and medical conferences.

In addition to conducting numerous ongoing internal and external research projects, during FY 2024, the GDUFA Regulatory Science and Research Program awarded seven new grants and six new contracts to advance external research collaborations in areas identified as FY 2024 GDUFA Science and Research Priority Initiatives for generics.[5] These research priorities were established based upon public input during the FY 2023 GDUFA public workshop and comments submitted to the docket for that workshop, as well as upon discussion with generic industry representatives in bi-annual meetings of the GDUFA Industry-FDA Working Group.

Among several notable ANDAs approved during FY 2024, FDA approved the first generic bupivacaine liposome injectable suspension, 1.3% (referencing Exparel®), which provides post-surgical, non-opioid pain management. This first generic approval is a notable achievement because of how scientifically challenging it was to develop a bioequivalence approach for this product, which uses a complex liposomal dosage form. FDA's GDUFA-funded research helped to develop recommendations for the physicochemical and structural (Q3) characterization of this product and to relate in vitro product characterizations to in vivo performance. FDA's GDUFA Science and Research program supported the development of a Product-Specific Guidance (PSG) for this product and prepared FDA to assess the adequacy of information ultimately submitted in the ANDA for this approved generic product.

As part of FDA's commitment to expanding its collaboration and communication with industry, the Agency has also continued to work closely with the GDUFA-funded Center for Research on Complex Generics (CRCG)[6] during FY 2024. The CRCG solicited detailed feedback from generic drug industry representatives, helping to ensure that GDUFA Regulatory Science and Research Priority Initiatives were focused on the most pressing scientific challenges and helping generic product developers to effectively utilize GDUFA research outcomes—including technical methods, study designs, data analyses, and other scientific insights—to successfully develop complex generics.

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[4] A detailed description of the GDUFA Science and Research Priority Initiatives for each fiscal year can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects.

[5] A detailed description of the FY 2024 GDUFA Science and Research Priority Initiatives can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects.

[6] Information about the CRCG may be found on its website at https://www.complexgenerics.org/.

Indeed, during FY 2024, FDA and the CRCG co-hosted four workshops, all of which included faculty from the generic drug industry, academia, and FDA.[7]

Overall, FDA hosted or co-hosted 13 scientific meetings, webinars, and public workshops during FY 2024 to promote transparency through regulatory and scientific outreach and to enhance collaboration and communications through dialogue with academic experts and pharmaceutical industry representatives. These meetings, webinars, and public workshops directly help address scientific challenges and can accelerate the development of generic products, including complex generics. A complete listing of these events is available in section IV of this report.

ANDA Development and Review Support Activities Highlights

FDA's efforts to increase review efficiency and thereby improve patient access to generic drugs were also greatly enhanced by the Agency's publication of policy documents on important topics related to generic drug development and assessment. In FY 2024, FDA issued various policy documents relating to generic drugs, including 16 guidances for industry (not including PSGs), five Manuals of Policies and Procedures, and one *Federal Register* notice.

In addition to the publication of policy documents, FDA provided important scientific guidance and recommendations to give generic drug applicants better opportunities to efficiently develop generic drug products and to prepare more complete ANDAs. These recommendations are often described in PSGs. In FY 2024, FDA issued 206 PSGs (109 for complex products). As of September 30, 2024, FDA had published 2,223 PSGs on FDA's Product-Specific Guidances for Generic Drug Development website.[8]

In FY 2024, FDA continued its successful implementation of the law widely known as "CREATES"[9] by issuing Covered Product Authorizations to eligible product developers seeking to obtain samples of brand products subject to a Risk Evaluation and Mitigation Strategy with Elements to Assure Safe Use. FDA issued 43 Covered Product Authorizations for eligible product developers seeking to develop generic products. Issuance of these Covered Product Authorizations allows generic product developers to more easily obtain the samples needed for product development and testing and, ultimately, for the submission of ANDAs.

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[7] Additional details about FDA-CRCG events are included in section V of the report under "GDUFA Regulatory and Scientific Outreach Activities Highlights."

[8] https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development.

[9] The enactment of "CREATES" or "the CREATES Act" made available a pathway for developers of potential drug and biological products to obtain samples of brand products that they need to support their applications. See P.L. 116-94 (Further Consolidated Appropriations Act, 2020, enacting Division N, Title I, Subtitle F, Section 610—Actions for Delays of Generic Drugs and Biosimilar Biological Products (Dec. 20, 2019)). The provisions of this law related to access to product samples were codified at 21 U.S.C. 355-2 and 355-1(l).

In April 2024, FDA published a new draft guidance for industry entitled *Content and Format of Composition Statements in NDAs and ANDAs and Corresponding Statement of Ingredients in Labeling* to assist drug applicants in submitting (1) an accurate and complete composition statement in their applications and (2) a corresponding statement of ingredients in the DESCRIPTION section of the prescribing information and in other types of FDA-approved labeling (e.g., patient labeling and carton and container labeling) as applicable. The draft guidance describes best practices for writing composition statements and corresponding statements of ingredients in the labeling, when applicable. The guidance not only includes examples of common, recurring problems identified during FDA's preliminary and substantive assessment of new drug applications and ANDAs with respect to the content and format of the composition statement in new drug applications and ANDAs and the corresponding statement of ingredients in labeling but also makes recommendations on how applicants can provide complete information with a goal of minimizing the number of assessment cycles for drug applications. The guidance can help streamline generic development and support FDA's Drug Competition Action Plan.

Table of Contents

Acronym List

ANDA	Abbreviated New Drug Application
AI	Artificial Intelligence
API	Active Pharmaceutical Ingredient
BCS	Biopharmaceutics Classification System
BE	Bioequivalence
CBER	Center for Biologics Evaluation and Research
CC	Controlled Correspondence
CDER	Center for Drug Evaluation and Research
CGMP	Current Good Manufacturing Practice
CPA	Capacity Planning Adjustment
CQA	Critical Quality Attributes
CR	Complete Response
CRL	Complete Response Letter
DDCP	Drug-Device Combination Products
DMF	Drug Master File
DRL	Discipline Review Letter
eCTD	Electronic Common Technical Document
EMRCM	Enhanced Mid-Cycle Review Meeting
ETASU	Elements to Assure Safe Use
EU	European Union
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDF	Finished Dosage Form
FTE	Full-Time Equivalent
FY	Fiscal Year (October 1 to September 30)
GBHI	Global Bioequivalence Harmonisation Initiative
GDUFA	Generic Drug User Fee Amendments
GDUFA I	Generic Drug User Fee Amendments of 2012
GDUFA II	Generic Drug User Fee Amendments of 2017
GDUFA III	Generic Drug User Fee Amendments of 2023
IA	Import Alert
IR	Information Request
LAI	Long-Acting Injectable
MAPP	Manual of Policies and Procedures
MIE	Model-Integrated Evidence
ML	Machine Learning
MR	Modified Release

MRA	Mutual Recognition Agreement
MRCM	Mid-Cycle Review Meeting
NCE	New Chemical Entity
NDA	New Drug Application
OAI	Official Action Indicated
OC	Office of the Commissioner
ORA	Office of Regulatory Affairs
PAI	Pre-Approval Inspection
PAS	Prior Approval Supplement
PBPK	Physiologically Based Pharmacokinetic
PD	Pharmacodynamic
PK	Pharmacokinetic
PSG	Product-Specific Guidance
REMS	Risk Evaluation and Mitigation Strategies
RLD	Reference Listed Drug
RPM	Regulatory Project Manager
RTR	Refuse to Receive
SBIA	Small Business & Industry Assistance
TA	Tentative Approval
USP	United States Pharmacopeia
VAI	Voluntary Action Indicated
WL	Warning Letter
WCF	Working Capital Fund

I. Introduction

Millions of Americans use generic drugs to treat a wide variety of medical conditions.[1] The Food and Drug Administration (FDA or Agency) helps to ensure that human generic drug products are thoroughly tested and shown to meet the statutory standards for approval, including to show that these products contain the same active ingredients and have the same route of administration, labeling (with certain exceptions), strength, and dosage form; are bioequivalent (e.g., deliver the same amount of active ingredients to the site of action); and maintain the same strict adherence to good manufacturing practice regulations as their brand-name counterparts.[2]

The Generic Drug User Fee Amendments (GDUFA) authorize FDA to collect user fees to support human generic drug activities. Throughout GDUFA I and II (which were the first and second iterations of the GDUFA program), FDA met or exceeded almost all of its GDUFA goals while maintaining its high standards for generic drug products regarding their safety, efficacy, and quality. GDUFA has provided the mechanism necessary to secure the resources needed to gain efficiencies, promote innovation, and enhance the overall generic drug review process. Each iteration of GDUFA has brought forth new commitments that have improved the efficiency, quality, and predictability of the generic drug program.

On September 30, 2022, the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180),[3] which contains the FDA User Fee Reauthorization Act of 2022 that reauthorized GDUFA for fiscal year (FY) 2023 through FY 2027 (GDUFA III). GDUFA III provides commitments that contain new enhancements to the GDUFA program that are designed to maximize the efficiency and utility of each assessment cycle, with the intent to reduce the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitate timely access to quality, affordable, safe, and effective generic medicines. The GDUFA III Commitment Letter, agreed to by FDA and industry, includes goals intended to enhance the transparency and efficiency of the generic drug review process.

[1] According to a report compiled by the Association for Accessible Medicines that was primarily based on data from IQVIA, the American healthcare system saved nearly $3.1 trillion in the last 10 years due to the availability of affordable generics. The report is available at https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[2] Some generic drugs are permitted, after the grant of a suitability petition, to deviate in minor ways from the innovator they copy. See section 505(j)(2)(C) of the FD&C Act.

[3] https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf.

A. Performance Presented in This Report

GDUFA commitments cover a wide range of improvements, including enhancing communications between FDA and industry throughout the review process, enhancing communications from FDA regarding inspections of facilities and sites, improving predictability and transparency, promoting the efficiency and effectiveness of the review process, enhancing drug master file (DMF) reviews, enhancing accountability and reporting, and advancing regulatory science initiatives. This report details FDA's updated performance results for the first year of GDUFA III (i.e., FY 2023) and preliminary performance results for the second year of GDUFA III (i.e., FY 2024). This report also presents the Agency's progress in accomplishing the program goals and enhancements of GDUFA III. Unless otherwise noted, updated data for FY 2023 and preliminary data for FY 2024 are as of September 30, 2024.

The information below provides some key terms and concepts used in this report.

- FDA will annually report GDUFA performance data for each fiscal year receipt cohort (defined as submissions received from October 1 to September 30). Some submissions received in a fiscal year receipt cohort may have associated goals in subsequent fiscal years. In these cases, FDA's performance will be reported in the subsequent fiscal year.

- For a review goal to be met, FDA must review the specified percentage of submissions within that goal. For example, in FY 2023, to meet the goal for standard original ANDAs, FDA must review and act on 90 percent of them within 10 months.

- To "act on an application" means that FDA will issue a complete response letter (CRL), an approval letter, a tentative approval (TA) letter, or a refuse-to-receive (RTR) letter.

- Submission types with shorter review goals (e.g., minor ANDA amendments with 3-month goal dates) tend to have a larger percentage of reviews completed by the end of the fiscal year, and their preliminary performance is a more reliable indicator of their final performance. However, submission types with longer review goals (e.g., standard original ANDA submissions with 10-month goal dates) tend to have a smaller percentage of reviews completed by the end of the fiscal year, and their preliminary performance is a less reliable indicator of their final performance.

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

II. GDUFA Performance Goals

In GDUFA III, most goal dates are measured against a 90 percent metric, and there are different review times for standard and priority ANDA submissions. The GDUFA III performance results are summarized below.

Table 1 reflects the ANDA performance goals for FYs 2023 to 2027.

Table 1. GDUFA III ANDA Performance Goals for FYs 2023 to 2027

GDUFA III Performance Goals by Submission Type	Review and Act on % Within	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Original ANDA Goals*						
Standard Original ANDA Submissions	10/30 months	90%	90%	90%	90%	90%
Priority Original ANDA Submissions	8/10/30 months	90%	90%	90%	90%	90%
Amendment Goals						
Standard Major ANDA Amendments	8/10 months	90%	90%	90%	90%	90%
Priority Major ANDA Amendments	6/8/10 months	90%	90%	90%	90%	90%
Standard and Priority Minor ANDA Amendments	3 months	90%	90%	90%	90%	90%
Prior Approval Supplement (PAS) Goals†						
Standard PAS	6/10 months	90%	90%	90%	90%	90%
Priority PAS	4/8/10 months	90%	90%	90%	90%	90%
PAS Amendment Goals						
Standard Major PAS Amendment	6/10 months	90%	90%	90%	90%	90%
Priority Major PAS Amendment	4/8/10 months	90%	90%	90%	90%	90%
Standard and Priority Minor PAS Amendments	3 months	90%	90%	90%	90%	90%
Unsolicited ANDA and PAS Amendment Goals‡						
Unsolicited ANDA and PAS Amendments§	Review and act on unsolicited ANDA amendments and PAS amendments by the later of the goal date for the original submission/solicited amendment or the goal date specifically assigned to the unsolicited amendment. An unsolicited amendment goal date is assigned in the same manner as the corresponding solicited amendment goal date.					
DMF						
Complete the initial completeness assessment review of Type II active pharmaceutical ingredient (API) DMFs	Within 60 calendar days of the later of the date of	90%	90%	90%	90%	90%

GDUFA III Performance Goals by Submission Type	Review and Act on % Within	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	DMF submission or DMF Fee payment					
Controlled Correspondence (CC)¶						
Level 1 CC	Within 60 calendar days of submission date	90%	90%	90%	90%	90%
Level 2 CC	Within 120 calendar days of submission date	90%	90%	90%	90%	90%
Submitter requests to clarify ambiguities in the CC	Within 21 calendar days of request receipt	90%	90%	90%	90%	90%

* Section I(A) of the GDUFA III Commitment Letter.
† Section I(B) of the GDUFA III Commitment Letter.
‡ Section I(C) of the GDUFA III Commitment Letter.
§ The GDUFA III Commitment Letter specifies that the reporting of unsolicited amendments submitted during the review cycle and unsolicited amendments submitted between review cycles should be performed separately. For the efficient treatment of these amendments, they are combined in this report.
¶ For CC that raises an issue that relates to one or more pending citizen petitions, the 60- or 120-day time frame starts on the date FDA responds to the petition (if there is only one petition) or the last pending petition.

Tables 2 and 3 represent FDA's FY 2023 updated performance data and FY 2024 preliminary performance data, respectively. The "Percent on Time" column shows the percentage of submissions reviewed on time as of September 30, 2024, excluding action pending within the GDUFA review goal, and the "Potential Range" column shows the potential for meeting the FY 2024 GDUFA review goal.

The FY 2023 preliminary performance table includes two columns to reflect review metrics when FDA applied the GDUFA III Commitment Letter's imminent action program enhancement to qualifying ANDAs. In accordance with the GDUFA III Commitment Letter, FDA may continue to work through the goal date if, in FDA's judgment, continued work would likely result in an imminent TA that could prevent forfeiture of 180-day exclusivity or in an imminent action. These imminent action performance numbers reflect FDA's decision to achieve an approval or TA within 60 days of the goal date rather than to act on the goal date, e.g., issue a CRL. Under the GDUFA III Commitment Letter, if an ANDA is approved or tentatively approved within 60 days after the goal date, the goal date will be considered to have been met. FDA will

also strive to act either prior to a goal date or prior to the 60-day period for an imminent action when the assessment is complete and there are no outstanding deficiencies.

A. FY 2023 Updated Performance Data

Table 2 contains the updated performance data for the FY 2023 cohort, which shows that FDA met or exceeded a majority of the goals for that cohort.

Table 2. GDUFA III FY 2023 Updated Performance Goal Results

GDUFA III FY 2023 Updated Performance Goals by Submission Type	Review Time Goal	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Action§	Imminent Action Potential Range
Original ANDA Goals						
Standard Original ANDA Submissions	10/30¶ months	509 of 566	93%	86% to 93%	96%	88% to 96%
Priority Original ANDA Submissions	8/10/30 months	143 of 155	88%	85% to 88%	93%	89% to 94%
Amendment Goals						
Standard Major ANDA Amendments	8/10 months	745 of 765	93%	92% to 93%	95%	94% to 95%
Priority Major ANDA Amendments	6/8/10 months	137 of 137	93%	93% to 93%	95%	95% to 95%
Standard and Priority Minor ANDA Amendments	3 months	734 of 735	87%	87% of 87%	97%	97% of 97%
Unsolicited ANDA Amendments	Varies	718 of 731	88%	88% to 88%	--	--
PAS Goals						
Standard PAS	6/10 months	1475 of 1477	98%	98% to 98%	99%	99% to 99%
Priority PAS	4/8/10 months	111 of 111	93%	93% to 93%	94%	94% to 94%
PAS Amendment Goals						
Standard Major PAS Amendment	6/10 months	134 of 134	99%	99% to 99%	100%	100% to 100%
Priority Major PAS Amendment	4/8/10 months	6 of 6	100%	100% to 100%	100%	100% to 100%
Standard and Priority Minor PAS Amendments	3 months	227 of 227	96%	96% to 96%	97%	97% to 97%
Unsolicited PAS Amendments	Varies	10 of 10	90%	90% to 90%	--	--
DMF Goals						
Complete the Initial Completeness Assessment Review of Type II API DMFs	60 calendar days	284 of 284	99%	99% to 99%	--	--
CC Goals						
Level I CC	60 calendar days	3251 of 3251	99%	99% to 99%	--	--

GDUFA III FY 2023 Updated Performance Goals by Submission Type	Review Time Goal	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Action§	Imminent Action Potential Range
Level II CC	120 calendar days	415 of 420	96%	96% to 96%	--	--
Clarification of Ambiguities in CC Response	21 calendar days	22 of 22	100%	100% to 100%	--	--

* "Actions Complete" includes any action taken regardless of whether it met the review-time goal. Even if no new submissions come in (in the cohort year), the size of the cohort will increase as the goal type is assigned and as actions are completed in the subsequent fiscal year.

† "Percent on Time" represents the current percentage of actions FDA completed within the review-time goal.

‡ "Potential Range" represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance during the subsequent fiscal year.

§ "On Time Imminent Action" represents the current percentage of actions FDA completed within the review-time goal. Under the GDUFA III Commitment Letter, imminent action counts as meeting the goal on time.

¶ If, upon initial submission, a standard or priority original ANDA contains a certification that a site/facility listed on the Form FDA 356h is not ready for inspection, a 30-month goal date may be assigned.

B. FY 2024 Preliminary Performance Data

Table 3 contains the preliminary performance data for the FY 2024 cohort.

Table 3. GDUFA III FY 2024 Preliminary Performance Goal Results

GDUFA III FY 2024 Preliminary Performance Goals by Submission Type	Review Time Goal	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Action§	Imminent Action Potential Range
Original ANDA Goals						
Standard Original ANDA Submissions	10/30¶ months	50 of 456	96%	11% to 99%	100%	11% to 99%
Priority Original ANDA Submissions	8/10/30 months	19 of 139	95%	13% to 99%	100%	14% to 100%
Amendment Goals						
Standard Major ANDA Amendments	8/10 months	172 of 588	94%	29% to 98%	99%	29% to 99%
Priority Major ANDA Amendments	6/8/10 months	45 of 106	94%	42% to 97%	98%	42% to 99%
Standard and Priority Minor ANDA Amendments	3 months	508 of 808	86%	57% to 91%	96%	62% to 98%
Unsolicited ANDA Amendments	Varies	340 of 530	82%	57% to 88%	--	--
PAS Goals						
Standard PAS	6/10 months	1040 of 1614	99%	64% to 99%	99%	64% to 99%

GDUFA III FY 2024 Preliminary Performance Goals by Submission Type	Review Time Goal	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Action§	Imminent Action Potential Range
Priority PAS	4/8/10 months	69 of 91	99%	75% to 99%	99%	75% to 99%
PAS Amendment Goals						
Standard Major PAS Amendment	6/10 months	57 of 89	95%	62% to 97%	96%	62% to 98%
Priority Major PAS Amendment	4/8/10 months	9 of 13	100%	69% to 100%	100%	69% to 100%
Standard and Priority Minor PAS Amendments	3 months	187 of 237	96%	78% to 97%	98%	78% to 98%
Unsolicited PAS Amendments	Varies	13 of 21	92%	57% to 95%	--	--
DMF Goals						
Complete the Initial Completeness Assessment Review of Type II API DMFs	Within 60 calendar days of the later of the date of DMF submission or DMF Fee payment	358 of 358	99%	99% to 99%	--	--
CC Goals						
Level I CC	Within 60 calendar days of submission date	2664 of 2980	99%	89% to 99%	--	--
Level II CC	Within 120 calendar days of submission date	323 of 448	99%	73% to 99%	--	--
Clarification of Ambiguities in CC Response	Within 21 calendar days of request receipt	16 of 16	94%	94% to 94%	--	--

* "Actions Complete" includes any action taken regardless of whether it met the review-time goal. Even if no new submissions come in (in the cohort year), the size of the cohort will increase as the goal type is assigned and as actions are completed in the subsequent fiscal year.

† "Percent on Time" represents the current percentage of actions FDA completed within the review-time goal.

‡ "Potential Range" represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance.

§ "On Time Imminent Action" represents the current percentage of actions FDA completed within the review-time goal. Under the GDUFA III Commitment Letter, imminent action counts as meeting the goal.

¶ If, upon initial submission, a standard or priority original ANDA contains a certification that a site/facility listed on the Form FDA 356h is not ready for inspection, a 30-month goal date may be assigned.

III. GDUFA Program Enhancement and Other Goals

Program enhancement goals differ from review goals in that "review goals" directly pertain to the review of a generic drug submission, whereas "program enhancements" are goals for activities that support generic drug review and approval in general. An example of a "review goal" is FDA's goal to review and act on 90 percent of standard original ANDAs within 10 months of the date of ANDA submission. Examples of "program enhancements" are FDA's Pre-Submission Meeting goals found in this section. Pre-Submission Meetings are not directly related to the review of a generic drug submission; however, it is important that FDA meet its Pre-Submission Meeting goals and other program enhancements to support efficient reviews and more generic drug approvals.

Under GDUFA III, FDA continues to leverage program enhancement goals to improve its predictability and transparency, promote the efficiency and effectiveness of the assessment process, minimize the number of assessment cycles necessary for approval, increase the overall rate of approval, and facilitate greater access to generic drug products. Table 4 reflects the program enhancement goals for FYs 2023 to 2027 described in sections II to VII of the GDUFA III Commitment Letter.

Table 4. GDUFA III Program Enhancement and Other Goals for FYs 2023 to 2027[4]

GDUFA III Program Enhancement Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Assessment Classification Changes During Assessment Cycle						
FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS	Within 14 calendar days of the date of the change	--	--	--	--	--
FDA to decide whether to reclassify a major amendment or standard assessment status	Within 30 calendar days of date of FDA's receipt of the request for a teleconference	90%	90%	90%	90%	90%
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Priority Amendments	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	--	--	--	--	--
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments	Within 60 calendar days of date of FDA's receipt of the request for a reclassification	--	--	--	--	--

[4] This table has been updated from the FY 2023 GDUFA performance report to reflect the program enhancement goals expressly identified in the GDUFA III Commitment Letter.

GDUFA III Program Enhancement Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Dispute Resolution						
FDA to respond to appeals above the Division level	Within 30 calendar days of FDA's receipt of the written appeal pursuant to the applicable goal	90%	90%	90%	90%	90%
Suitability Petitions						
FDA to review and respond to suitability petitions that have been assigned a goal date	Within 6 months after completeness assessment, up to the maximum number of suitability petitions completed as described in Section III.B. of the GDUFA III Commitment Letter*	--	50%	70%	80%	90%
PSGs for Complex and Non-Complex Drug Products						
Complex products approved in new drug applications (NDAs)	Within 2 years of approval	50%	50%	50%	50%	50%
Complex products approved in NDAs	Within 3 years of approval	75%	75%	75%	75%	75%
Non-complex products approved in NDAs that contain a new chemical entity (NCE)	Within 2 years of approval	90%	90%	90%	90%	90%
PSG Teleconference and Meetings						
FDA to conduct a PSG Teleconference granted	Within 30 calendar days from receipt of request	--	--	--	--	--
FDA to grant or deny a meeting request for a Pre-Submission PSG Meeting if the applicant has not submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--	--
FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA	Within 120 calendar days from receipt of request	--	--	--	--	--
FDA to grant or deny a meeting request for a Post-Submission PSG Meeting if the applicant has submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--	--
FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA	Within 90 calendar days from receipt of request	--	--	--	--	--
Product Development Meetings						
FDA to grant or deny Product Development Meeting Requests	Within 14 calendar days from receipt of request	90%	90%	90%	90%	90%
FDA to conduct or provide written response to Product Development Meetings granted	Within 120 calendar days after the meeting is granted	90%	90%	90%	90%	90%
Unless FDA is providing a written response to satisfy the meeting goal, FDA will aspire to provide preliminary written comments	5 calendar days before the meeting	--	--	--	--	--

GDUFA III Program Enhancement Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
before each Product Development Meeting						
FDA to provide meeting minutes	Within 30 calendar days following the meeting	--	--	--	--	--
Pre-Submission Meetings						
FDA to grant or deny Pre-Submission Meeting Requests	Within 30 calendar days from receipt of request	90%	90%	90%	90%	90%
FDA to conduct Pre-Submission Meetings granted	Within 60 calendar days from receipt of request	90%	90%	90%	90%	90%
If appropriate to the purpose of the meeting, FDA to provide preliminary written comments	5 calendar days before each meeting	--	--	--	--	--
FDA to provide meeting minutes	Within 30 calendar days of the meeting	--	--	--	--	--
Mid-Cycle Review Meeting (MCRM)						
FDA to conduct a MCRM granted	Within 30 calendar days after the date the sponsor submits a meeting request	--	--	--	--	--
Enhanced Mid Cycle Review Meeting (EMCRM)						
FDA to conduct a EMCRM granted	Within 90 calendar days after issuance of the last mid-cycle DRL	--	--	--	--	--
Post-CRL Teleconference Meetings						
FDA to provide a scheduled date for a requested Post-CRL teleconference	Within 14 calendar days of the request for a teleconference	90%	90%	90%	90%	90%
FDA to conduct requested Post-CRL teleconferences on the FDA-proposed date	Within 30 calendar days of the receipt of the written request	90%	90%	90%	90%	90%
Post-CRL Scientific Meetings						
FDA to grant or deny Post-CRL scientific meeting requests	Within 14 calendar days from receipt of request	--	--	--	--	--
FDA to conduct or provide written response to Post-CRL scientific meeting granted	Within 90 calendar days of granting request	--	--	--	--	--
DMF First Cycle Review Deficiency						
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days from receipt of request	--	--	--	--	--
Foreign Regulators						
FDA to issue written communication conveying the current compliance status for establishment physically located in the United States that has been included as part of a marketing application submitted to a foreign regulator	Within 30 calendar days of date of receipt of request	--	--	--	--	--

GDUFA III Program Enhancement Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Post-Warning Letter (WL) Meetings						
FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting	Within 30 calendar days from receipt of request	--	50%	70%	80%	80%
Re-Inspection						
FDA agrees to notify the facility of the Agency's decision to re-inspect	Within 30 calendar days from receipt of request	--	--	--	--	--
If re-inspection is granted, FDA to re-inspect the facility:						
Domestic	Within 4 months of the letter to the facility indicating FDA's intent to reinspect	--	60%	70%	80%	80%
International	Within 8 months of the letter to the facility indicating FDA's intent to reinspect	--	60%	70%	80%	80%

* As described in Section III.B. of the GDUFA III Commitment Letter, the maximum number of suitability petitions to which FDA intends to review and respond increases each year of GDUFA III.

A. FY 2023 Updated Program Enhancement and Other Goal Results

Table 5 represents FDA's FY 2023 updated program enhancement goal results, which shows that FDA met or exceeded almost all of the goals for the FY 2023 cohort.

Table 5. GDUFA III FY 2023 Updated Program Enhancement and Other Goal Results

GDUFA III FY 2023 Updated Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
Assessment Classification Changes During Assessment Cycle					
FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS	Within 14 calendar days of the date of the change	--	50 of 50	100%	100% to 100%
FDA to decide whether to reclassify a major amendment or standard assessment status	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	90%	98 of 98	97%	97% to 97%

GDUFA III FY 2023 Updated Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Priority Amendments	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	--	11 of 11	91%	91% to 91%
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments	Within 60 calendar days of date of FDA's receipt of the request for a reclassification	--	44 of 50	98%	86% to 98%
Dispute Resolution					
FDA to respond to appeals above the Division level	Within 30 calendar days of FDA's receipt of the written appeal pursuant to the applicable goal	90%	4 of 4	100%	100% to 100%
Suitability Petitions					
FDA to review and respond to suitability petitions that have been assigned a goal date	Within 6 months after completeness assessment, up to the maximum number of suitability petitions completed as described in Section III.B. of the GDUFA III Commitment Letter	--	--	--	--
PSGs for Complex and Non-Complex Drug Products					
Complex products approved in NDAs	Within 2 years of approval	50%	--	--	--
Complex products approved in NDAs	Within 3 years of approval	75%	--	--	--
Non-complex products approved in NDAs that contain an NCE	Within 2 years of approval	90%	35 of 35	100%	100%-100%
PSG Teleconference and Meetings					
FDA to conduct a PSG Teleconference granted	Within 30 calendar days from receipt of request	--	2 of 2	100%	100% to 100%
FDA to grant or deny a meeting request for a Pre-Submission PSG Meeting if the applicant has not submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--
FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA	Within 120 calendar days of receipt of request	--	--	--	--

GDUFA III FY 2023 Updated Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
FDA to grant or deny a meeting request for a Post-Submission PSG Meeting if the applicant has submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--
FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA	Within 90 calendar days of receipt of request	--	--	--	--
Product Development Meetings					
FDA to grant or deny Product Development Meeting Requests	Within 14 calendar days from receipt of request	90%	99 of 99	100%	100% to 100%
FDA to conduct or provide written response to Product Development Meetings granted	Within 120 calendar days after the meeting is granted	90%	71 of 71	100%	100% to 100%
Unless FDA is providing a written response to satisfy the meeting goal, FDA to aspire to provide preliminary written comments before each Product Development Meeting	5 calendar days before the meeting	--	44 of 44	100%	100% to 100%
FDA to provide meeting minutes	Within 30 calendar days following the meeting	--	30 of 30	100%	100% to 100%
Pre-Submission Meetings					
FDA to grant or deny Pre-Submission Meeting Requests	Within 30 calendar days from receipt of request	90%	9 of 9	89%	89% to 89%
FDA to conduct Pre-Submission Meetings granted	Within 60 calendar days from receipt of request	90%	--	--	--
If appropriate to the purpose of the meeting, FDA to provide preliminary written comments	5 calendar days before each meeting	--	--	--	--
FDA to provide meeting minutes	Within 30 calendar days of the meeting	--	--	--	--
Mid-Cycle Review Meeting (MCRM)					
FDA to conduct a MCRM granted	Within 30 calendar days after the date the sponsor submits a meeting request	--	1 of 1	100%	100% to 100%
Enhanced Mid Cycle Review Meeting (EMCRM)					

GDUFA III FY 2023 Updated Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
FDA to conduct a EMCRM granted	Within 90 calendar days after issuance of the last mid-cycle DRL	--	1 of 1	100%	100% to 100%
Post-CRL Teleconference Meetings					
FDA to provide a scheduled date for a requested Post-CRL teleconference	Within 14 calendar days of the request for a teleconference	90%	64 of 64	95%	95% to 95%
FDA to conduct requested Post-CRL teleconferences on the FDA-proposed date	Within 30 calendar days of the receipt of the written request	90%	64 of 64	91%	91% to 91%
Post-CRL Scientific Meetings					
FDA to grant or deny Post-CRL scientific meeting requests	Within 14 calendar days from receipt of the request	90%	20 of 20	95%	95% to 95%
FDA to conduct or provide written response to Post-CRL scientific meeting granted	Within 90 calendar days of granting request	90%	14 of 14	100%	100% to 100%
DMF First Cycle Review Deficiency					
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days from receipt of request	--	4 of 4	100%	100% to 100%
Foreign Regulators					
FDA to issue written communication conveying the current compliance status for establishment physically located in the United States that has been included as part of a marketing application submitted to a foreign regulator	Within 30 calendar days of date of receipt of request	--	22 of 22	100%	100% to 100%
Post-WL Meetings					
FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting	Within 30 calendar days from receipt of request	--	3 of 3	N/A	N/A
Re-Inspection					
FDA agrees to notify the facility of the Agency's decision to re-inspect	Within 30 calendar days from receipt of request	--	5 of 5	N/A	N/A
If re-inspection is granted, FDA to re-inspect the facility:					

GDUFA III FY 2023 Updated Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
Domestic	Within 4 months of the letter to the facility indicating FDA's intent to reinspect	--	--	--	--
International	Within 8 months of the letter to the facility indicating FDA's intent to reinspect	--	4 of 4	100%	100% to 100%

* "Actions Completed" includes any action taken regardless of whether it met the review-time goal.
† "Percent on Time" represents the current percentage of actions FDA completed within the review-time goal.
‡ "Potential Range" represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance during the subsequent fiscal year.

B. FY 2024 Preliminary Program Enhancement and Other Goal Results

Table 6 represents FDA's FY 2024 preliminary program enhancement goal results, which shows that FDA met or exceeded a majority of the goals for the FY 2024 cohort.

Table 6. GDUFA III FY 2024 Preliminary Program Enhancement and Other Goal Results

GDUFA III FY 2024 Preliminary Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
Assessment Classification Changes During Assessment Cycle					
FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority during an assessment cycle of an ANDA or PAS	Within 14 calendar days of the date of the change	--	16 of 16	100%	100% to 100%
FDA to decide whether to reclassify a major amendment or standard assessment status	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	90%	85 of 92	99%	91% to 99%
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Priority Amendments	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	--	21 of 21	100%	100% to 100%
FDA to decide on a request for reclassification of a Facility-Based Major CRL Amendment for Standard Amendments	Within 60 calendar days of date of FDA's receipt of the request for a reclassification	--	125 of 126	99%	97% to 99%

GDUFA III FY 2024 Preliminary Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
Dispute Resolution					
FDA to respond to appeals above the Division level	Within 30 calendar days of FDA's receipt of the written appeal pursuant to the applicable goal	90%	4 of 5	100%	80% to 100%
Suitability Petitions					
FDA to review and respond to suitability petitions that have been assigned a goal date	Within 6 months after completeness assessment, up to a maximum of 50 suitability petitions completed	50%	78 of 103	97%	74% to 98%
PSGs for Complex and Non-Complex Drug Products					
Complex products approved in NDAs	Within 2 years of approval	50%	--	--	--
Complex products approved in NDAs	Within 3 years of approval	75%	--	--	--
Non-complex products approved in NDAs that contain an NCE	Within 2 years of approval	90%	19 of 19	100%	100% to 100%
PSG Teleconference and Meetings					
FDA to conduct a PSG Teleconference granted	Within 30 calendar days from receipt of request	--	1 of 1	100%	100% to 100%
FDA to grant or deny a meeting request for a Pre-Submission PSG Meeting if the applicant has not submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--
FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA	Within 120 calendar days of receipt	--	--	--	--
FDA to grant or deny a meeting request for a Post-Submission PSG Meeting if the applicant has submitted an ANDA	Within 14 calendar days from receipt of request	--	--	--	--
FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA	Within 90 calendar days of receipt of request	--	--	--	--
Product Development Meetings					
FDA to grant or deny Product Development Meeting Requests	Within 14 calendar days from receipt of request	90%	85 of 85	99%	99% to 99%
FDA to conduct or provide written response to Product Development Meetings granted	Within 120 calendar days after the meeting is granted	90%	58 of 69	100%	84% to 100%
Unless FDA is providing a written response to satisfy the meeting goal, FDA to aspire to provide preliminary written comments	5 calendar days before the meeting	--	29 of 42	100%	69% to 100%

GDUFA III FY 2024 Preliminary Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
before each Product Development Meeting					
FDA to provide meeting minutes	Within 30 calendar days following the meeting	--	15 of 20	100%	75% to 100%
Pre-Submission Meetings					
FDA to grant or deny Pre-Submission Meeting Requests	Within 30 calendar days from receipt of request	90%	3 of 3	100%	100% to 100%
FDA to conduct Pre-Submission Meetings granted	Within 60 calendar days of receipt of request	90%	--	--	--
If appropriate to the purpose of the meeting, FDA to provide preliminary written comments	5 calendar days before each meeting	--	--	--	--
FDA to provide meeting minutes	Within 30 calendar days of the meeting	--	--	--	--
Mid-Cycle Review Meeting (MCRM)					
FDA to conduct an MCRM granted	Within 30 calendar days after the date the sponsor submits a meeting request	--	4 of 4	100%	100% to 100%
Enhanced Mid Cycle Review Meeting (EMCRM)					
FDA to conduct an EMCRM granted	Within 90 calendar days after issuance of the last mid-cycle DRL	--	4 of 4	100%	100% to 100%
Post-CRL Teleconference Meetings					
FDA to provide a scheduled date for a requested Post-CRL teleconference	Within 14 calendar days of the request for a teleconference	90%	70 of 70	89%	89% to 89%
FDA to conduct requested Post-CRL teleconferences on the FDA-proposed date	Within 30 calendar days of the receipt of the written request	90%	68 of 70	96%	91% to 96%
Post-CRL Scientific Meetings					
FDA to grant or deny Post-CRL scientific meeting requests	Within 14 calendar days of the request for a teleconference	--	14 of 14	93%	93% to 93%
FDA to conduct or provide written response to Post-CRL scientific meeting granted	Within 90 calendar days of the receipt of the written request	--	6 of 10	100%	60% to 100%
DMF First Cycle Review Deficiency					
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days from receipt of request	--	1 of 1	100%	100% to 100%
Foreign Regulators					

GDUFA III FY 2024 Preliminary Performance	Review Goal	Goal	Actions* Completed	Percent on† Time	Potential‡ Range
FDA to issue written communication conveying the current compliance status for establishment physically located in the United States that has been included as part of a marketing application submitted to that foreign regulator	Within 30 calendar days of date of receipt of request	--	25 of 25	100%	100% to 100%
Post-WL Meetings					
FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting	Within 30 calendar days from receipt of request	50%	5 of 5	80%	80% - 80%
Re-Inspection					
FDA agrees to notify the facility of the Agency's decision to re-inspect	Within 30 calendar days from receipt of request	--	--	--	--
If re-inspection is granted, FDA to re-inspect the facility:					
Domestic	Within 4 months of the letter to the facility indicating FDA's intent to reinspect	60%	--	--	--
International	Within 8 months of the letter to the facility indicating FDA's intent to reinspect	60%	--	--	--

* "Actions Complete" includes any action taken regardless of whether it met the review-time goal.

† " Percent on Time" represents the current percentage of actions FDA completed within the review-time goal.

‡ **"**Potential Range" represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance during the subsequent fiscal year.

IV. Additional Activities to Implement GDUFA Commitments

FDA is committed to meeting the performance goals and enhancements previously described in this report. This section highlights several additional measures taken by FDA that are above and beyond the specific commitments.

A. Policy Document Highlights

In FY 2024, FDA published many guidances for industry[5] and Manuals of Policies and Procedures (MAPPs)[6] that provide important information for generic drug developers. These efforts support development of high-quality applications, streamlined application assessments, and ultimately can help facilitate faster generic drug approvals. In FY 2024, FDA published the following guidances for industry and MAPPs:

- Draft guidance for industry: *Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry* (October 2023)
- Draft guidance for industry: *Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry* (December 2023)
- Draft guidance for industry: *Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry* (December 2023)
- Final guidance for industry: *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene* (December 2023)
- Draft guidance for industry: *Requests for Reconsideration at the Division Level Under GDUFA* (October 2024)
- Final guidance for industry: *ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs* (January 2024)
- Final guidance for industry: Revising ANDA Labeling Following Revision of the RLD Labeling (January 2024)
- Draft guidance for industry: *Handling and Retention of Bioavailability and Bioequivalence Testing Samples* (March 2024)
- Final guidance for industry: *Controlled Correspondence Related to Generic Drug Development* (March 2024)
- Draft guidance for industry: *Data Integrity for In Vivo Bioavailability and Bioequivalence Studies* (April 2024)

[5] FDA's guidance documents may be accessed at www.fda.gov/regulatoryinformation/guidances/.

[6] These MAPPs may be accessed at www.fda.gov/about-fda/center-drug-evaluation-and-research/cder-manual-policies-procedures-mapp.

- Draft guidance for industry: *Content and Format of Composition Statement and Corresponding Statement of Ingredients in Labeling in NDAs and ANDAs* (April 2024)
- Final guidance for industry: *Electronic Submission of Expedited Safety Reports from IND - Exempt BA/BE Studies* (April 2024)
- Final guidance for industry: *Facility Readiness: Goal Date Decisions Under GDUFA* (June 2024)
- Final guidance for industry: *Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA* (August 2024)
- Final guidance for industry: *ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA* (September 2024)
- Revised final guidance for industry: *Control of Nitrosamine Impurities in Human Drugs* (September 2024)
- MAPP 5200.14 Revision 1: *Filing Review of Abbreviated New Drug Applications* (October 2023)
- MAPP 5241.3 Revision 1: *Good Abbreviated New Drug Application Assessment Practices* (October 2023)
- MAPP 5230.3 Revision 2: *Generic Drug Labeling Revisions Under Section 505(j)(10) of the Federal Food, Drug, and Cosmetic Act* (December 2023)
- MAPP 5021.5 Revision 1: *Assessment of Facility-Based Deficiency Major-to-Minor Reclassification Requests* (January 2024)
- MAPP 5015.14: *Prioritization of Solicited DMF Amendments Associated With ANDAs or PASs not Concurrently Under Assessment* (May 2024)

These guidances and MAPPs have helped bring greater transparency to the ANDA assessment and approval process and have provided industry with a range of useful information to assist them in developing generic drug products and in improving the overall quality of their ANDA submissions, supporting efficient assessment and timely approval of ANDAs. For example, in April 2024, FDA published the draft guidance for industry "Data Integrity for In Vivo Bioavailability and Bioequivalence Studies" providing recommendations to applicants and testing site management on achieving and maintaining data integrity[7] for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drugs, NDAs, and ANDAs, and the bioanalytical portion of clinical pharmacologic studies supporting Center for Drug Evaluation and Research (CDER)-regulated biologic license applications, as well as amendments and supplements to these applications.

[7] As used in this April 2024 draft guidance, *data integrity* refers to the accuracy, completeness, and reliability of data. Accurate, complete, and reliable data should be attributable to the person generating the data, legible, contemporaneously recorded, original or a true copy, and accurate. Draft guidance for Industry "Data Integrity for In Vivo Bioavailability and Bioequivalence Studies" (April 2024) at page 2.

In recent years, FDA has observed data integrity concerns during the inspection of clinical testing sites and analytical testing sites and during the assessment of BA and BE study data submitted in support of applications. Data integrity concerns can impact application acceptance for filing, assessment, regulatory actions, and approval, as well as post-approval actions, such as therapeutic equivalence ratings. FDA published this guidance to help applicants and testing sites achieve and maintain data integrity throughout a product's data lifecycle.

In FY 2024, FDA continued to engage in other efforts to increase transparency and enhance communications with generic drug developers. For example, to support the Agency's implementation of GDUFA III, FDA published multiple policy documents to highlight program changes, enhancements, and new information about GDUFA III for current and prospective ANDA applicants and others interested in generic drug development and regulation. These publications included multiple new and revised guidances and new and revised Manuals of Policy and Procedure (MAPPs) addressing significant performance goals and program enhancements under GDUFA III. FDA has now published all the guidances and MAPPs delineated in Section IX of the GDUFA III Commitment Letter, including the MAPPs FDA committed to issue in FY 2024.

B. Suitability Petition Highlights

Certain differences between a reference listed drug (RLD) and a proposed generic drug product may be permitted in an ANDA if these differences are the subject of an approved suitability petition submitted under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and pursuant to 21 CFR 314.93.

Under the GDUFA III Commitment Letter, FDA agreed to conduct a completeness assessment for suitability petitions submitted in FYs 2024 to 2027. Table 7 reflects the timeframe for suitability petition completeness assessments.

Table 7. GDUFA III Timeframe for Suitability Petition Completeness Assessments

GDUFA III Suitability Petition	Timeline
Conduct completeness assessment for suitability petitions	21 calendar days after the date of petition submission
If an information request (IR) is issued as part of the completeness assessment and the petitioner submits a response, finish completeness assessment	21 calendar days after the date of receipt of the IR response

Beginning in FY 2024, FDA committed to reviewing and responding to suitability petitions that have been assigned a goal date. Table 8 reflects the suitability petition goals as described in section III of the GDUFA III Commitment Letter.

Table 8. GDUFA III Suitability Petition Goals

GDUFA III Suitability Petition Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Review and respond to suitability petitions that have been assigned a goal date	6 months after completeness assessment	--	50%*	70%†	80%‡	90%§

* Up to a maximum of 50 suitability petitions completed
† Up to a maximum of 70 suitability petitions completed
‡ Up to a maximum of 80 suitability petitions completed
§ Up to a maximum of 90 suitability petitions completed

In FY 2024, 103 suitability petitions were submitted to FDA and assigned goal dates.

Table 9 provides information on the suitability petition completeness assessments conducted in FY 2024.

Table 9. FY 2024 Suitability Petition Completeness Assessments

GDUFA III Suitability Petition	Timeline	Actions* Completed	Percent on Time
Conduct completeness assessment for suitability petitions	21 days after the date of petition submission	103	100%
If an IR is issued as part of the completeness assessment and the petitioner submits a response	21 days after the date of receipt of the IR response	17	100%

In FY 2024, FDA completed 78 suitability petitions. Table 10 reports the percentage of suitability petitions completed within 6 months after FDA had completed the completeness assessment.

Table 10. FY 2024 Suitability Petition Goal Results

GDUFA III FY 2024 Preliminary Suitability Petition Goal Results	Review Goal	Goal	Actions* Completed	Percent on Time	Potential Range
Review and respond to suitability petitions that have been assigned a goal date	6 months after completeness assessment up to a maximum of 50 suitability petitions completed	50%	78	97%	74%-98%

C. GDUFA Regulatory Science and Research Highlights

1. Outreach Highlights

In FY 2024, as shown in Table 11, FDA hosted or co-hosted 13 meetings, webinars, and public workshops to promote transparency through regulatory and scientific outreach and to facilitate enhanced communications through dialogue with academic experts and pharmaceutical industry representatives on numerous issues impacting generic drugs.

Table 11. FDA's GDUFA-Related Meetings, Webinars, and Public Workshops in FY 2024

GDUFA-Related Meetings, Webinars, and Public Workshops	Date Held
FDA and Center for Research on Complex Generics Co-Hosted Workshop: Advances in Physiologically Based Pharmacokinetic (PBPK) Modeling and its Regulatory Utility for Oral Drug Product Development[8] This public workshop facilitated a discussion of the challenges to, experiences of, and advances to the development of PBPK absorption modeling to support the establishment of bio-predictive in vitro testing (e.g., dissolution) and to address risks associated with the extrapolation of BE in various contexts, such as from a fasting to a fed state, from subjects with normal to elevated gastric pH, for a biopharmaceutics classification system (BCS)-based biowaiver, assessing BE in pediatrics and with other risk-based BE assessments for oral products. This workshop included live presentations and interactive panel discussions for all attendees (including virtual attendees), as well as additional workshop activities for in-person attendees, including round-table discussions with deliberations among industry and academic and regulatory experts on a selection of the most important topics and key issues that will influence best practices in this field.	10/12/2023
FDA and Center for Research on Complex Generics Co-Hosted Workshop: Characterization of Complex Excipients and Formulations[9] This public workshop facilitated a discussion of the scientific principles and practical considerations that inform current FDA thinking about the characterization of complex excipients and formulations to support generic product development and assessment. The workshop provided an update on the progress of research activities supported by the GDUFA science and research program, explored challenging issues that would benefit from a broader discussion, identified areas that need further research, and discussed opportunities for coordination and collaboration among FDA, the generic drug industry, academic institutions, excipient vendors, contract research organizations, consultants, and other stakeholders.	12/07/2023 – 12/08/2023
FDA SBIA Webinar: A Deep Dive: FDA's Model-Integrated Evidence (MIE) Industry Meeting Pilot Program for Generic Drugs[10]	01/18/2024

[8] https://www.complexgenerics.org/education-training/advances-in-pbpk-modeling-and-its-regulatory-utility-for-oral-drug-product-development/

[9] https://www.complexgenerics.org/education-training/characterization-of-complex-excipients-formulations/

[10] https://www.fda.gov/drugs/news-events-human-drugs/deep-dive-fdas-model-integrated-evidence-mie-industry-meeting-pilot-program-generic-drugs-01182024

GDUFA-Related Meetings, Webinars, and Public Workshops	Date Held
This public webinar facilitated a discussion of the MIE meeting pilot program, including considerations and expectations when meeting with FDA under the Industry Meeting Pilot MIE Program and the types of potential topics that will be granted under the pilot program.	
FDA SBIA Webinar: Expanding Generic Drug Access Through International Engagements[11] This public webinar facilitated a discussion of the FDA and European Medicines Agency Parallel Scientific Advice Pilot Program for complex generics/hybrid products, addressing currently available international engagement opportunities. This included a panel discussion on topics pertinent to the generic drug industry and a live Q&A session with FDA and other global regulatory experts.	02/28/2024
FDA and Center for Research on Complex Generics Co-Hosted Workshop: Drug-Device Combination Products: Updates and Challenges with Demonstrating Generic Substitutability[12] This public workshop facilitated a discussion of topics relevant to generic user interface development, comparative user interface assessment challenges, therapeutic equivalence/generic substitutability considerations for generic drug-device combination products (DDCPs), and DDCP device performance, manufacturing, and sustainability across the product lifecycle.	03/14/2024 – 03/15/2024
FDA SBIA Generic Drugs Forum (GDF) 2024: Regulatory Considerations to Enhance Generic Drug Access[13] This public forum offered attendees the opportunity to hear from FDA subject-matter experts from every part of the generic drug assessment program. The goal of the forum was to provide information to aid potential and current applicants by offering practical advice and taking a deep dive into the ANDA assessment process.	04/10/2024 – 04/11/2024
FDA/PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative (GBHI): 6th International Workshop[14] This public workshop was intended to support the process of global harmonization via scientific discussion among international stakeholders. The first GBHI Conference, held in March 2015, and all subsequent conferences have been successful due to the active participation and presentation by speakers and participants from global academia, industry, and regulatory agencies. The GBHI workshop provided a platform for scientists from the pharmaceutical industry and academia to exchange their experiences and views with regulators and to engage in active scientific discussions. The GBHI workshop location alternates between Amsterdam, the Netherlands, and the United States.	04/16/2024 – 04/17/2024
FDA/PQRI Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development[15]	04/18/2024

[11] https://www.fda.gov/drugs/news-events-human-drugs/expanding-generic-drug-access-through-international-engagements-02282024

[12] https://www.complexgenerics.org/education-training/drug-device-combination-products-updates-and-challenges-with-demonstrating-generic-substitutability/

[13] https://sbiaevents.com/gdf2024/

[14] https://www.fda.gov/drugs/news-events-human-drugs/pqrieufeps-global-bioequivalence-harmonisation-initiative-gbhi-6th-international-workshop-04162024

[15] https://www.fda.gov/drugs/news-events-human-drugs/pqri-workshop-challenges-and-opportunities-modified-release-oral-drug-product-development-04182024

GDUFA-Related Meetings, Webinars, and Public Workshops	Date Held
This public workshop brought together leaders and subject matter-experts from regulatory agencies, industry, and academia to discuss critical topics related to modified release (MR) drug products for oral administration. This workshop was intended to facilitate interaction among stakeholders to review recent advances in pharmaceutical science and technology for MR drug products, discuss special topics related to demonstrating BE for generic MR products, discuss the current state of modeling approaches for the BE assessment for MR drug products to support regulatory approval, and identify factors constituting alternative in vitro approaches to support a demonstration of BE for additional strengths of MR products.	
FDA Workshop on Streamlining Drug Development and Improving Public Health through Quantitative Medicine: An Introduction to the CDER Quantitative Medicine Center of Excellence[16] This public workshop introduced the CDER Quantitative Medicine Center of Excellence, providing an overview of the scope, goals, and current state, while gaining feedback from the public on needs and opportunities in education, outreach, and policy. The newly established center is a coordinating body intended to spur innovation and foster comprehensive integration of quantitative medicine approaches to advance therapeutic medical product development and promote public health. As part of its goal to engage the drug development, research, and patient communities, the newly established center held this workshop to orient stakeholders to its mission and scope and to initiate a dialogue on opportunity areas.	04/25/2024
FDA and Center for Research on Complex Generics Co-Hosted Workshop: Considerations and Potential Regulatory Applications for a Model Master File)[17] This public workshop facilitated a discussion of the concept, scope, and operational aspects for Modern Master File implementation in regulatory submissions. The workshop engaged experts from FDA, new and generic drug developers, academic institutions, contract research organizations, consultants, and others involved in drug product development to improve FDA's understanding of the role of Modern Master Files in supporting drug product development and enhancing regulatory consistency and efficiency. The workshop allowed all interested parties to coordinate and collaborate toward the implementation of MIE to increase efficiency in drug product development and to streamline drug product approval.	05/02/2024 – 05/03/2024
FDA SBIA Webinar on Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval[18] This public webinar provided an overview of the types of Pre-ANDA meetings under GDUFA III, with specific focuses on changes and new features of Pre-Submission Meetings. FDA addressed how the redesigned scope and features of the Pre-Submission Meeting may benefit preparation of an ANDA submission and its regulatory assessment post submission, discussed a hypothetical case to illustrate how to prepare a successful Pre-Submission Meeting request, hosted a panel discussion on topics pertinent to the generic drug industry, and answered questions during a live Q&A session with FDA experts.	05/09/2024

[16] https://www.fda.gov/drugs/news-events-human-drugs/streamlining-drug-development-and-improving-public-health-through-quantitative-medicine-introduction

[17] https://www.complexgenerics.org/education-training/considerations-and-potential-regulatory-applications-for-a-model-master-file/

[18] https://www.fda.gov/drugs/news-events-human-drugs/redesigned-pre-submission-meetings-gdufa-iii-benefits-anda-submission-and-approval-05092024

GDUFA-Related Meetings, Webinars, and Public Workshops	Date Held
Fiscal Year 2024 Generic Drug Science and Research Initiatives Public Workshop[19] This hybrid (virtual and in-person) public workshop provided an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA sought this input from the generic drug industry, academia, patient advocates, professional societies, and other interested parties as part of its commitment under GDUFA III to develop an annual list of science and research initiatives specific to generic drugs. FDA considered the information from this public workshop when developing its FY 2025 GDUFA science and research priorities.	05/20/2024 – 05/21/2024
FDA SBIA Workshop on Advancing Generic Drug Development: Translating Science to Approval 2024[20] This public workshop facilitated a discussion of the GDUFA Science and Research Program's transformative impact on generic drug development, regulation, and approval. Presentations and panel discussions dissected complex scientific challenges for generic product development and assessment with FDA experts, shared insights on complex products and associated scientific issues, discussed the development of PSGs, and contextualized the value of Pre-ANDA and ANDA meeting discussions. The workshop also highlighted innovative science and cutting-edge methodologies in generic drug development both within the United States and globally.	09/24/2024 – 09/25/2024

D. Contract and Grant Highlights

Research outcomes serve as the scientific basis for the development of PSGs and specific pre-ANDA communications. Since FY 2013, FDA has awarded 236 research contracts and grants. A complete list of FY 2013 through FY 2024 awards can be found at https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The number of new and ongoing grants and contracts in GDUFA III by fiscal year is provided in Table 12.

Table 12. GDUFA III New and Ongoing Grants and Contracts by Fiscal Year

Fiscal Year	Number of External Research Contracts and Grants Awarded Using GDUFA Funds	
	New Contracts and Grants	Ongoing Contracts and Grants Receiving Funding
2023	20	25
2024	13	27

[19] https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2024-generic-drug-science-and-research-initiatives-public-workshop-05202024

[20] https://www.fda.gov/drugs/news-events-human-drugs/advancing-generic-drug-development-translating-science-approval-2024-09242024

E. FY 2024 Research Highlights

In addition to serving as the scientific basis for the development of PSGs and specific pre-ANDA communications, research outcomes from intramural and extramural research are published in peer-reviewed scientific literature and are presented and discussed at major medical and scientific meetings to facilitate the path toward generic drug product development and to contribute to general guidance development.

The FY 2024 GDUFA Science and Research Program included the following eight research areas that correspond to the eight GDUFA Science and Research Priority Initiatives for FY 2024.[21]

1. Develop Methods for Generics to Address Impurities Such as Nitrosamines
2. Enhance the Efficiency of BE Approaches for Complex Active Ingredients
3. Enhance the Efficiency of BE Approaches for Complex Dosage Forms and Formulations
4. Enhance the Efficiency of BE Approaches for Complex Routes of Delivery
5. Enhance the Efficiency of BE Approaches for Complex Drug-Device Combination Products
6. Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products
7. Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE
8. Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools

A synopsis of the research activities and accomplishments in each research program area during FY 2024 is provided in Appendix B of this report.

In addition, one example is included below that illustrates how the GDUFA science and research program's accomplishments facilitate the development of complex generics and enhance patient access to high quality, affordable generic products.

[21] A detailed description of the FY 2024 GDUFA Science and Research Priority Initiatives can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The lists of research initiatives for earlier fiscal years are also available on FDA's Generic Drug Research Priorities and Projects web page.

1. Impact Stories on GDUFA Science and Research

On December 12, 2023, FDA posted the Office of Generic Drugs-authored impact story titled "Integration of Biorelevant Pediatric Dissolution Methodology into PBPK Modeling to Predict In Vivo Performance and Bioequivalence of Generic Drugs in Pediatric Populations: A Carbamazepine Case Study."[22] The story described how FDA researchers conducted a study of the anticonvulsant medication carbamazepine to determine the dissolution of this orally administered generic tablet in the gastrointestinal fluids of pediatric patients using in vitro testing methods. Typically, the use of simulated intestinal fluid dissolving methods to test dissolution in human gastrointestinal systems are conducted with adult patients in mind. In this study, FDA researchers looked for potential differences in dissolution profiles based on gastrointestinal fluid volume, composition, and bile salt concentrations in adult and pediatric patients. This research shows that certain generic products can be substituted in pediatric patients without the need for additional BE studies.

F. FY 2024 Preliminary Research Highlights

Similar to the GDUFA I and GDUFA II Commitment Letters, FDA agreed in the GDUFA III Commitment Letter to consult with industry and the public to create an annual list of regulatory science initiatives specific to research on generic drugs.

From May 20 to 21, 2024, FDA held the FY 2024 Generic Drug Science and Research Initiatives Public Workshop, which provided an overview of the status of the generic drug science and research program and an opportunity for public input in developing the FY 2025 research priorities. Information obtained during the public workshop and other inputs (e.g., comments to the public docket) were considered in developing the FY 2025 GDUFA Science and Research Priority Initiatives.[23]

Following the public workshop, feedback and comments received at the workshop and through the docket were discussed with generic industry representatives in bi-annual meetings of the GDUFA Industry-FDA Working Group, resulting in the revision and expansion for FY 2025 of certain details within the same eight priority areas mentioned above from FY 2024. These eight priority areas are expected to remain the major focus areas of regulatory science and research throughout GDUFA III, and FDA will continue to track and report on these priority initiatives during GDUFA III. In each year of

[22] Available at https://www.fda.gov/drugs/regulatory-science-action/integration-biorelevant-pediatric-dissolution-methodology-pbpk-modeling-predict-in-vivo-performance-and.

[23] A detailed description of the FY 2024 GDUFA Science and Research Priority Initiatives can be found at www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects. The lists of research initiatives for earlier fiscal years are also available on FDA's Generic Drug Research Priorities and Projects web page.

GDUFA III, FDA may revise the list and indicate when the priority initiatives are complete.

A description of these topic areas and revised and expanded priorities is provided in the GDUFA Science and Research Priority Initiatives for FY 2025 on FDA's Generic Drug Research Priorities & Projects website.[24]

[24] See https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects.

V. Inspections Performance

FDA is committed to ensuring consistency and transparency regarding inspections.

This section satisfies the annual reporting commitment created by the GDUFA III Commitment Letter for FY 2024 to communicate final facility inspection activities for human generic drugs.

A. GDUFA III Commitments

In the GDUFA III Commitment Letter, FDA committed to include the following metrics annually as part of the fiscal year GDUFA performance reports (identified by section X(C) of the GDUFA III Commitment Letter):

1. Number of inspections conducted by domestic or foreign establishment location and inspection type (pre-approval inspection (PAI), surveillance, BE clinical and BE analytical) and facility type (finished dosage form (FDF), API);

2. Median time from beginning of the inspection to the issuance of Form FDA 483 (483), *Inspectional Observations*;[25]

3. Median time from 483 issuance to WL, Import Alert (IA), and Regulatory Meeting for inspections with final classification of Official Action Indicated (OAI) or equivalent; and

4. Median time from the date of the WL, IA, or Regulatory Meeting to the resolution of OAI status or equivalent.

FDA interprets the GDUFA III Commitment Letter as follows:

- It is limited to "GDUFA facilities," which are defined as facilities associated with an ANDA that:
    - Is approved, pending, or has a TA; or
    - Was withdrawn and/or received a complete response (CR) during the given fiscal year, unless the withdrawn or CR date precedes the inspection start date.

[25] More information about 483s can be found at www.fda.gov/ICECI/Inspections/ucm256377.htm.

- If multiple applications were covered under one unique PAI, this report counts them as one inspection.

- 483 is a list of observations of objectionable conditions issued by FDA investigators to the inspected facility's management at the conclusion of an inspection. Inspections not resulting in issuance of a 483 are excluded from paragraphs "7" and "8" of the GDUFA III Commitment Letter (section X(C)). Further, most facilities receiving a 483 are classified as Voluntary Action Indicated (VAI), and no compliance action (WL, IA, or Regulatory Meeting) is taken.

- Only PAIs of ANDAs are counted in this report. If there was a PAI of an NDA or a biologics license application in a facility that is also identified as a GDUFA facility, that PAI is not counted in this report. A PAI is not always performed at facilities named in pending applications. When performed, the PAI evaluates one or more applications pending approval with FDA. (Note that FDA may inspect facilities (1) associated with an application that are not required to self-identify under GDUFA and (2) that may not be required to register under 21 CFR part 207. Inspections of such facilities are included in the data and analysis provided below because such inspections may impact application decisions.)

- FDA conducts other types of inspections of facilities in which a conclusion of non-compliance may result in a delay or denial of application approval. Inspections other than PAIs that can also impact an application's approvability include surveillance and for-cause inspections. The result of a PAI may be a decision that an application is not approvable. Issuance of a WL, an addition to an IA, or the holding of a Regulatory Meeting, could follow other types of inspections, though not typically as a result of a PAI alone. For that reason, FDA interprets paragraphs "8" and "9" of the GDUFA III Commitment Letter (section X(C)) to apply to inspections other than PAIs.

- FDA understands paragraphs "8" and "9" of the GDUFA III Commitment Letter (section X(C)) to apply, consistent with its terms, to inspections resulting in a WL, an addition to an IA, or the holding of a Regulatory Meeting. FDA notes that there are situations in which a surveillance inspection would lead directly to a more serious enforcement action, such as a seizure, injunction, or prosecution, without a WL, IA, or Regulatory Meeting. Such rare circumstances, if they occur, would not be included.

- BE inspections have Untitled Letters issued only after an OAI inspection. An Untitled Letter is not equivalent to a WL and is not included in this report.

This report reflects progress on commitments made in connection with GDUFA III that started in FY 2023. Thus, this report does not include information about events that occurred before FY 2023 except as described below. Accordingly:

- For subparagraphs "6" and "7" of the GDUFA III Commitment Letter (section X(C)), this report includes an inspection for which the inspection ended in the reporting fiscal year, even if the inspection started before the reporting fiscal year. Multiple products/applications can be covered in one inspection assignment; these are counted as one inspection.

- For subparagraph "8" of the GDUFA III Commitment Letter (section X(C)), this report counts WLs, IAs, and Regulatory Meetings that were issued or held in the reporting fiscal year, even if they are based on an inspection for which the 483 was issued before the reporting fiscal year, provided it was issued during the period covered by the GDUFA III Commitment Letter.

- For subparagraph "9" of the GDUFA III Commitment Letter (section X(C)), this report counts resolutions of WLs, IAs, and Regulatory Meetings when the resolutions occurred in the reporting fiscal year, even if the WLs, IAs, or Regulatory Meetings were issued or held prior to the reporting fiscal year, provided they were issued or held in or after FY 2023, the effective starting year for GDUFA III reporting.

Table 13 reflects the number of FY 2024 inspections[26] conducted by domestic or international establishment locations, the inspection type (PAI, surveillance, BE clinical, and BE analytical), and facility type (FDF and API) associated with a generic application as well as the number of 483s issued with the inspections.

Table 13. Inspection Type by Location Totals

	Location			
Inspection Type	**Domestic**	**Foreign**	**Total***	**Number of 483s Issued**
PAI (API) †	4	66	70	44
PAI (API/FDF) †	5	12	17	11
PAI (FDF) †	21	56	77	51
PAI (Other) †	11	26	37	27
Surveillance (API)	24	159	183	111

[26] FDA does not include inspection classification decisions associated with inspections performed by other regulatory inspectorates, such as the European Union (EU) member state inspections that FDA may review in implementing the U.S.-EU Mutual Recognition Agreement. Such inspections are generally surveillance-only type inspections, and the inspections may have been performed and completed well before FDA requested a copy of the inspection report, which would complicate the assessment of median days to review and classification.

Surveillance (API/FDF)	16	30	46	38
Surveillance (FDF)	55	83	138	105
Surveillance (Other)	49	49	98	57
BE Clinical†	15	67	82	11
BE Analytical†	3	22	25	7

* This table may overrepresent the number of unique inspections as some inspection assignments cover both PAI and Current Good Manufacturing Practice (CGMP) inspections.
† Other inspections include facilities such as contract testing laboratories and repackagers.

Table 14 shows the median time (in calendar days) between the start of inspections and the issuance of a 483 in FY 2024.

Table 14. Median Time from Beginning of Inspection to 483 Issuance in FY 2024

User Fee Program	FY 2024 Median Time (Calendar Days)
GDUFA	5

Table 15 shows the median time (in calendar days) in FY 2024 between the issuance of a 483 and the issuance of a WL, IA, and date of a Regulatory Meeting. This includes WLs, IAs, and Regulatory Meetings that were issued or held in the reporting fiscal year, even if they were based on an inspection for which the 483 was issued before the reporting fiscal year. The same facility may receive multiple compliance actions, for example a WL and an IA, following issuance of a 483. Most surveillance inspections resulting in a 483 are classified as VAI, and no WL, IA, or Regulatory Meeting is issued or held.

Table 15. Median Time from 483 Issuance to WL, IA, and Regulatory Meeting for Inspections with Final Classification of OAI (or Equivalent) (Calendar Days)

User Fee Program	FY 2024 Median Time 483 to WL	FY 2024 Median Time 483 to IA	FY 2024 Median Time 483 to Reg. Meeting
GDUFA	187	159	169

The following table shows the median time (in calendar days) between the issuance or holding of a WL, IA, and Regulatory Meeting and OAI resolution in FY 2024. "OAI resolution" includes the time to remediate CGMP issues at a site classified as OAI and the time for FDA to re-inspect the facility to confirm whether adequate remediation has taken place. The compliance action is considered resolved when the firm has sufficiently addressed the violations or deviations to allow the site to be reclassified by FDA as VAI or No Action Indicated, and, in the case of an IA or a WL, the Agency has also removed the facility from the IA or closed the WL. This includes OAI resolution of WLs, IAs, and Regulatory Meetings that were issued or held in the reporting fiscal year. The same facility may receive more than one compliance action, for example a WL and

an IA, following issuance of a 483. The OAI finalized date is when the facility was classified as OAI and is different from the date of issuance of a WL, IA, or Regulatory Meeting.

Table 16. Median Time from Date of WLs, IAs, and Regulatory Meetings to Resolution of OAI Status (Calendar Days)

User Fee Program	FY 2024 Median Time OAI Finalized to Resolution	FY 2024 Median Time WL to OAI Resolution	FY 2024 Median Time IA to OAI Resolution	FY 2024 Median Time Reg. Meeting to OAI Resolution
GDUFA	1461	1288	1703	838

During FY 2024, there were 26 facilities that were issued a WL, IA and/or had a Regulatory Meeting with an OAI resolution occurring in or after FY 2024. Seven of these facilities were issued a WL, two were issued an IA, and 18 had Regulatory Meetings. Resolution includes the firm addressing the CGMP violations or deviations that resulted in the OAI outcome, as well as a reinspection and classification of the site as VAI or No Action Indicated, when appropriate.

Significant remediation efforts by the firm to resolve the CGMP issues at a site classified as OAI and subsequent reinspection by FDA to determine if the CGMP issues have been resolved are usually required before reclassification. It is unlikely that a regulatory action (e.g., WL, IA, or Regulatory Meeting) is taken, the firm's remediation efforts are completed, and the facility is reinspected and reclassified within a single fiscal year. In some instances, firms either chose not to remediate or never adequately remediate, and violations observed at their facilities and compliance actions indefinitely remain open.

B. Inspection Efficiency Enhancements

The Agency has implemented various changes and continues to improve how it conducts inspections to verify pharmaceutical quality; the Agency also has improved transparency and timeliness in determining regulatory outcomes from inspections.[27] In 2012, with the passage of the Food and Drug Administration Safety and Innovation Act,[28] Congress gave FDA the authority to enter into arrangements with a foreign government or an Agency of a foreign government to recognize foreign inspections after a determination that the foreign government has the capability to conduct inspections in accordance with section 809 of the FD&C Act. FDA currently has mutual recognition

[27] See www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619435.htm.

[28] www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.

agreements (MRAs)[29] with the European Union (EU), SwissMedic, and the United Kingdom (UK) that allow drug inspectors to rely upon information from drug inspections conducted within each other's borders. FDA expects to perform fewer routine surveillance inspections in foreign countries with a capable inspectorate. FDA, the EU, SwissMedic, and the UK are now implementing these MRAs related to drug quality surveillance inspections. FDA accomplished the agreed-upon goal of making a capability determination for all EU member states and UK inspectorates of human drugs, including biologicals, by July 15, 2019. As a result of that accomplishment and as provided for in the FDA-EU MRA, the EU has stopped sampling and testing U.S.-produced drug batches distributed in the EU.

C. Outreach and Facility Assessment

FDA has completed several commitments under the GDUFA III program to provide greater transparency regarding prioritization and scheduling of inspections, as well as to communicate information following inspections. These efforts include updating FDA's publicly available inspection classifications database, communicating with foreign regulatory authorities regarding the compliance status of establishments, providing information on the Agency's Risk-Based Site Selection Model, and communicating information from inspections that may impact approvability to applicants and facility owners.

As part of this commitment, upon receipt of a request by an establishment physically located in the United States that has been included as part of a marketing application submitted to a foreign regulator, FDA will issue, within 30 days of receipt of the request, a declaration to an identified foreign regulator conveying the current CGMP compliance status for the establishment.

FDA met this goal in FY 2024 by responding within 30 days of receipt to 25 requests for CGMP declarations. In addition to CGMP declarations, there are other ways that FDA is enhancing communication and transparency with foreign regulatory authorities regarding the compliance status of establishments in the United States. For example, foreign regulators can also find the CGMP status of an establishment by checking the inspection classification database[30] for the most recent inspection classification that is publicly available.

The inspection classifications database provides the most recent classifications based on FDA's final assessments following an inspection of manufacturing facilities for

[29] See www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra.

[30] See https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database.

routine surveillance purposes or sites conducting BE/BA studies. FDA updates the database weekly. Previously, the Agency updated the database every 180 days and did not include inspection classifications of sites conducting clinical BE/bioavailability studies. The Agency also updated the database to build on its progress implementing the MRA with the EU, SwissMedic, and the UK, and the database now supports inclusion of facility status information based on the classification of inspection reports from foreign regulatory authorities and indicates when a classified inspection was based on an MRA partner inspection report.

VI. Continued Enhancement of User Fee Resource Management

GDUFA III includes several commitments to ensure the sustainability of resources for the GDUFA program and to enhance the operational agility of the GDUFA program. These commitments build on the financial enhancements included in GDUFA II and continue activities in GDUFA III to ensure the optimal use of user fee resources and the alignment of staff to workload through the continued maturation and assessment of the Agency's resource capacity planning capability. This section details the status of these activities.

Table 17. FDA's Progress in Meeting the Continued Enhancement of User Fee Resource Management Commitments

Activity	Due Date/Deadline	Status
FDA to publish an implementation plan that describes how resource capacity planning and time reporting will continue to be utilized during GDUFA III. The plan will cover topics such as the continued maturation of resource capacity planning capability; the continual improvement of time reporting and its utilization in the Capacity Planning Adjustment (CPA); the integration of resource capacity planning in the Agency's resource and operational decision-making processes; and the implementation of the CPA, with a first year of adjustment for FY 2024 user fees.	By the end of the second quarter of FY 2023	FDA published the implementation plan (https://www.fda.gov/media/166677/download?attachment) on March 29, 2023.
FDA to publish annual updates on its website on the Agency's progress relative to the activities detailed in the implementation plan.	By the end of the second quarter of each subsequent fiscal year	FDA published the first annual update to the implementation plan (https://www.fda.gov/media/177222/download?attachment) on March 22, 2024.
FDA will implement the CPA under the FD&C Act for the GDUFA Program with a first year of adjustment for FY 2024 fees.	Justification for the adjustment to be published in the *Federal Register* not later than 60 days before the start of the fiscal year	FDA implemented the CPA for FY 2024 fees and included a justification for this adjustment in the *Federal Register* notice publishing FY 2024 GDUFA fees (https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024) on July 28, 2023.
FDA will document in the annual GDUFA financial report how any fee revenues derived from the CPA are being utilized.	120 days after the end of the fiscal year	GDUFA financial reports are published and posted at the following link: https://www.fda.gov/about-fda/user-fee-financial-reports/gdufa-financial-reports. The first GDUFA financial report that will contain

		updates on fee revenues adjusted under the CPA will be the FY 2024 GDUFA financial report.
By the end of FY 2025, an independent contractor to complete and publish an evaluation of the resource capacity planning capability. The evaluation findings and any related recommendations will be discussed at the FY 2026 GDUFA Five-Year Financial Plan public meeting.	Evaluation to be published by the end of FY 2025	N/A

FDA also agreed to conduct activities to evaluate the financial administration of the GDUFA program to help identify areas to enhance operational and fiscal efficiency.

Table 18. FDA's Financial Transparency and Efficiency

Activity	Due Date/Deadline	Status
FDA to publish a GDUFA Five-Year Financial Plan.	No later than the second quarter of FY 2023	FDA published the FY 2023 GDUFA Five-Year Financial Plan (www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) in April 2023.
FDA to publish updates to the GDUFA Five-Year Financial Plan.	No later than the second quarter of each subsequent fiscal year	FDA published the FY 2024 GDUFA Five-Year Financial Plan Update (www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans) in April 2024
FDA to convene a public meeting to discuss the GDUFA Five-Year Financial Plan, along with the Agency's progress in implementing modernized time reporting and resource management planning.	No later than the third quarter of each fiscal year starting in FY 2024	FDA held a public meeting on Financial Transparency and Efficiency of GDUFA (https://www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act) on June 6, 2024.

VII. FY 2024 Performance Report Metrics

In the GDUFA III Commitment Letter, FDA committed to publish monthly and quarterly performance metrics on its website. These metrics can be found at www.fda.gov/industry/generic-drug-user-fee-amendments/enhanced-accountability-reporting. FDA also committed to publishing more performance metrics in its annual GDUFA performance reports.

Table 19 summarizes FDA's GDUFA III commitment to promote accountability and transparency by providing the mean and median approval times for generic drug reviews for the FYs 2023-2027 receipt cohorts. These metrics include only applications approved or tentatively approved at the time this report was prepared. In future reports to Congress, these metrics will be revised to include applications that are approved or tentatively approved in subsequent fiscal years. Thus, the current numbers are a measure of both the earliest and fastest submissions reaching approval. The approval times and numbers of cycles will increase with each re-analysis of the cohort. These re-analyses will be presented in future reports to Congress.

Table 19. Mean and Median Approval Times for Generic Drug Reviews

GDUFA III	FY 2023	FY 2024
Receipt Cohort		
Mean Approval Time (Calendar Days)	408	294
Median Approval Time (Calendar Days)	405	301
First Cycle Mean Approval Time (Calendar Days)	360	294
First Cycle Median Approval Time (Calendar Days)	348	301
Mean Tentative Approval Time (Calendar Days)	420	--
Median Tentative Approval Time (Calendar Days)	418	--
First Cycle Mean Tentative Approval Time (Calendar Days)	370	--
First Cycle Median Tentative Approval Time (Calendar Days)	341	--
Mean Number of ANDA Assessment Cycles to Approval	1	1
Median Number of ANDA Assessment Cycles to Approval	1	1
Mean Number of ANDA Assessment Cycles to Tentative Approval	2	--
Median Number of ANDA Assessment Cycles to Tentative Approval	1	--
Missed Goal Date for Original ANDAs by More Than 6 months	7	--
Missed Goal Date for Original ANDAs by More Than 9 months	5	--
Missed Goal Date for Original ANDAs by More Than 12 months	2	--

Per the GDUFA III Commitment Letter, FDA also committed to reporting on the following metrics annually in its fiscal year GDUFA performance reports.

Per section X.C. of the GDUFA III Commitment Letter, Tables 20 and 21 summarize FDA's commitment to publish other metrics not already included in this report.

Table 20. FY 2024 Fiscal Year Performance Report Metrics

GDUFA III	FY 2023	FY 2024
Application Receipt		
Number of applications received	627	572
Number of applications refused to receive	33	18
Average time to receipt decision (i.e., number of calendar days)	39	39
ANDA Review		
Number of ANDA applications received by FDA for standard assessment	492	436
Number of ANDA applications received by FDA for priority assessment	135	136
Percentage of ANDA proprietary name requests reviewed within 180 days of receipt	92%	100%
Suitability Petitions		
Beginning in FY 2024, number of suitability petitions submitted and assigned a goal	--	103
Beginning in FY 2024, number of suitability petitions completed within 6 months after FDA completed the completeness assessment	--[31]	76
Beginning in FY 2024, percent of suitability petitions completed within 6 months after FDA completed the completeness assessment	--	97%
Number of citizen petitions to determine whether a listed drug has been voluntarily withdrawn from sale for reasons of safety or effectiveness pending a substantive response for more than 270 days from the date of receipt	5	2
DMF		
Number of DMF First Adequate Letters issued status (or equivalent)	301	394
DMF Email Exchanges		
Number of initial (first cycle) email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in DMF deficiency letters	39	61
Number of follow-up email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in follow-up cycle DMF deficiency letters	8	9

[31] Petitions submitted prior to FY 2024 did not receive goal dates, and prior to FY 2024, FDA did not have a goal for the maximum amount of petitions to complete within 6 months after completeness assessment. Per the GDUFA III Commitment Letter, FDA worked in FY 2023 to review and respond to pending suitability petitions, closing 102 petitions in that fiscal year.

Table 21. GDUFA Meeting Management Initiatives

GDUFA III		FY 2023	FY 2024
FDA to grant or deny **Product Development Meeting** Requests within 14 calendar days from receipt of request*	Meetings Requested	99	85
	Meetings Granted	71	69
	Meetings Denied	28	16
	Meetings Conducted	71	58
FDA to grant or deny **Pre-Submission Meeting** Requests within 30 calendar days from receipt of request*	Meetings Requested	9	3
	Meetings Granted	0	0
	Meetings Denied	9	3
	Meetings Conducted	0	0
FDA to grant or deny a meeting request for a **Pre-Submission PSG Meeting** if the applicant within 14 days after receipt of the request has not submitted an ANDA*	Meetings Requested	0	0
	Meetings Granted	0	0
	Meetings Denied	0	0
	Meetings Conducted	0	0
FDA to conduct granted **PSG teleconferences** within 30 days of receipt*	Teleconference Requested	2	1
	Teleconference Granted	2	1
	Teleconference Denied	0	0
	Teleconference Conducted	2	1
FDA to grant or deny a meeting request for a **Post-Submission PSG Meeting** if the applicant has submitted an ANDA within 14 days after receipt of the request*	Meetings Requested	0	0
	Meetings Granted	0	0
	Meetings Denied	0	0
	Meetings Conducted	0	0
FDA to grant or deny a meeting request for an **MCRM***	Meetings Requested	1	6
	Meetings Granted	1	4
	Meetings Denied	0	2
	Meetings Conducted	1	4
FDA to conduct an **EMCRM** within 90 calendar days after issuance of the last mid-cycle DRL*	Meetings Requested	1	4
	Meetings Granted	0	4
	Meetings Denied	1	0
	Meetings Conducted	0	4
FDA to provide a scheduled date for a requested **Post-CRL teleconference** within 14 calendar days of the request for a teleconference*	Teleconferences Requested	64	70
	Teleconferences Granted	53	45
	Teleconferences Denied	11	25
	Teleconferences Conducted	53	44
FDA to grant or deny **Post-CRL scientific meeting** requests within 14 days after receipt of the request*	Meetings Requested	20	14
	Meetings Granted	14	10
	Meetings Denied	6	4
	Meetings Conducted	14	20
FDA to strive to grant **DMF first cycle assessment deficiency teleconferences**	Teleconferences Requested	4	1
	Teleconferences Granted	4	1
	Teleconferences Denied	0	0
	Teleconferences Conducted	0	0
	Email exchanges in lieu of Teleconferences	39 initial	61 initial

GDUFA III		FY 2023	FY 2024
		and 8 follow-up	and 9 follow-up
FDA to grant, deny, or defer in favor of re-inspection a **Post-WL Meeting** within 30 calendar days from receipt of request	Meetings Requested	3	5
	Meetings Granted	2	5
	Meetings Denied	1	0
	Meetings Conducted	1	4
When requested by the ANDA applicant, FDA will schedule a teleconference to clarify issues and answer questions on reclassifying a major amendment or standard review status.	Meetings Requested	10	11
	Meetings Granted	10	11
	Meetings Denied	0	0
	Meetings Conducted	7	9

* FDA may close out a request for a meeting by (1) holding the meeting or (2) responding, in writing, to questions in the applicant's meeting package in lieu of holding the meeting.

VIII. Rationale for GDUFA Program Changes

Section 744C(a)(3) of the FD&C Act requires the following annual GDUFA performance reporting:

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 301(b) of the Generic 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 744B, 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 generic drug activities, including:

(i) identify drivers of such changes; and
(ii) changes in the total average cost per full-time equivalent in the generic 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 abbreviated new drug application.

The information below fulfills these reporting requirements.

A. Changes in the Number of Individuals Hired as Agreed in the GDUFA III Commitment Letter, the Number of Remaining Vacancies, the Number of FTEs Funded by Fees Collected Pursuant to Section 744B, and the Number of

FTEs Funded by Budget Authority by Division Within CDER, CBER, ORA[32], and OC

This section addresses the requirement to provide data, analysis, and discussion of the changes in (1) the number of individuals hired as agreed upon in the letters described in section 301(b) of the FDA User Fee Reauthorization Act of 2022, (2) the number of remaining vacancies, (3) the number of FTEs funded by fees, and (4) the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, ORA, and OC.

1. Changes in the Number of Individuals Hired

Table 22. Number of Individuals Hired to Meet GDUFA III Commitments

Center	Number Hired in FY 2023	Number Hired in FY 2024	Change in Number Hired	Remaining Vacancies in FY 2023	Remaining Vacancies in FY 2024	Change in Number of Remaining Vacancies
CDER	100	10	-90	14	4	-10
CBER	0	0	0	0	0	0
ORA	5	4	-1	8	4	-4
OC	0	1	1	1	0	-1
Total	105	15	-90	23	8	-15

FDA committed to hiring 128 individuals in FY 2023. The Agency successfully hired 120 FTEs as of September 30, 2024.

2. Changes 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 Table 23 show the changes in the number of FTEs funded by GDUFA fees collected and the number of FTEs funded by budget authority in FY 2023 by each division within CDER, CBER, ORA, and OC. This table reflects changes in the number of FTEs by funding source for the GDUFA III program. For purposes of this table, "budget authority" refers to FDA's non-user fee annual appropriations. To address the requirement that information on changes in the number of FTEs funded by fees and by budget authority be presented "by each division," the information in this table is broken

[32] All references in this report to the Office of Regulatory Affairs (ORA) reflect the organization as it existed during FY 2024. ORA was reorganized into the Office of Inspections and Investigations (OII) effective October 1, 2024.

down to the office level for the Centers, ORA, and OC. FDA uses a 2,080-hour workload to equate to one FTE, and this calculation is reflected in Table 21. The number of FTEs funded by budget authority for FY 2024 are those FTEs as of September 30, 2024.

Table 23. Changes in the Number of FTEs Funded by GDUFA Fees and by Budget Authority

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
CDER						
Office of Communications	10.49	5.70	-4.79	15.15	24.13	8.97
Office of Compliance*	25.00	20.21	-4.79	51.42	58.31	6.89
Office of the Center Director	5.95	3.19	-2.77	6.09	7.91	1.82
Office of Executive Programs	9.83	6.87	-2.96	18.41	22.51	4.10
Office of Generic Drugs	28.21	11.82	-16.39	497.60	536.02	38.42
Office of Medical Policy	3.06	-0.08	-3.14	0.09	0.20	0.11
Office of Management	11.61	5.41	-6.20	46.51	54.64	8.13
Office of New Drugs	1.53	1.61	0.08	0.00†	0.00	0.00
Office of Pharmaceutical Quality	46.47	27.81	-18.66	625.02	662.99	37.97
Office of Regulatory Policy	4.44	2.48	-1.96	4.88	6.24	1.36
Office of Surveillance and Epidemiology	19.02	7.03	-11.99	64.35	67.42	3.07
Office of Strategic Planning	17.49	7.12	-10.37	56.32	70.27	13.95
Office of Information Management and Technology	--	--	0.00	--	--	--
Office of Translational Sciences	16.42	24.15	7.73	49.38	59.49	10.11

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Other Offices	1.08	0.85	-0.24	1.54	1.22	-0.32
Working Capital Fund (WCF)*	29.64	30.90	1.26	87.13	105.55	18.42
CBER						
Office of Biostatistics and Pharmacovigilance‡	-0.97§	0.03	1.00	0.97	0.00	-0.97
Office of Blood Research and Review	0.18	0.78	0.60	0.56	0.00	-0.56
Office of Compliance and Biologics Quality	0.04	0.22	0.18	0.45	0.00	-0.45
Office of Therapeutic Products#	0.00	0.00	0.00	0.00	0.00	0.00
Office of Vaccines Research and Review	0.00†	0.01	0.01	0.00†	0.00	0.00
Office of Communication Outreach and Development	0.01	0.06	0.05	0.06	0.00	-0.06
Office of the Center Director	0.00†	0.04	0.04	0.04	0.00	-0.04
Office of Regulatory Operations¶	0.02	0.08	0.06	0.05	0.00	-0.05
Office of Management	0.05	0.13	0.08	0.08	0.00	-0.08
Office of Information Management and Technology	0.01	0.01	0.00	0.00	0.00	0.00
Working Capital Fund	0.06	0.05	-0.01	0.00	0.00	0.00
OC						
OC of the Commissioner - Immediate Office	0.29	1.98	1.69	5.68	7.79	2.11
Office of the Chief Counsel	1.45	6.8	5.35	28.61	26.73	-1.88
Office of the Chief Scientist	0.04	0.22	0.18	0.83	0.86	0.03

Center and Office	Number of FTEs Funded by Budget Authority in FY 2023	Number of FTEs Funded by Budget Authority in FY 2024	Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees in FY 2023	Number of FTEs Funded by Fees in FY 2024	Change in the Number of FTEs Funded by Fees
Office of Clinical Policy and Programs	0.04	0.17	0.13	0.86	0.66	-0.2
Office of Digital Transformation	0.01	0.09	0.08	0.26	0.34	0.08
Office of Enterprise Management Services	0.75	0.00	-0.75	14.75	0.00	-14.75
Office of External Affairs	0.25	1.32	1.07	5.02	5.17	0.15
Office of Global Policy and Strategy	0.83	3.84	3.01	16.34	15.09	-1.25
Office of Operations	1.19	3.39	2.20	23.5	13.32	-10.18
Office of Policy, Legislation, and International Affairs	0.8	3.95	3.15	15.78	15.53	-0.25
WCF	2.64	7.61	4.97	9.18	11.43	2.25
ORA						
Office of Pharmaceutical Quality Operations	29.00	0.00	-29.00	257.08	320.32	63.24
WCF	17.89	21.51	3.62	19.61	19.93	0.32

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

[†] FTEs are rounded to the hundredth decimal. Offices with fewer than 0.01 FTEs are shown as 0.00.

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

[§] In FY 2023, the negative budget authority FTE (-0.97) in the Office of Biostatistics and Pharmacovigilance was an error entry in the FDA financial system. The net of user fee and budget authority FTE was zero, meaning no GDUFA spending, which reflected the actuals.

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

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

FDA reported a decrease in overall FTEs funded by budget authority in FY 2024 compared to FY 2023. The decrease in reported FTEs was attributable in part to a re-baselining of payroll distribution percentages between annual appropriations and GDUFA fees, as well as a major reorganization of ORA implemented in FY 2024.

B. Changes in the Fee Revenue Amounts and Costs for the Human Generic Drug Activities

Section 744C(a)(3) of the FD&C Act also requires that FDA provide data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including identifying drivers of such changes in the total average cost per FTE in the generic drug review program. Accordingly, Table 24 provides data for the GDUFA fee revenue amounts, the FY 2023 and FY 2024 total average cost per FTE in the generic drug review program, and the changes in these costs from FY 2023 to FY 2024.

In FY 2024, FDA had net collections of $569,359,591 in human generic drug user fees, spent $612,964,654 in user fees for human generic drug activities, and carried a cumulative balance of $89,171,695 forward for future fiscal years. Detailed financial information for the GDUFA user fee program can be found in the FY 2024 GDUFA financial report.

The target revenue amount for FY 2024 for GDUFA III was $613,538,000. For FY 2024, this amount included an inflation adjustment of $22,631,290 and a capacity planning adjustment of $8,406,725.

FDA may, in addition to the inflation and capacity planning adjustments, apply the operating reserve adjustment under section 744B(c)(3) of the FD&C Act to further increase the target revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section. If the estimated carryover balance exceeds 12 weeks of operating reserves, FDA is required to decrease fees for that fiscal year to reduce the operating reserve to not more than 12 weeks. No operating reserve adjustment was made in the setting of FY 2024 fees.

In FY 2024, GDUFA review process costs had a small increase compared to FY 2023.

Table 24. GDUFA Fee Revenue Amounts, the FY 2023 and FY 2024 Total Average Cost Per FTE, and the Changes in These Costs from FY 2023 to FY 2024

Revenue/Cost	FY 2023	FY 2024	Change from FY 2023 to FY 2024
Fee Revenue Amounts (Net Collections)	$551,653,777	$569,359,591	3%
Cost of Activities	$743,860,085	$758,357,084	2%
Changes in average total cost per FTE	**$200,059**	**$206,590**	3%

C. Number of Employees for Whom Time Reporting Is Required

Section 744C(a)(3) of the FD&C Act also requires that FDA provide, for CDER, CBER, ORA, and OC, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required. Accordingly, Table 25 provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2024.

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

Table 25. Time Reporting Requirement for FY 2024

Center	FTEs for Whom Time Reporting Is Required	FTEs for Whom Time Reporting Is Not Required
CDER	5,802	0
CBER	1,362	2
ORA	4,563	0
OC	68	2,771
Total	11,795	2,773

D. Changes in the Average FTE Hours Required to Complete Review of Each Type of ANDA

Section 744C(a)(3) of the FD&C Act requires that FDA provide data, analysis, and discussion of the changes in the average FTE hours required to complete review of each type of ANDA.[33]

[33] Per section 744A(1)(A) of the FD&C Act, "ANDA" means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the enactment date of the Food and Drug Administration Modernization Act of 1997), or an ANDA submitted pursuant to regulations in effect prior to the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman amendments). Because the latter two types of ANDAs are no longer submitted, this report provides information regarding the average FTE hours required to complete review of original ANDAs submitted under section 505(j) of the FD&C Act.

Table 26. Average FTE Hours Required to Complete Review

Application Type	Hours Required to Complete Application Reviews FY 2023	Hours Required to Complete Application Reviews FY 2024	Change from FY 2023 to FY 2024
Original ANDAs Submitted	1,265	1,385	120
Total	1,265	1,385	120

To calculate the average hours required to complete review of original ANDAs, FDA summed the total number of hours over the last 3 fiscal years (FY 2021 to FY 2023 and FY 2022 to FY 2024). The sum was then divided by the total number of applications over the same 3-year period.

Appendix A: Definitions of Key Terms

The text below provides the definitions used in this report of key terms.

A. **Act on an Application** - means that FDA will issue a CRL, an approval letter, a TA letter, or an RTR action.

B. **Active pharmaceutical ingredient (API)** - means:

1. a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or
2. a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become the final API as defined in paragraph (1).

C. **Ambiguity in the Controlled Correspondence response** - means the Controlled Correspondence response or a critical portion if it merits further clarification.

D. **Amendments to an ANDA** - FDA considers each submission to an application under review (or a supplement) to be an amendment. 21 CFR 314.96(a) states that an applicant may amend an ANDA that is submitted but not yet approved, to revise existing information or provide additional information. The GDUFA III Commitment Letter continues the classification of review goals for amendments to ANDAs and PASs from the GDUFA II Commitment Letter; review goals depend on whether the amendment is designated as a standard or priority, whether the amendment is classified as major or minor, and whether a PAI is needed.

E. **Abbreviated new drug application (ANDA)** - is defined as "the application described under [21 CFR] 314.94, including all amendments and supplements to the application." See 21 CFR 314.3(b); also see footnote 25.

F. **Bioequivalence (BE)** - is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

G. **Capacity Planning Adjustment (CPA)** - Methodology used in calculating GDUFA fees that annually adjusts inflation-adjusted target revenue to account for additional resource needs due to increases in workload for human generic drug activities. See section 744B(c)(2) of the FD&C Act.

H. **Complete response letter (CRL)** - refers to a written communication to an applicant or DMF holder from FDA usually describing all the deficiencies that the Agency has identified in an ANDA (including pending amendments) or a DMF that must be satisfactorily addressed before the ANDA can be approved. CRLs will reflect a complete assessment, which includes an application-related facilities assessment and will require a CR from industry to trigger another review cycle with an attendant goal date. Refer to 21 CFR 314.110 for additional details. When a citizen petition may impact the approvability of the ANDA, FDA will strive to identify, when possible, valid issues raised in a relevant citizen petition in the CRL. If a citizen petition raises an issue that would delay only part of a CR, a response that addresses all other issues will be considered a CR.

I. **Complete Assessment** - refers to a full division-level review from all relevant assessment disciplines, including inspections, and includes other matters relating to the ANDAs and associated DMFs, as well as consults with other Agency components.

J. **Complex product** - generally includes:

1. Products with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients); complex formulations (e.g., liposomes, colloids); complex routes of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions or gels) or complex dosage forms (e.g., transdermal systems, metered dose inhalers, extended release injectables);
2. Complex drug-device combination products (e.g., auto injectors, metered dose inhalers); and
3. Other products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.

K. **Complex Generic Product** - refers to a generic version of a Complex Product.

L. **Controlled Correspondence – Level 1** - GDUFA III Commitment Letter - means correspondence submitted to the Agency, by or on behalf of generic drug manufacturer or related industry:

1. Requesting information on a specific element of generic drug product development:

    a. Prior to ANDA submission;
    b. After a PSG Teleconference if a prospective applicant or applicant seeks further feedback from FDA;
    c. After issuance of a CRL or TA;
    d. After ANDA approval; or

2. Concerning post-approval submission requirements that are not covered by CDER post-approval changes guidance and are not specific to an ANDA.

M. **Controlled Correspondence – Level 2** - GDUFA III Commitment Letter - means correspondence that meets the definition of Level 1 correspondence, and:

1. Involves evaluation of clinical content;
2. Requests a Covered Product Authorization and review of BE protocols for development and testing that involves human clinical trials for an ANDA where the RLD is subject to a Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU);
3. Requests a Covered Product Authorization to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU when development and testing does not involve clinical trials;
4. Requests evaluations of alternative BE approaches (e.g., pharmacokinetic, in vitro, clinical); or
5. Requires input from another office or center (e.g., questions regarding device constituent parts of a combination product).

P. **Covered Product Authorization** - a letter from FDA authorizing an eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for product development and testing purposes, as described in section 610 of Division N of the Further Consolidated Appropriations Act, 2020 (21 U.S.C. 355-2), commonly referred to as the “CREATES Act.”

Q. **Days** - unless otherwise specified, means calendar days.

R. **Discipline review letter (DRL)** - means a letter used to convey preliminary thoughts on possible deficiencies found by a discipline assessor and/or assessment team for its portion of the pending application at the conclusion of the discipline assessment.

S. **First Adequate Letter** - a communication from FDA to DMF holder indicating that the DMF has no open issues related to the assessment of the referencing ANDA.

This communication is issued only at the conclusion of the first DMF assessment cycle that determines the DMF does not have any open issues.

T. **First Generic** - any received ANDA: (1) for a First Applicant as described in section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act or for which there are no blocking patents or exclusivities; and (2) for which there is no previously approved ANDA for the drug product.

U. **Facility** - is described as a business or other entity under one management, either direct or indirect, and at one geographic location or address, engaged in manufacturing or processing an API or an FDF, but does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

V. **Finished Dosage Form (FDF)** - means:

1. a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;
2. a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or
3. any combination of an API with another component of a drug product for purposes of production of such a drug product.

W. **GDUFA** – Generic Drug User Fee Amendments

X. **GDUFA I** – Generic Drug User Fee Amendments for Fiscal Years 2013 to 2017

Y. **GDUFA II** – Generic Drug User Fee Amendments for Fiscal Years 2018 to 2022

Z. **GDUFA III** – Generic Drug User Fee Amendments for Fiscal Years 2023 to 2027

AA. **Information Request (IR)** - means a communication that is sent to an applicant during an assessment to request further information or clarification that is needed or would be helpful to allow completion of the discipline assessment.

BB. **Major Amendment** – GDUFA III Commitment Letter - means a Major Amendment as described in the guidance for industry *ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018) and any subsequent revision.

CC. **Minor Amendment** – GDUFA III Commitment Letter - means a minor amendment as described in the guidance for industry on *ANDA Submissions — Amendments*

to Abbreviated New Drug Applications Under GDUFA (July 2018) and any subsequent revision.

DD. **Original ANDA** - The initial submission of an ANDA to CDER's Office of Generic Drugs or to CBER.

EE. **Pre-Submission Meeting** – As described in the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2022), means a meeting in which an applicant has an opportunity to present unique or novel data or information that will be included in the ANDA submission such as formulation, key studies, justifications, and/or methods used in product development, as well as the interrelationship of the data and information in the ANDA. Although the proposed content of the ANDA will be discussed, Pre-Submission Meetings will not include a substantive review of summary data or full study reports.

FF. **Prior Approval Supplement (PAS)** - means a request to the Secretary of Health and Human Services to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved ANDA when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.[1]

GG. **Priority** - means submissions affirmatively identified as eligible for expedited assessment pursuant to CDER's MAPP 5240.3, *Prioritization of the Review of Original ANDAs, Amendments and Supplements*, as revised.[2]

HH. **Product Development Meeting** - means a meeting involving a scientific exchange to discuss specific issues (e.g., a proposed study design, alternative approach or additional study expectations) or questions, in which FDA will provide targeted advice regarding an ongoing ANDA development program.

II. **Reference Listed Drug (RLD)** - means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.

JJ. **Refuse to Receive (RTR)** - means refusal to receive an ANDA for review. See 21 CFR 314.101 and the guidance for industry *ANDA Submissions – Refuse-to-Receive Standards* (December 2016).[3]

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[1] See section 744A(11) of the FD&C Act.

[2] See https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp.

[3] See www.fda.gov/regulatory-information/search-fda-guidance-documents.

KK. **Review Status Update** - means a response from the regulatory project manager (RPM) to the applicant to update the applicant concerning, at a minimum, the categorical status of relevant assessment disciplines with respect to the submission at that time. The RPM will advise the applicant that the update is preliminary only based on the RPM's interpretation of the submission and subject to change at any time.

LL. **Standard** - means submissions not affirmatively identified as eligible for expedited assessment pursuant to the CDER Prioritization MAPP.

MM. **Submission** - refers to an ANDA, an amendment to an ANDA, a PAS to an ANDA, or an amendment to a PAS.

NN. **Submission date** - means the date that a generic drug submission or Type II DMF is deemed to be "submitted" pursuant to Section 744B(a)(6) of the FD&C Act, which states that a generic drug submission or Type II DMF is deemed to be "submitted" if it is submitted via an FDA electronic gateway, on the day when transmission to that electronic gateway is completed, except that, when the submission or DMF arrives on a weekend, Federal holiday, or day when the FDA office that will review that submission is not otherwise open for business, the submission shall be deemed to be submitted on the next day when that office is open for business. In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements in guidance. Refer to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).[4]

OO. **Teleconference** - means a verbal communication by telephone, not a written response, unless otherwise agreed to by the applicant.

PP. **Tentative Approval (TA) Letter** - If an ANDA meets the substantive requirements for approval but cannot be approved because of a patent or exclusivity issue, FDA issues a TA letter to the applicant, and the TA letter details the basis for the TA. FDA will not issue a final approval of the ANDA until all patent or exclusivity issues have been resolved or, in some cases, until a 30-month stay associated with patent litigation has expired. A TA does not allow the applicant to market the generic drug product.

QQ. **Type II API Drug Master File (DMF)** - A submission of information to FDA concerning the manufacture of a pharmaceutical active ingredient by a person that

[4] Ibid.

intends to authorize FDA to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

RR. **Unsolicited Amendment** - an amendment with information not requested by FDA except for those unsolicited amendments considered routine or administrative in nature that do not require scientific review (e.g., requests for final ANDA approval, patent amendments, and general correspondence).

Appendix B: Synopsis of FY 2024 GDUFA Science and Research Accomplishments

GDUFA-funded research aims to improve the efficiency with which generic drugs can be developed and assessed, and this research benefits public health by making it more feasible for manufacturers to develop generic drugs, which can reduce the risk of drug shortages and facilitate competition. This research is intended to enhance patient access to drug treatment by helping make these products more widely available, which may help patients in the United States to obtain medicines they need. Multiple resources for public input, including the *Federal Register* notice (public docket (FDA-2023-N-0119)[1]) opened for public comments, as well as input shared at the Fiscal Year 2024 Generic Drug Science and Research Initiatives Public Workshop[2] helped FDA, in collaboration with industry and academia stakeholders, to identify eight GDUFA Science and Research Priority Initiatives for FY 2025[3] that could expand and accelerate patient access to generic drugs. Summarized below are a selection of highlighted accomplishments in each of the eight priority areas that illustrate the types of scientific insights being developed, as well as a ninth area highlighting additional generic drug science and research during FY 2024. More detailed information in all nine areas is provided in the FY 2024 GDUFA Science and Research Report, including comprehensive lists of new, ongoing, and completed grants and contracts for research relevant to each area, as well as lists of the research outcomes in each area during FY 2024. These outcomes include general guidances for industry and PSGs published in FY 2024 that were supported by research in each area, as well as scientific journal articles, posters, and presentations.

A. Impurities Such as Nitrosamines

The advancement of research in this area during FY 2024 focused on understanding how ingredients in drug products may either contribute to or mitigate the formation of potentially harmful impurities such as nitrosamine adducts (e.g., nitrosamine drug substance-related impurities), evaluating the risk of human exposure to these impurities, and developing methods for ANDA applicants to efficiently address the potential risks.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to assess the risk of forming N-nitrosamines including nitrosamine drug

[1] https://www.federalregister.gov/documents/2024/02/12/2024-02841/fiscal-year-2024-generic-drug-science-and-research-initiatives-workshop-public-workshop-request-for

[2] https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2024-generic-drug-science-and-research-initiatives-public-workshop-05202024

[3] See https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects.

substance-related impurities. This included developing analytical methods for the quantitation of impurities and understanding the toxicological risks of these impurities. The research explored strategies to prevent or mitigate the formation of these impurities by reformulating drug products with suitable antioxidants or pH modifiers, and the research focused on evaluating whether such formulation changes might impact the BE of an approved generic product. Please see Chapter 1 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

B. Complex Active Ingredients

The advancement of research in this area during FY 2024 focused on improving orthogonal methods for the characterization of chemical compositions, molecular structures, and distributions of complex APIs such as peptides and oligonucleotides, as well as associated impurities. These methods can be used to elucidate attributes of complex APIs and support immunogenicity risk assessments that may be critical to the performance of these methods, thereby, supporting the development of efficient characterization-based BE and pharmaceutical equivalence approaches.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to develop modern state-of-the-art analytical methods to characterize complex active ingredient products with diverse structures and complex impurities resulting from process differences. Research on oligonucleotide drugs included an analysis of the diastereomeric compositional of inotersen while research on small interfering ribonucleic acid (siRNA) drugs included an assessment of the contribution of each diastereomer to the overall biological activity of inclisiran. Please see Chapter 2 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

C. Complex Dosage Forms and Formulations

The advancement of research in this area during FY 2024 focused on improving efficient characterization-based (in vitro) BE approaches for long-acting injectable, insertable, or implantable (collectively, long-acting injectable (LAI)) products and nanotechnology products. This research sought to identify the critical quality attributes (CQAs) that control how these complex dosage forms and formulations work and to develop suitable test methods for characterizing these CQAs in an RLD product and matching them in a prospective generic product.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to continue developing new analytical methods for the characterization of complex polymeric excipients in LAI product formulations. This research also continued to develop imaging technologies, in vitro release test methods, and PBPK models for

LAI products. In parallel, GDUFA-funded research on nanomaterials continued to enhance FDA's understanding of CQAs that determine lipid nanoparticle performance. This included developing improved methods to characterize the complexity of nanomaterial-containing drug products, which could also support the development of efficient BE approaches for these products. Please see Chapter 3 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

D. Complex Routes of Delivery

The advancement of research in this area during FY 2024 focused on improving efficient characterization-based BE approaches for locally acting gastrointestinal, buccal, sublingual, inhalation, nasal, ophthalmic, otic, and topical dermatological, vaginal, and rectal products. This research sought to elucidate how ingredients and other aspects of a formulation influence drug absorption via complex routes of delivery, building in vivo predictive models, identifying how these products work, and evaluating how differences in CQAs may alter the therapeutic performance of the product.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to investigate myriad aspects of products with complex routes of delivery. The research on locally acting gastrointestinal, buccal, and sublingual drug products focused on improving in vitro BE methods and developing biopredictive in silico models. The research on inhalation products focused on evaluating potential alternatives to in vivo bioequivalence studies that are currently recommended in FDA's PSGs for orally inhaled and nasal drug products. The research on ophthalmic and otic products focused on (1) identifying and characterizing critical physicochemical and structural attributes that influence their in vitro, ex vivo, and in vivo performance and (2) integrating evidence from in silico approaches to elucidate how these attributes modulate product performance. The research on topical products continued to focus on the development and implementation of efficient characterization-based bioequivalence approaches that could be used for prospective generic products whose formulation composition is well matched to that of the reference standard, as well as for those that may have certain compositional differences relative to the reference standard. Please see Chapter 4 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

E. Complex Drug-Device Combination Products

The advancement of research in this area during FY 2024 focused on enhancing the efficiency of equivalence approaches for complex DDCPs. This focus involved evaluating the impact of identified differences in the user interfaces, hardware, software,

or propellants between a prospective generic and the RLD on the bioequivalence, therapeutic equivalence, or post-marketing safety of generic DDCPs.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to evaluate the impact of differences between a generic DDCP and its RLD on substitutability, bioequivalence, therapeutic equivalence, and post-marketing safety. Please see Chapter 5 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

F. Oral and Parenteral Generic Products

The advancement of research in this area during FY 2024 focused on understanding how ingredients in oral and parenteral drug products may modulate bioavailability and on improving biorelevant dissolution methods, as well as in silico models, to support the expansion of BCS-based biowaivers and the harmonization of regulatory standards for oral drug products. This research also included exploring how to manage potential risks related to subject safety more consistently when developing clinical bioequivalence study recommendations and elucidating mechanisms by which the bioavailability or bioequivalence of a prospective generic drug product may be altered in specific populations, such as pediatric or geriatric patients.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to develop biopredictive in vitro methods to evaluate the impact of different product designs, food effects, and drug-drug interactions on the assessment of bioequivalence. Please see Chapter 6 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

G. Model Integrated Evidence (MIE) of Bioequivalence

The advancement of research in this area during FY 2024 focused on developing tools and advancing approaches to integrate complementary in silico (modeling), in vivo, and in vitro evidence in ways that collectively mitigate the risk of failure modes for bioequivalence and support a framework for virtual bioequivalence studies. For example, while it may not be feasible to adequately characterize the long-term bioavailability of drugs from LAI products using in vivo or in vitro methods alone, it may be feasible to integrate limited in vivo and in vitro data with PBPK models that generate the remaining evidence needed to support a demonstration of bioequivalence. Similarly, PBPK models can help predict the impact of formulation excipients, food, or gastric pH on the bioavailability and bioequivalence of oral dosage forms, even for specific populations such as pediatric patients. In addition, MIE can complement quantitative clinical pharmacology assessments to evaluate failure modes for

bioequivalence and to optimize the design of bioequivalence studies in numerous contexts.

During FY 2024, FDA conducted internal research studies and funded external research collaborations to integrate evidence from limited in vivo and in vitro data with insights from PBPK models that generate the remaining evidence needed to support a demonstration of bioequivalence for a variety of different drug products. Research on orally inhaled drug products focused on refining regional lung deposition computational fluid dynamics and PBPK modeling approaches, as well as the development of a new in vivo nuclear imaging method to support the validation of these models. Other research on topical dermatological drug products focused on assessing the capability of mechanistic skin absorption models to account for metamorphosis phenomena and predicting skin permeation in the presence of selected inactive ingredients. Also during FY 2024, FDA conducted research on oral absorption models that evaluated the utility of integrating data from in vitro biopredictive tests and PBPK modeling. For immediate release products, this research focused on evaluating bioequivalence under fed conditions and supporting the potential expansion of biowaivers for BCS Class III Drugs. For modified release products, the focus was to enhance PBPK absorption modeling capabilities, which could help establish best practices for virtual bioequivalence study designs. In addition, FDA advanced research involving quantitative clinical pharmacology focused on issues related to partial area under the concentration-time curve (AUC) recommendations for pharmacokinetic assessments that evaluate the concentration of drug that is systemically available during a clinically relevant phase of drug release, narrow therapeutic index drug classifications, and the harmonization of regulatory standards with other regulatory agencies; this research included developing innovative study designs for bioequivalence studies conducted in patients, such as those with a reduced or sparse sampling scheme for studies with oncology products, alternative study designs for LAI products with shorter study durations or reduced sample size, and adaptive designs. Please see Chapter 7 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

H. Artificial Intelligence (AI) and Machine Learning (ML) Tools

The advancement of research in this area during FY 2024 focused on building systems and infrastructure that support the functionality of AI and ML tools that FDA can use to improve the efficiency and consistency of scientific assessments and advice. These systems and infrastructure include AI/ML tools that facilitate planning and resource allocation to support GDUFA commitments.

During FY 2024, FDA conducted internal research studies and funded external research collaborations focused on building systems and infrastructure that support the functionality of AI/ML tools that FDA can use to improve the efficiency and consistency

of scientific assessments. This research included using AI/ML tools such as natural language processing that automate the assembly of key information routinely assessed during the development of PSGs, or during the assessment of ANDAs, as well as AI/ML tools that facilitate planning and resource allocation to support the fulfillment of FDA's GDUFA commitments. Please see Chapter 8 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

I. Other Generic Drug Science and Research

Other generic drug science and research during FY 2024 focused on post-approval monitoring of generic products, generic product substitution, and attitudes among patients, caregivers, and prescribers related to the perceived therapeutic performance of generic products. It also encompassed research to facilitate the availability of generic products that help address the public health emergency related to opioids,[4] particularly drug products related to the treatment of addiction and for rescue from overdose.

During FY 2024, FDA conducted research to support the development of generic products designed to prevent relapse to opioid dependence or to reverse an overdose. Ongoing research related to opioid products with abuse-deterrent formulations also continued toward completion. Please see Chapter 9 of the FY 2024 GDUFA Science and Research Report for a more detailed description of the current research in this area, including notable scientific outcomes.

[4] Renewed by the Secretary of Health and Human Services, effective December 22, 2024, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d. See https://aspr.hhs.gov/legal/PHE/Pages/Opioid-Renewal-20Dec2024.aspx.

Appendix C: Analysis of Performance in Meeting Goals

The FD&C Act requires the annual performance reports for each of the human medical product user fee programs to include specified analyses. These analyses relate to meeting performance goals and in the case of GDUFA, include—per section 744C(a)(4)—examining differences between aggregate numbers of ANDA submissions and approvals or CRLs, determining the causes affecting the agency's ability to meet performance goals, and issuing corrective action reports on FDA's efforts to improve its attainment of applicable performance goals.

A. Aggregate Number of ANDAs Received and Certain Types of Regulatory Decisions

Although the mandate is to report the number of ANDAs filed, the term "received" is used instead of "filed" in the statute with respect to ANDAs. FDA will thus report on the aggregate number of ANDAs received. Per 21 CFR 314.101(b)(1), an ANDA will be reviewed after it is submitted to determine whether the ANDA can be "received." "Receipt of an ANDA" means that FDA made a threshold determination that the ANDA is substantially complete. A "substantially complete ANDA" is an ANDA that on its face is sufficiently complete to permit a substantive review. "Sufficiently complete" means that the ANDA contains all the information required under section 505(j)(2)(A) of the FD&C Act and does not contain a deficiency described in 21 CFR 314.101(d) and (e). The number of ANDAs received in Tables C-1 and C-2 do not account for submissions that were determined to not be substantially complete.

Table C-1. FY 2023 Updated Performance by Goal Type

Goal Type	Review Goal	Received	Received with Goal Post FY 2023	Approved	Tentatively Approved	Complete Response	Missed Goal*	Percent on Time†	Potential Range†	On Time Imminent Approval†	Imminent Approval Potential Range†
I. Original ANDA Review											
Standard Original ANDA Submissions	10/30 months	539	486	79	14	388	39	93%	86% to 93%	96%	88% to 96%
Priority Original ANDA Submissions	8/10/30 months	145	126	35	1	96	18	88%	85% to 88	93%	89% to 94%
II. Amendment Review											
Standard Major ANDA Amendments	8/10 months	765	527	167	32	543	56	93%	92% to 93%	95%	94% to 95%
Priority Major ANDA Amendments	6/8/10 months	137	77	37	3	97	10	93%	93% to 93%	95%	95% to 95%
Standard and Priority Minor ANDA Amendments	3 months	735	240	394	102	237	93	87%	87% to 87%	97%	97% to 97%

* A "Missed Goal" includes submissions that have not had an action and have passed the goal date.

† These percentages include Refuse-to-Receive actions, withdrawn submissions, and Pending submissions, in addition to Approval, TA, and CR actions.

Table C-2. FY 2024 Preliminary Performance by Goal Type

Goal Type	Review Goal	Received	Received with Goal Post FY 2024	Approved	Tentatively Approved	Complete Response	Missed Goal*	Percent on Time†	Potential Range††	On Time Imminent Approval†	Imminent Approval Potential Range†
I. Original ANDA Review											
Standard Original ANDA Submissions	10/30 months	440	404	4	0	28	2	96%	11% to 99%	100%	11% to 100%
Priority Original ANDA Submissions	8/10/30 months	137	123	4	0	12	1	95%	13% to 99%	100%	14% to 100%
II. Amendment Review											
Standard Major ANDA Amendments	8/10 months	588	419	39	10	122	11	94%	29% to 98%	99%	29% to 99%
Priority Major ANDA Amendments	6/8/10 months	106	61	15	1	29	3	94%	42% to 97%	98%	42% to 99%
Standard and Priority Minor ANDA Amendments	3 months	808	295	249	64	195	72	86%	57% to 91%	96%	62% to 98%

* A “Missed Goal” includes submissions that have not had an action and have passed the goal date.
† These percentages include Refuse-to-Receive actions, withdrawn submissions, and Pending submissions, in addition to Approval, TA, and CR actions.

B. Performance Enhancement Goals Met

Table C-3 addresses section 744C(a)(4) 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 letter described in section 301(b) of the Generic Drug User Fee Amendments of 2022 (i.e., the GDUFA III Commitment Letter) for the applicable fiscal year.

For the purposes of this report, “performance enhancement goals” are defined as any non-review goals described in the GDUFA III Commitment Letter with a specified goal date that falls within the applicable fiscal year.

Table C-3. FY 2024 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Pre-ANDA				
Update website information related to upcoming new and revised PSGs to support the development and approval of safe and effective generic drug products, including the projected date of PSG publication, which may be subject to change.	Quarterly	Y	Quarterly	https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development
Update the Inactive Ingredient Database on an ongoing basis and post quarterly notice of updates made.	Quarterly	Y	Quarterly	www.fda.gov/drugs/drug-approvals-and-databases/most-recent-changes-iid-database
Conduct a public workshop to solicit input from industry and stakeholders about the annual prioritization of PSGs and GDUFA III Regulatory Science Initiatives.	Annually	Y	Public Workshop held 5/20/2024 – 5/21/2024	https://www.fda.gov/drugs/news-events-human-drugs/fiscal-year-2024-generic-drug-science-and-research-initiatives-public-workshop-05202024
Report on FDA’s website the extent to which GDUFA regulatory science-funded projects support the development of generic drug products, the generation of evidence needed to support the efficient review and timely approval of ANDAs, and the evaluation of generic drug equivalence.	Annually	Y	Not yet available but when it becomes available it will be posted on the website noted in next column.	https://www.fda.gov/drugs/generic-drugs/generic-drug-research-related-guidances-reports

Hold meetings between FDA and industry's GDUFA III regulatory science working group to collaborate on matters related to the GDUFA Science and Research Program, including the annual prioritization of PSGs and GDUFA III Regulatory Science Initiatives.	Biannually	Y	First Meeting held 11/17/2023 Second Meeting held 08/28/2024	www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects
Facilities				
Update the Inspection Classification Database to reflect FDA's final assessment of the facility or site following an FDA inspection and assessment of the inspected entity's timely response to any documented observations.	Monthly	Y	Monthly	
Continued Enhancement of User Fee Resource Management				
Publish updates to the GDUFA Five-Year Financial Plan no later than the second quarter of each subsequent fiscal year.	Annually 3/31/2024	N	4/19/2024	FDA published the GDUFA III Five-Year Financial Plan – 2024 Update in April 2024 (available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans).
Provide annual updates on FDA's website on the Agency's progress relative to activities detailed in the implementation plan that describes how resource capacity planning and time reporting will continue to be utilized during GDUFA III.	Annually 3/31/2024	Y	3/22/2024	FDA published the Resource Capacity and Modernized Time Reporting Implementation Plan Annual Update in March 2024 (available at https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting).
Convene a public meeting no later than the third quarter of each fiscal year starting in FY 2024 to discuss the GDUFA Five-Year Financial Plan, along with the Agency's progress in implementing modernized time reporting and resource management planning.	Annually 6/30/2024	Y	6/06/2024	FDA held a public meeting on June 6, 2024 (see. https://www.fda.gov/drugs/news-events-human-drugs/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act).
Confirm progress in the hiring of GDUFA III staff in the GDUFA Five-Year Financial Plan.	Annually	Y	4/19/2024	See page 21 of GDUFA III Five-Year Financial Plan – 2024 Update (available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans).
Guidances and MAPPs				
Issue a MAPP on the process for reclassification of Facility-Based Major CRL Amendments set forth in section II(C)(7).	6/30/2024	Y	1/15/2024	https://www.fda.gov/media/169330/download?attachment

Issue a MAPP on the prioritization of FDA's assessment of solicited DMF amendments described in section VI(F)(2).	6/30/2024	Y	5/28/2024	https://www.fda.gov/media/178300/download?attachment
Performance Reporting				
Publish monthly reporting metrics set forth under section X(A) of the GDUFA III Commitment Letter.	Monthly	Y	Monthly	https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report
Publish quarterly reporting metrics set forth under section X(B) of the GDUFA III Commitment Letter.	Quarterly	Y	Quarterly	https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report
Publish fiscal year performance reporting metrics set forth under section X(C) of the GDUFA III Commitment Letter.	Annually	Y	Annually	See the Performance Reporting section of this FY 2024 GDUFA performance report
Post fiscal year reporting metrics on the web set forth under section X(D) of the GDUFA III Commitment Letter.	Annually	Y	Annually	https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-2023-fiscal-year-web-posting

C. Common Causes and Trends Impacting Ability to Meet Goals

This section addresses section 744C(a)(4) of the FD&C Act, which requires FDA to identify the most common causes and trends for external or other circumstances affecting the ability of FDA to meet the review time and performance enhancement goals identified in the GDUFA III Commitment Letter.

Table C-4 represents FDA's FY 2023 updated performance results.

Table C-4. FY 2023 GDUFA III Updated Performance Results

Cause or Trend	Impact on FDA's Ability to Meet Goals
Performance Goals	In last year's report, the Agency could not fully report on this category because some submissions received in FY 2023 had associated review goals that fell within the subsequent fiscal year. The Agency has the following updates: • "Standard Original ANDA Submissions" and "Priority Original ANDA Submissions": Based on currently available data, FDA is meeting these goals. Some submissions have associated review goals that fall within the next fiscal year, and this performance will be updated in the FY 2025 report. • FDA met the remaining FY 2023 performance goals.

Program Enhancement Goals and Other Goals	In last year's report, the Agency could not fully report on this category because some submissions received in FY 2023 had associated program enhancement goals that fell within the subsequent fiscal year. The Agency has the following updates: • FDA did not meet the FY 2023 program enhancement goal "FDA to grant or deny Pre-Submission Meeting Requests." Due to the small number of Pre-Submission Meeting requests received (i.e., nine total), missing the goal for a single submission resulted in dropping below the GDUFA metric of 90 percent. FDA missed this goal due to human error with processing one Pre-Submission Meeting request. FDA has updated its processes to prevent this type of error from occurring in the future. • FDA met the remaining FY 2023 program enhancement goals.

Table C-5 represents FDA's FY 2024 preliminary performance results.

Table C-5. FY 2024 GDUFA III Preliminary Performance Results

Cause or Trend	Impact on FDA's Ability to Meet Goals
Performance Goals	Because some submissions received in FY 2024 have associated performance goals that fall within subsequent fiscal years (e.g., FY 2025), FDA cannot yet evaluate and report on the FY 2024 performance goals. FDA will provide an update next year.
Program Enhancement and Other Goals	Because some submissions received in FY 2024 have associated program enhancement goals that fall within subsequent fiscal years (e.g., FY 2025), FDA cannot yet evaluate and report on the FY 2024 program enhancement and other goals. FDA will provide an update next year.

Appendix D: FY 2023 Corrective Action Report

Under section 744C(c) of the FD&C Act, FDA is required to issue a corrective action report that details FDA's performance in meeting the review and performance enhancement goals identified in the letter described in section 301(b) of GDUFA III (i.e., the GDUFA III Commitment Letter) for the applicable fiscal year.

If the Secretary of Health and Human Services determines, based on the analysis presented in the annual GDUFA performance report, that 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.[1]

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 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 nonetheless providing this information in an effort to be complete.

This section satisfies this reporting requirement.

A. Executive Summary

1. FY 2023 Updated Performance Results

Table D-1 represents FDA's FY 2023 updated performance results for goal types that the Agency was not able to fully report on in last year's report.

[1] Section 744C(c)(1) of the FD&C Act (21 U.S.C. 379j-43(c)(1)).

Table D-1. FY 2023 GDUFA III Updated Performance Results for Goal Types Not Fully Reported Last Year

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Performance Goals	Standard Original ANDA Submissions: It is too soon to determine.	Based on currently available data, FDA is meeting this goal. Some submissions have associated review goals that fall within next fiscal year, and this performance will be updated in the FY 2025 report.
	Priority Original ANDA Submissions: It is too soon to determine.	Based on currently available data, FDA is preliminarily meeting this goal. Some submissions have associated review goals that fall within next fiscal year, and this performance will be updated in the FY 2025 report.
	All remaining FY 2023 goals were met.	No corrective action plan is needed.
Program Enhancement Goals and Other Goals	FDA did not meet the FY 2023 program enhancement goal "FDA to grant or deny Pre-Submission Meeting Requests." Due to the small number of Pre-Submission Meeting requests received (i.e., nine total), missing the goal for a single submission resulted in dropping below the GDUFA metric of 90 percent. FDA missed this goal due to human error with processing one Pre-Submission Meeting request.	FDA has updated its processes to prevent this type of error from occurring in the future.
	All remaining FY 2023 goals were met.	No corrective action plan is needed.
Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management	FDA's publication of the annual update to the GDUFA Five-Year Financial Plan did not occur by the second quarter of FY 2023. 120 of 128 GDUFA III hires were complete as of the end of FY 2024.	FDA has implemented automation for some processes involved in generating the Five-Year Financial Plans. The newly introduced system integrates data from multiple sources and automates complex calculations, significantly reducing the need for manual data entry. By automating these tasks, FDA expects to improve accuracy, minimize errors, and expedite the publication process. This automation not only reduces the likelihood of future delays but also enhances the overall efficiency and reliability of financial reporting. FDA has completed 120 of 128 GDUFA III hires. CDER has identified candidates and anticipates filling the remaining positions in FY 2025.

2. FY 2024 Performance Results

Table D-2 represents FDA's FY 2024 preliminary performance results.

Table D-2. FY 2024 Preliminary Performance Results

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Performance Goals	It is too soon to determine.	Because some submissions received in FY 2024 have associated performance goals that may fall within subsequent fiscal years (e.g., FY 2025), FDA cannot yet evaluate and report on the performance for FY 2024 performance goals. FDA will provide an evaluation next year.
Program Enhancement and Other Goals	It is too soon to determine.	Because some submissions received in FY 2024 have associated program enhancement goals that fall within a subsequent fiscal year (e.g., FY 2025), FDA cannot yet evaluate and report on the performance for FY 2024 program enhancement goals. FDA will provide an evaluation next year.
Performance Enhancement Goal: Pre-ANDA	All FY 2024 goals were met.	No corrective action plan is needed.
Performance Enhancement Goal: Facilities	All FY 2024 goals were met.	No corrective action plan is needed.
Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management	FDA's publication of the annual update to the GDUFA Five-Year Financial Plan did not occur by the second quarter of FY 2024.	FDA has implemented automation for some processes involved in generating the Five-Year Financial Plans. The newly introduced system integrates data from multiple sources and automates complex calculations, significantly reducing the need for manual data entry. By automating these tasks, FDA expects to improve accuracy, minimize errors, and expedite the publication process. This automation not only reduces the likelihood of future delays but also enhances the overall efficiency and reliability of financial reporting.
	All remaining FY 2024 goals were met.	No corrective action plan is needed.
Performance Enhancement Goal: Guidance and MAPPs	All FY 2024 goals were met.	No corrective action plan is needed.
Performance Enhancement Goal: Performance Reporting	All FY 2024 goals were met.	No corrective action plan is needed.

B. GDUFA Performance Goals

This section addresses section 744C(c)(2) of the FD&C Act, which requires FDA to provide a justification for the determination of review goals missed during FYs 2023 and 2024 and a description of the circumstances and any trends related to missed review goals. In particular, this section presents GDUFA performance and workload information for all review performance goals for ANDAs.

1. FY 2023 Performance Goal Performance

Summary of Performance

FDA has no missed performance goals to report at this time. Because some submissions have associated review goals that fall within next fiscal year (i.e., "Standard Original ANDA Submissions" and "Priority Original ANDA Submissions"), FDA will provide an evaluation in the FY 2025 report.

Justification Regarding Missed Goals

It is too soon to determine the justification.

FY 2023 Corrective Actions

It is too soon to determine if a corrective action is needed.

2. FY 2024 Performance Goal Performance

Summary of Performance

Because some submissions received in FY 2024 have associated performance goals that may fall within subsequent fiscal years (e.g., FY 2025), FDA cannot yet evaluate and report on the FY 2024 performance goals. FDA will provide an evaluation in the FY 2025 report.

Justification Regarding Missed Goals

It is too soon to determine the justification.

FY 2024 Corrective Actions

It is too soon to determine if a corrective action is needed.

C. GDUFA Performance Enhancement Goals

The following section addresses section 744C(c)(2) of the FD&C Act, which requires FDA to provide a detailed description of the efforts it has put in place for the fiscal year in which the report is submitted to improve FDA's ability to meet performance enhancement goals during FY 2023 and FY 2024.

This section presents non-review performance enhancement goals cited in the GDUFA III Commitment Letter with specified completion dates in FYs 2023 and 2024. For the purposes of this report, "performance enhancement goals" are defined as any non-review performance goal with a specified deadline in the GDUFA III Commitment Letter.

1. FY 2023 Program Enhancement and Other Goals

Summary of Performance

FDA did not meet the FY 2023 program enhancement goal “FDA to grant or deny Pre-Submission Meeting Requests.”

Justification Regarding Missed Goals

FDA did not meet the FY 2023 program enhancement goal “FDA to grant or deny Pre-Submission Meeting Requests.” Due to the small number of Pre-Submission Meeting requests received (i.e., nine total), missing the goal for a single submission resulted in dropping below the GDUFA metric of 90 percent. FDA missed this goal due to human error with processing one Pre-Submission Meeting request.

FY 2023 Corrective Actions

FDA has updated its processes to prevent this type of error from occurring in the future.

2. FY 2024 Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management

Summary of Performance

120 of 128 GDUFA III hires were complete as of the end of FY 2024.

Justification Regarding Missed Goals

CDER identified four candidates at the end of the fiscal year, which didn’t allow enough time for the candidates to onboard before the end of FY 2024. FDA continues to work to fill these difficult-to-fill positions and anticipates meeting the hiring goal next year.

FY 2024 Corrective Actions

FDA has completed 120 of 128 GDUFA III hires. CDER has identified candidates and anticipates filling the remaining four CDER positions in FY 2025.

3. FY 2024 Program Enhancement and Other Goals

Summary of Performance

Because some submissions received in FY 2024 have associated program enhancement goals that fall within a subsequent fiscal year (e.g., FY 2025), FDA cannot yet evaluate and report on the FY 2024 program enhancement goals. FDA will provide an evaluation in the FY 2025 report.

Justification Regarding Missed Goals

It is too soon to determine the justification.

FY 2024 Corrective Actions

It is too soon to determine if a corrective action is needed.

4. FY 2024 Performance Enhancement Goal: Pre-ANDA

Summary of Performance

All FY 2024 goals were met.

Justification Regarding Missed Goals

No justification is needed.

FY 2024 Corrective Actions

No corrective action is needed.

5. FY 2024 Performance Enhancement Goal: Facilities

Summary of Performance

All FY 2024 goals were met.

Justification Regarding Missed Goals

No justification is needed.

FY 2023 Corrective Actions

No corrective action is needed.

6. FY 2024 Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management

Summary of Performance

FDA's publication of the annual update to the GDUFA Five-Year Financial Plan did not occur by the second quarter of FY 2024.

Justification Regarding Missed Goals

The delay occurred due to the challenges posed by a heavily manual financial reporting process, which significantly impacted the efficiency and contributed to the late publication of the Five-Year Financial Plan.

FY 2024 Corrective Actions

FDA has implemented automation for some processes involved in generating the Five-Year Financial Plans. The newly introduced system integrates data from multiple sources and automates complex calculations, significantly reducing the need for manual data entry. By automating these tasks, FDA expects to improve accuracy, minimize errors, and expedite the publication process. This automation not only reduces the likelihood of future delays but also enhances the overall efficiency and reliability of financial reporting.

7. FY 2024 Performance Enhancement Goal: Guidance and MAPPs

Summary of Performance

All FY 2024 goals were met.

Justification Regarding Missed Goals

No justification is needed.

FY 2023 Corrective Actions

No corrective action is needed.

8. FY 2024 Performance Enhancement Goal: Performance Reporting

Summary of Performance

All FY 2024 goals were met.

Justification Regarding Missed Goals

No justification is needed.

FY 2023 Corrective Actions

No corrective action is needed.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management. For information on obtaining additional copies, please contact:

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