



April 16, 2024

The Honorable Bill Cassidy, M.D.  
Ranking Member  
Committee on Health, Education, Labor and Pensions  
United States Senate  
Washington, DC 20510

Dear Senator Cassidy:

I am pleased to present the Food and Drug Administration's (FDA's) fiscal year (FY) 2023 performance report to Congress for the Generic Drug User Fee Amendments (GDUFA) program. This annual report not only presents preliminary data on FDA's success in meeting its FY 2023 review performance goals and commitments but also updates FDA's performance results for the previous fiscal year of GDUFA.

FDA has made significant progress in meeting the challenges and responsibilities of the generic drug program. A few noteworthy accomplishments have included the following:

- In FY 2023, FDA approved 782 abbreviated new drug applications (ANDAs) and tentatively approved 172 ANDAs.
- During the COVID-19 public health emergency that ended on May 11, 2023, FDA issued more than 2,000 approvals related to generic drug products for patients suffering from COVID. More than 125 original ANDAs for these products were approved, and more than 1,800 supplements were approved.

FDA looks forward to continued success of the generic drug review process, which will be made achievable by GDUFA.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in blue ink, appearing to read "Melanie Anne Egorin", is written over the typed name and title.

Melanie Anne Egorin, PhD  
Assistant Secretary for Legislation

Enclosure



April 16, 2024

The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Pallone:

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April 16, 2024

The Honorable Cathy McMorris Rodgers  
Chair  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20515

Dear Chair Rodgers:

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Melanie Anne Egorin, PhD  
Assistant Secretary for Legislation

Enclosure





April 16, 2024

The Honorable Bernard Sanders  
Chair  
Committee on Health, Education, Labor and Pensions  
United States Senate  
Washington, DC 20510

Dear Chair Sanders:

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Assistant Secretary for Legislation

Enclosure

**Report to Congress**

# **Generic Drug User Fee Amendments**

**FY 2023**



**U.S. FOOD & DRUG  
ADMINISTRATION**

## Executive Summary

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On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act,<sup>1</sup> 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,<sup>2</sup> 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),<sup>3</sup> 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 not only presents preliminary data on FDA's success in meeting FY 2023 review performance goals and commitments for GDUFA III but also updates the data for FY 2022 (the final year of GDUFA II).

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<sup>1</sup> <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>.

<sup>2</sup> <http://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf>.

<sup>3</sup> <https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf>.

## Highlighted Achievements – FY 2023

In FY 2023, FDA continued to experience the impact of the Coronavirus Disease 2019 (COVID-19) public health emergency.<sup>4</sup> Despite this, FDA met or exceeded a majority of its FY 2022 review performance goals with associated goal dates falling in FY 2023. Highlights of these activities are provided below.

### *Generic Drug Assessment and Approval Activity Highlights*

In FY 2023, FDA approved 782 abbreviated new drug applications (ANDAs) and tentatively approved (TAs) 172 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 2023 include:

- Tofacitinib tablets (reference listed drug (RLD) Xeljanz) – approved October 2022
- Obeticholic acid tablets (RLD Ocaliva) – approved May 2023
- Naltrexone for Extended-Release Injectable Suspension (RLD Vivitrol) – approved July 2023
- Saxagliptin Tablets (RLD Onglyza) – approved July 2023
- Palbociclib Tablets (RLD Ibrance) – approved August 2023

During the COVID-19 public health emergency that ended on May 11, 2023, FDA issued more than 2,000 approvals related to generic drug products for patients suffering from COVID. More than 125 original ANDAs for these products were approved, and more than 1,800 supplements were approved. Some original ANDAs were approved in just over a few months, well ahead of the performance goals in the applicable GDUFA Commitment Letter. Some supplements were approved in just a few days.

### *GDUFA Regulatory Science and Research Highlights*

During FY 2023, FDA's GDUFA Regulatory Science and Research Program generated more than 70 peer-reviewed scholarly articles, more than 100 external posters related to generic drugs, and more than 230 external talks presented at national and international scientific and medical conferences.

In addition to conducting numerous ongoing internal and external research projects, during FY 2023, the GDUFA Regulatory Science and Research Program awarded eight

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<sup>4</sup> The Department of Health and Human Services announced that the public health emergency for COVID-19 ended on May 11, 2023. See <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>.

new grants and 12 new contracts to advance external research collaborations in areas identified as FY 2023 GDUFA Science and Research Priority Initiatives for generics.<sup>5</sup> These research priorities were established based upon public input during the FY 2022 GDUFA public workshop and comments submitted to the docket for that workshop, as well as discussion with generic industry representatives in bi-annual meetings of the GDUFA Industry-FDA Working Group.

Among several notable ANDAs approved during FY 2023, FDA approved the first generic naltrexone extended-release injectable suspension (referencing Vivitrol®) to treat alcohol dependence and prevent relapse to opioid dependence. This suspension is an important drug product that addresses two major public health needs affecting millions of individuals in the United States. This approval was a notable achievement because of how scientifically challenging it was to develop, manufacture, and demonstrate bioequivalence for this generic product, which uses a long-acting injectable (LAI) biodegradable poly(lactide-co-glycolide) (PLGA) polymer microsphere technology. This approval exemplifies what can be achieved with effective coordination between FDA and the generic drug industry and demonstrates the value and enduring impact of the GDUFA Regulatory Science and Research Program. The GDUFA-funded research on such PLGA-based LAI products in 2013, as well as ongoing research during the last decade, has systematically advanced scientific insights and developed new tools that could support an efficient demonstration of bioequivalence for complex generic LAI products like this one.

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,<sup>6</sup> 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.

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)<sup>7</sup> during FY 2023. 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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<sup>5</sup> A detailed description of the FY 2023 GDUFA Science and Research Priority Initiatives can be found at [www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects](http://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects).

<sup>6</sup> 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](http://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects).

<sup>7</sup> Information about the CRCG may be found on its website at <https://www.complexgenerics.org/>.



Indeed, during FY 2023, FDA and the CRCG co-hosted five workshops and one training course, all of which included faculty from the generic drug industry, academia, and FDA.<sup>8</sup>

Overall, FDA hosted or co-hosted 13 scientific meetings, webinars, trainings, and public workshops during FY 2023 to promote transparency through regulatory and scientific outreach and to enhance collaboration and communications through dialogue with academic experts and pharmaceutical industry representatives on numerous issues impacting generic drugs. A complete listing of these events is available in section V 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 2023, FDA issued various policy documents, including 23 guidances for industry (not including Product-Specific Guidances (PSGs)), eight 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 2023, FDA issued 244 PSGs (174 for complex products). As of September 30, 2023, FDA had published 2,136 PSGs on FDA's [Product-Specific Guidances for Generic Drug Development website](https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development).<sup>9</sup>

In FY 2023, FDA continued its successful implementation of the law widely known as "CREATES"<sup>10</sup> 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 19 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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<sup>8</sup> Additional details about FDA-CRCG events are included in section V of the report under "GDUFA Regulatory and Scientific Outreach Activities Highlights."

<sup>9</sup> <https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development>.

<sup>10</sup> 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. This law was enacted in section 610, Actions for Delays of Generic Drugs and Biosimilar Biological Products, of Division N of Pub. L. 116-94, the Further Consolidated Appropriations Act, 2020 (21 U.S.C. 355-2), including amendments to section 505-1 of the FD&C Act (21 U.S.C. 355-1).

In February 2019, FDA outlined a program via a draft guidance by which stakeholders could propose pharmaceutical quality standards for recognition by the Center for Drug Evaluation and Research, providing industry with additional resources for pharmaceutical development and manufacturing. In July 2023, FDA issued the final guidance for this program, *CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality*, and launched a new portal to submit standards for potential recognition. This program is intended for all drugs, including brand, generic, biologic, biosimilar, and over-the-counter monograph drugs. It will help create efficiencies in generic and biosimilar manufacturing, which is an important part of streamlining generic and biosimilar development and spurring competition in support of FDA's Drug Competition Action Plan and Biosimilars Action Plan.

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## Acronym List

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<b>ANDA</b>	Abbreviated New Drug Application
<b>AI</b>	Artificial Intelligence
<b>API</b>	Active Pharmaceutical Ingredient
<b>BE</b>	Bioequivalence
<b>CBER</b>	Center for Biologics Evaluation and Research
<b>CDER</b>	Center for Drug Evaluation and Research
<b>CGMP</b>	Current Good Manufacturing Practice
<b>CR</b>	Complete Response
<b>CRL</b>	Complete Response Letter
<b>CFD</b>	Computational Fluid Dynamics
<b>DMF</b>	Drug Master File
<b>DRL</b>	Discipline Review Letter
<b>eCTD</b>	Electronic Common Technical Document
<b>EU</b>	European Union
<b>FDA</b>	Food and Drug Administration
<b>FD&amp;C Act</b>	Federal Food, Drug, and Cosmetic Act
<b>FDF</b>	Finished Dosage Form
<b>FTE</b>	Full Time Equivalent
<b>FY</b>	Fiscal Year (October 1 to September 30)
<b>GDUFA</b>	Generic Drug User Fee Amendments
<b>GDUFA I</b>	Generic Drug User Fee Amendments of 2012
<b>GDUFA II</b>	Generic Drug User Fee Amendments of 2017
<b>GDUFA III</b>	Generic Drug User Fee Amendments of 2023
<b>IA</b>	Import Alert
<b>IR</b>	Information Request
<b>IVRT</b>	In Vitro Release Test
<b>MAPP</b>	Manual of Policies and Procedures
<b>MRA</b>	Mutual Recognition Agreement
<b>NAI</b>	No Action Indicated
<b>OAI</b>	Official Action Indicated
<b>OC</b>	Office of the Commissioner
<b>ORA</b>	Office of Regulatory Affairs
<b>PAI</b>	Pre-Approval Inspection
<b>PAS</b>	Prior Approval Supplement
<b>PBPK</b>	Physiologically Based Pharmacokinetic
<b>PD</b>	Pharmacodynamic

<b>PFC</b>	Pre-Submission Facility Correspondence
<b>PK</b>	Pharmacokinetic
<b>PSG</b>	Product-Specific Guidance
<b>RLD</b>	Reference Listed Drug
<b>RPM</b>	Regulatory Project Manager
<b>RTR</b>	Refuse to Receive
<b>SBIA</b>	Small Business & Industry Assistance
<b>TA</b>	Tentative Approval
<b>USP</b>	United States Pharmacopeia
<b>UL</b>	Untitled Letter
<b>VAI</b>	Voluntary Action Indicated
<b>WL</b>	Warning Letter
<b>WCF</b>	Working Capital Fund

## I. Introduction

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Millions of Americans use generic drugs to treat a wide variety of medical conditions.<sup>1</sup> The Food and Drug Administration (FDA or Agency) helps 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.<sup>2</sup>

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 a majority 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 drugs program.

On September 30, 2022, the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180),<sup>3</sup> 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.

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<sup>1</sup> According to a report compiled by the Association for Accessible Medicines that was primarily based on data from IQVIA, generic drugs saved the American healthcare system nearly \$2.9 trillion in the last 10 years due to the availability of affordable generics. The report is available at <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>.

<sup>2</sup> 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.

<sup>3</sup> <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 final year of GDUFA II (i.e., FY 2022) and preliminary performance results in the first year of GDUFA III (i.e., FY 2023). This report also presents the Agency's progress in accomplishing the FY 2022 program goals and enhancements of GDUFA II and its preliminary progress in accomplishing the program goals and enhancements of GDUFA III. Unless otherwise noted, updated data for FY 2022 and preliminary data for FY 2023 are as of September 30, 2023.

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.
- The sections in this report may not look identical when comparing GDUFA II to GDUFA III due to the differences in the commitments and organization of the GDUFA II Commitment Letter and the GDUFA III Commitment Letter. 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 (CC). Each section of this report accurately reports the commitments for each commitment letter.
- 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-accept (RTA) 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 (e.g., standard original ANDA submissions) with longer review goals (e.g., a 10-month goal date) 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 Workload: FY 2022

Table 1 summarizes the GDUFA II workload, including final data for FY 2022. The GDUFA III Commitment Letter does not continue the presentation of this information in the same format as the GDUFA II Commitment Letter; however, per the GDUFA III Commitment Letter, this information is presented elsewhere throughout this report and/or through committed monthly, quarterly, or annually publicly available postings on FDA's website.

**Table 1. GDUFA II Workload**

GDUFA II Workload	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022*
<b>Original ANDAs</b>					
Total Original ANDAs Submitted	1,044	909	865	810	857
ANDAs Submitted After RTR for Failure to Pay User Fees	16	14	10	7	8
ANDAs Submitted After RTR for Technical Reasons	81	51	42	47	49
<b>ANDA Solicited Amendments</b>					
Total Solicited ANDA Amendments Submitted	2,328	2,275	2,028	1,911	1,814
<b>Prior Approval Supplements (PASs)</b>					
Total PAS Submissions	1,103	889	1,133	1,351	1,296
<b>PAS Solicited Amendments</b>					
Total Solicited PAS Amendments Submitted	160	199	268	260	391
<b>DMFs<sup>†</sup></b>					
Total DMFs Submitted	377	346	291	272	284
<b>CC</b>					
Total CC Submitted	2,933	3,206	3,596	3,924	3,730

\* Numbers were revised to reflect updates to the data presented in the FY 2022 GDUFA performance report.

† DMF submissions include only DMFs for which the holder has paid fees. Thus, the number of DMF submissions in a fiscal year will increase as fees get paid.

### III. GDUFA Performance Goals

In both GDUFA II and 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 performance goals in the GDUFA III Commitment Letter are different from those in the GDUFA II Commitment Letter. The performance results for GDUFA II and GDUFA III accurately reflect the reporting requirements for each GDUFA reauthorization.

#### A. FY 2022 (GDUFA II) Updated Performance Goal Results

Table 2 reflects the GDUFA II ANDA review goals for FYs 2018 to 2022.

**Table 2. GDUFA II Performance Goals for FYs 2018 to 2022**

GDUFA II Review Goals by Submission Type	Review and Act on % Within	FY 2018	FY 2019	FY 2021	FY 2021	FY 2022
<b>Original ANDA Review*</b>						
Standard Original ANDA Submissions	10 months	90%	90%	90%	90%	90%
Priority Original ANDA Submissions (if applicant meets the requirements of a Pre-Submission Facility Correspondence (PFC))	8 months	90%	90%	90%	90%	90%
Priority Original ANDA Submissions (if applicant does not meet the requirements of a PFC)	10 months	90%	90%	90%	90%	90%
<b>Amendment Review</b>						
Standard Major ANDA Amendments (if pre-approval inspection (PAI) is not required)	8 months	90%	90%	90%	90%	90%
Standard Major ANDA	10 months	90%	90%	90%	90%	90%



<b>GDUFA II Review Goals by Submission Type</b>	<b>Review and Act on % Within</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2021</b>	<b>FY 2021</b>	<b>FY 2022</b>
Amendments (if PAI is required)						
Priority Major ANDA Amendments (if PAI is not required)	6 months	90%	90%	90%	90%	90%
Priority Major ANDA Amendments (if PAI is required and applicant meets the requirements of a PFC)	8 months	90%	90%	90%	90%	90%
Priority Major ANDA Amendments (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	90%	90%	90%	90%	90%
Standard and Priority Minor ANDA Amendments	3 months	90%	90%	90%	90%	90%
<b>PAS Review Time†</b>						
Standard PAS (if PAI is not required)	6 months	90%	90%	90%	90%	90%
Standard PAS (if PAI is required)	10 months	90%	90%	90%	90%	90%
Priority PAS (if PAI is not required)	4 months	90%	90%	90%	90%	90%
Priority PAS (if PAI is required and applicant meets the requirements of a PFC)	8 months	90%	90%	90%	90%	90%
Priority PAS (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	90%	90%	90%	90%	90%
<b>PAS Amendments</b>						

GDUFA II Review Goals by Submission Type	Review and Act on % Within	FY 2018	FY 2019	FY 2021	FY 2021	FY 2022
Standard Major PAS Amendment (if PAI is not required)	6 months	90%	90%	90%	90%	90%
Standard Major PAS Amendment (if PAI is required)	10 months	90%	90%	90%	90%	90%
Priority Major PAS Amendment (if PAI is not required)	4 months	90%	90%	90%	90%	90%
Priority Major PAS Amendment (if PAI is required and applicant meets the requirements of a PFC)	8 months	90%	90%	90%	90%	90%
Priority Major PAS Amendment (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	90%	90%	90%	90%	90%
Standard and Priority Minor PAS Amendments	3 months	90%	90%	90%	90%	90%
Unsolicited ANDA and PAS Amendments <sup>‡</sup>						
Unsolicited ANDA and PAS Amendments <sup>§</sup>	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 DMF submission or DMF Fee payment	90%	90%	90%	90%	90%
CC <sup>¶</sup>						

GDUFA II Review Goals by Submission Type	Review and Act on % Within	FY 2018	FY 2019	FY 2021	FY 2021	FY 2022
Standard CC	Within 60 calendar days of submission date	90%	90%	90%	90%	90%
Complex CC	Within 120 calendar days of submission date	90%	90%	90%	90%	90%
Submitter requests to clarify ambiguities in the CC	Within 14 calendar days of request receipt	90%	90%	90%	90%	90%

\* Section I(1) of the GDUFA II Commitment Letter.

† Section I(B) of the GDUFA II Commitment Letter.

‡ Section I(C) of the GDUFA II Commitment Letter.

§ The GDUFA II 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.

Table 3 shows the updated performance for the FY 2022 cohort. The data show that FDA met or exceeded a majority of the goals for the FY 2022 cohort.

**Table 3. GDUFA II FY 2022 Updated Performance Goal Results**

GDUFA II FY 2022 Updated Performance Goals by Submission Type	Review and Act on 90 % Within	Actions Complete*	Percent on Time†	Potential Range‡	On Time Imminent Action	Imminent Action Potential Range
<b>Original ANDA Goals</b>						
Standard Original ANDA Submissions	10 months	574 of 628	93%	87% to 93%	95%	89% to 96%
Priority Original ANDA Submissions (if applicant meets requirements of a PFC)	8 months	41 of 41	95%	95% to 95%	98%	98% to 98%
Priority Original ANDA Submissions (if applicant does not meet requirements of a PFC)	10 months	169 of 180	92%	88% to 94%	97%	92% to 97%
<b>Amendment Goals</b>						

<b>GDUFA II FY 2022 Updated Performance Goals by Submission Type</b>	<b>Review and Act on 90 % Within</b>	<b>Actions Complete*</b>	<b>Percent on Time†</b>	<b>Potential Range‡</b>	<b>On Time Imminent Action</b>	<b>Imminent Action Potential Range</b>
Standard Major ANDA Amendments (if PAI is not required)	8 months	775 of 797	90%	90% to 90%	94%	94% to 94%
Standard Major ANDA Amendments (if PAI is required)	10 months	64 of 72	88%	82% to 89%	90%	83% to 90%
Priority Major ANDA Amendments (if PAI is not required)	6 months	129 of 131	92%	92% to 92%	98%	98% to 98%
Priority Major ANDA Amendments (if PAI is required and applicant meets the requirements of a PFC)	8 months	--	--	--	--	--
Priority Major ANDA Amendments (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	13 of 14	79%	79% to 79%	93%	93% to 93%
Standard and Priority Minor ANDA Amendments	3 months	805 of 810	84%	84% to 84%	96%	96% to 96%
<b>PAS Goals</b>						
Standard PAS (if PAI is not required)	6 months	1112 of 1119	97%	97% to 97%	98%	98% to 98%
Standard PAS (if PAI is required)	10 months	53 of 53	92%	92% to 92%	94%	94% to 94%
Priority PAS (if PAI is not required)	4 months	95 of 95	99%	99% to 99%	100%	100% to 100%
Priority PAS (if PAI is required and applicant meets the requirements of a PFC)	8 months	1 of 1	100%	100% to 100%	100%	100% to 100%



<b>GDUFA II FY 2022 Updated Performance Goals by Submission Type</b>	<b>Review and Act on 90 % Within</b>	<b>Actions Complete*</b>	<b>Percent on Time†</b>	<b>Potential Range‡</b>	<b>On Time Imminent Action</b>	<b>Imminent Action Potential Range</b>
Priority PAS (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	9 of 9	100%	100% to 100%	100%	100% to 100%
<b>PAS Amendment Goals</b>						
Standard Major PAS (if PAI is not required)	6 months	154 of 154	99%	99% to 99%	99%	99% to 99%
Standard Major PAS (if PAI is required)	10 months	15 of 15	93%	93% to 93%	93%	93% to 93%
Priority Major PAS (if PAI is not required)	4 months	13 of 13	100%	100% to 100%	100%	100% to 100%
Priority Major PASs (if PAI is required and applicant meets the requirements of a PFC)	8 months	--	--	--	--	--
Priority Major PASs (if PAI is required and applicant does not meet the requirements of a PFC)	10 months	2 of 2	100%	100% to 100%	100%	100% to 100%
Standard and Priority Minor PAS Amendments	3 months	207 of 208	99%	99% to 99%	99%	99% to 99%
<b>DMF</b>						
Complete the initial completeness assessment review of Type II API DMF	60 calendar days	397 of 397	99%	99% to 99%	--	--
<b>CC</b>						
Standard CC	60 calendar days	3428 of 3437	99%	99% to 99%	--	--
Complex CC	120 calendar days	292 of 293	99%	99% to 99%	--	--
Clarification of Ambiguities in CC Response	14 calendar days	28 of 28	89%	89% of 89%	--	--

- \* “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.
- † “Percent on Time” represents the current percentage of actions FDA completed within the review-time goal.
- ‡ “Range” represents the minimum (all pending become late) and maximum (all pending reviewed on time) performance.

## B. FY 2023 Preliminary Performance Goals

Table 4 reflects the ANDA performance goals for FYs 2023 to 2027.

**Table 4. 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%
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 API DMFs	Within 60 calendar days of the later of the date of DMF submission or DMF Fee payment	90%	90%	90%	90%	90%
CC¶						
Level 1 CC	Within 60 calendar days	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
		of submission date					
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 II 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.

Table 5 represents FDA’s FY 2023 preliminary performance data. The “Percent on Time” column shows the percentage of submissions reviewed on time as of September 30, 2023, excluding action pending within the GDUFA review goal, and the “Potential Range” column shows the potential for meeting the FY 2023 GDUFA review goal.

Like GDUFA II, 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.

**Table 5. GDUFA III FY 2023 Preliminary Performance Goal Results**

<b>GDUFA III FY 2023 Preliminary Performance Goals by Submission Type</b>	<b>Review Time Goal</b>	<b>Actions Complete*</b>	<b>Percent on Time†</b>	<b>Potential Range‡</b>	<b>On Time Imminent Action§</b>	<b>Imminent Action Potential Range</b>
<b>Original ANDA Goals</b>						
Standard Original ANDA Submissions	10/30 months	76 of 511	93%	15% to 99%	100%	15% to 100%
Priority Original ANDA Submissions	8/10/30 months	27 of 139	93%	19% to 99%	100%	19% to 100%
<b>Amendment Goals</b>						
Standard Major ANDA Amendments	8/10 months	237 of 766	90%	30% to 97%	96%	30% to 99%
Priority Major ANDA Amendments	6/8/10 months	60 of 130	94%	45% to 97%	95%	45% to 98%
Standard and Priority Minor ANDA Amendments	3 months	494 of 716	88%	62% to 91%	97%	68% to 98%
<b>PAS Goals</b>						
Standard PAS	6/10 months	863 of 1466	99%	59% to 99%	99%	59% to 99%
Priority PAS	4/8/10 months	66 of 108	93%	57% to 95%	94%	57% to 96%
<b>PAS Amendment Goals</b>						
Standard Major PAS Amendment	6/10 months	91 of 132	100%	69% to 100%	100%	69% to 100%
Priority Major PAS Amendment	4/8/10 months	4 of 6	100%	67% to 100%	100%	67% to 100%
Standard and Priority Minor PAS Amendments	3 months	174 of 224	97%	76% to 98%	99%	78% to 99%
<b>DMF Goals</b>						
Complete the Initial Completeness Assessment Review of Type II API DMFs	60 calendar days	284 of 284	99%	99% to 99%	--	--
<b>CC Goals</b>						
Level I CC	60 calendar days	2923 of 3260	99%	90% to 99%	--	--
Level II CC	120 calendar days	296 of 408	95%	71% to 97%	--	--
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.

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

‡ "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 on time.

## IV. 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. An example of “program enhancements” is 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. Table 6 reflects these program enhancement goals for FYs 2018 to 2022.

**Table 6. GDUFA II Program Enhancement Goals for FYs 2018 to 2022**

	Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
<b>Dispute Resolution</b>						
FDA to respond to appeals above the division level	Within 30 calendar days of the Center for Drug Evaluation and Research’s (CDER’s) receipt of the written appeal pursuant to the applicable goal	70%	80%	90%	90%	90%
<b>Product Development Meetings</b>						
FDA to grant or deny Product Development Meeting Requests	Within 30 calendar days from receipt of request	90%	90%	-	-	-
	Within 14 calendar days from receipt of request	-	-	90%	90%	90%
FDA to conduct Product Development Meetings granted	Within 120 calendar days of granting them	60%	70%	80%	90%	90%
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	-	-	-	-	-
FDA to provide meeting minutes	Within 30 calendar days of the meeting	-	-	-	-	-
<b>Pre-Submission Meetings</b>						
FDA to grant or deny Pre-Submission Meeting Requests	Within 30 calendar days from receipt of request	90%	90%	-	-	-
	Within 14 calendar days from receipt of request	-	-	90%	90%	90%
FDA to conduct Pre-Submission Meetings granted	Within 120 calendar days of granting them	60%	70%	80%	90%	90%

	Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
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	-	-	-	-	-
<b>DMF First Cycle Review Deficiency</b>						
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days	-	-	-	-	-
<b>Review Classification Changes During Review Cycle</b>						
FDA to notify the applicant if the review classification of the ANDA or PAS changes from standard to priority during a review cycle of an ANDA or PAS	Within 14 calendar days of the date of the change	-	-	-	-	-
FDA to notify the applicant if a previous ANDA or ANDA amendment was subject to priority review but a subsequent ANDA amendment is subject to a standard review	Within 14 calendar days of the date of receipt of the solicited amendment	-	-	-	-	-
FDA to decide whether to reclassify a major amendment or standard review status	Within 30 calendar days of date of FDA's receipt of the request for a reclassification	90%	90%	90%	90%	90%
<b>Post-CRL</b>						
FDA to provide a scheduled date for a requested post-CRL teleconference	Within 10 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%
<b>Safety Determination Letters</b>						
FDA to issue safety determination letters	Within 60 calendar days of the date of submission of disclosure authorization	90%	90%	90%	90%	90%

## A. FY 2022 GDUFA II Program Enhancement Goals

Table 7 represents FDA's FY 2022 updated performance on the GDUFA II program enhancement goals. The data show that FDA met or exceeded a majority of the goals for the FY 2022 cohort.

**Table 7. GDUFA II Updated FY 2022 Program Enhancement Goal Results**

<b>GDUFA II FY 2022 Updated Performance*</b>	<b>Review Goal</b>	<b>Goal</b>	<b>Actions Completed†</b>	<b>Percent on Time‡</b>	<b>Potential Range§</b>
<b>Dispute Resolution</b>					
FDA to respond to appeals above the division level	Within 30 calendar days of CDER's receipt of the written appeal pursuant to the applicable goal	90%	12 of 12	92%	92% to 92%
<b>Product Development Meetings</b>					
FDA to grant or deny Product Development Meeting Requests	Within 14 calendar days from receipt of request	90%	113 of 113	98%	98% to 98%
FDA to conduct Product Development Meetings granted	Within 120 calendar days of granting them	90%	83 of 83	99%	99% to 99%
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	-	40 of 40	100%	100% to 100%
FDA to provide meeting minutes	Within 30 calendar days following the meeting	-	26 of 26	100%	100% to 100%
<b>Pre-Submission Meetings</b>					
FDA to grant or deny Pre-Submission Meeting Requests	Within 14 calendar days from receipt of request	90%	8 of 8	100%	100% to 100%
FDA to conduct Pre-Submission Meetings granted	Within 120 days of granting them	90%	2 of 2	100%	100% to 100%
If appropriate to the purpose of the meeting, FDA to provide preliminary written comments	5 calendar days before each meeting	-	2 of 2	100%	100% to 100%
FDA to provide meeting minutes	Within 30 calendar days of the meeting	-	2 of 2	100%	100% to 100%
<b>DMF First Cycle Review Deficiency</b>					
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days	-	8 of 8	75%	75% to 75%
<b>Review Classification Changes During Review Cycle</b>					
FDA to notify the applicant if the review classification of the ANDA or PAS changes from standard to priority during a review cycle of an ANDA or PAS	Within 14 calendar days of the date of the change	-	32 of 32	100%	100% to 100%
FDA to notify the applicant if a previous ANDA or ANDA amendment was subject to priority review, but a subsequent ANDA amendment is subject to a standard review	Within 14 calendar days of the date of receipt of the solicited amendment	-	115 of 115	93%	93% to 93%
FDA to decide whether to reclassify a major amendment or standard review status	Within 30 calendar days of the date of FDA's receipt of the	90%	103 of 103	100%	100% to 100%



GDUFA II FY 2022 Updated Performance*	Review Goal	Goal	Actions Completed†	Percent on Time‡	Potential Range§
	request for a reclassification				
<b>Post-CRL</b>					
FDA to provide a scheduled date for a requested post-CRL teleconference	Within 10 calendar days of the request for a teleconference	90%	66 of 66	88%	88% to 88%
FDA to conduct requested post-CRL teleconferences on the FDA-proposed date	Within 30 calendar days of the receipt of the written request	90%	66 of 66	100%	100% to 100%
<b>Safety Determination Letters</b>					
FDA to issue safety determination letters¶	Within 60 calendar days of the date of submission of disclosure authorization	90%	-	-	-

\* Numbers were changed to reflect updates to the data presented in the FY 2022 GDUFA performance report.

† "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.

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

¶ The law widely known as the CREATES Act, enacted in December 2019 as part of the Further Consolidated Appropriations Act of 2020, makes available a pathway for developers of potential drug and biological products to obtain samples of brand products that they need to support their applications. As part of the CREATES implementation, FDA is no longer issuing the Safety Determination Letters to generic product developers that FDA had been issuing prior to CREATES under the December 2014 draft guidance for industry *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD*. Instead, FDA now issues Covered Product Authorizations under CREATES, which are accounted for under the Level 2 CC GDUFA category (in the case of Covered Product Authorizations sought for ANDA development). FDA published a draft guidance *How to Obtain a Covered Product Authorization* in September 2022, which replaced the December 2014 draft guidance for industry *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD*.

## B. Preliminary Program Enhancement and Other Goal Results – FY 2023

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 8 reflects the program enhancement goals for FYs 2023 to 2027 described in sections II to VII of the GDUFA III Commitment Letter.

**Table 8. GDUFA III Program Enhancement and Other Goals for FYs 2023 to 2027**

GDUFA III Program Enhancement Goals	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
<b>Assessment Classification Changes During Assessment Cycle</b>						
FDA to notify the applicant if the assessment classification of the ANDA or PAS changes from standard to priority	Within 14 calendar days of the date of the change	90%	90%	90%	90%	90%

<b>GDUFA III Program Enhancement Goals</b>	<b>Goal</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
during an assessment cycle of an ANDA or PAS						
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%	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	90%	90%	90%	90%	90%
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	90%	90%	90%	90%	90%
<b>Dispute Resolution</b>						
FDA to respond to appeals above the Division level	Within 30 calendar days of CDER's receipt of the written appeal pursuant to the applicable goal	90%	90%	90%	90%	90%
<b>Suitability Petitions</b>						
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%	70%	80%	90%
<b>PSGS for Complex and Non-Complex Drug Products</b>						
Complex products approved in 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%
<b>PSG Teleconference and Meetings</b>						
FDA to conduct a PSG Teleconference granted	Within 30 calendar days from receipt of request	90%	90%	90%	90%	90%
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	90%	90%	90%	90%	90%
FDA to schedule Pre-Submission PSG Meeting granted if the applicant has not submitted an ANDA	Within 120 days from receipt of request	90%	90%	90%	90%	90%
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	90%	90%	90%	90%	90%

<b>GDUFA III Program Enhancement Goals</b>	<b>Goal</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
FDA to schedule Post-Submission PSG Meeting granted if the applicant has submitted an ANDA	Within 90 calendar days from receipt of request	90%	90%	90%	90%	90%
<b>Product Development Meetings</b>						
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 before each Product Development Meeting	5 calendar days before the meeting	90%	90%	90%	90%	90%
FDA to provide meeting minutes	Within 30 calendar days following the meeting	90%	90%	90%	90%	90%
<b>Pre-Submission Meetings</b>						
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	90%	90%	90%	90%	90%
FDA to provide meeting minutes	Within 30 calendar days of the meeting	90%	90%	90%	90%	90%
<b>Mid-Cycle Review Meeting (MCRM)</b>						
FDA to conduct a MCRM granted	Within 30 calendar days from receipt of request	90%	90%	90%	90%	90%
<b>Enhanced Mid Cycle Review Meeting (EMCRM)</b>						
FDA to conduct a EMCRCM granted	Within 90 calendar days after issuance of the last mid-cycle DRL	90%	90%	90%	90%	90%
<b>Post-CRL Teleconference Meetings</b>						
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%
<b>Post-CRL Scientific Meetings</b>						

<b>GDUFA III Program Enhancement Goals</b>	<b>Goal</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
FDA to grant or deny post-CRL Scientific meeting requests	Within 14 calendar days from receipt of request	90%	90%	90%	90%	90%
FDA to conduct or provide written response to post-CRL scientific meeting granted	Within 90 calendar days of granting request	90%	90%	90%	90%	90%
<b>DMF First Cycle Review Deficiency</b>						
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days from receipt of request	-	-	-	-	-
<b>Foreign Regulators</b>						
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	-	-	-	-	-
<b>Post-Warning Letter (WL) Meetings</b>						
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%
<b>Re-Inspection</b>						
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%

\* The absolute number of suitability petitions will increase each year.

Table 9 represents FDA's FY 2023 preliminary program enhancement goal results.

**Table 9. GDUFA III FY 2023 Preliminary Program Enhancement and Other Goal Results**

<b>GDUFA III FY 2023 Preliminary Performance</b>	<b>Review Goal</b>	<b>Goal</b>	<b>Actions* Completed</b>	<b>Percent on Time</b>	<b>Potential Range</b>
<b>Assessment Classification Changes During Assessment Cycle</b>					

<b>GDUFA III FY 2023 Preliminary Performance</b>	<b>Review Goal</b>	<b>Goal</b>	<b>Actions* Completed</b>	<b>Percent on Time</b>	<b>Potential Range</b>
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%	90 of 98	98%	90% to 98%
FDA to make a decision 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	100%	100% to 100%
FDA to make a decision 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%
<b>Dispute Resolution</b>					
FDA to respond to appeals above the Division level	Within 30 calendar days of the CDER's receipt of the written appeal pursuant to the applicable goal	90%	2 of 3	100%	67% to 100%
<b>Suitability Petitions</b>					
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	-	-	-	-
<b>PSGs for Complex and Non-Complex Drug Products</b>					
Complex products approved in NDAs	Within 2 years of approval	50%	21 of 59	36%	36%-50%
Complex products approved in NDAs	Within 3 years of approval	75%	36 of 59	54%	54%-75%
Non-complex products approved in NDAs that contains a new chemical entity (NCE)	Within 2 years of approval	90%	32 of 32	100%	100%-100%
<b>PSG Teleconference and Meetings</b>					
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 days of receipt	-	-	-	-

<b>GDUFA III FY 2023 Preliminary Performance</b>	<b>Review Goal</b>	<b>Goal</b>	<b>Actions* Completed</b>	<b>Percent on Time</b>	<b>Potential Range</b>
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	-	-	-	-
<b>Product Development Meetings</b>					
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%	56 of 71	100%	79% 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	-	29 of 37	100%	78% to 100%
FDA to provide meeting minutes	Within 30 calendar days following the meeting	-	15 of 23	100%	65% to 100%
<b>Pre-Submission Meetings</b>					
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 days of receipt	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	-	-	-	-
<b>Mid-Cycle Review Meeting (MCRM)</b>					
FDA to conduct a MCRM granted	Within 30 calendar days after the date the sponsor submits a meeting request	90%	1 of 1	100%	100% to 100%
<b>Enhanced Mid Cycle Review Meeting (EMCRM)</b>					
FDA to conduct a EMCRM granted	Within 90 calendar days after issuance of the last mid-cycle DRL	90%	1 of 1	100%	100% to 100%
<b>Post-CRL Teleconference Meetings</b>					
FDA to provide a scheduled date for a requested post-CRL teleconference	Within 14 calendar days of the request for a teleconference	90%	65 of 65	91%	91% to 91%

<b>GDUFA III FY 2023 Preliminary Performance</b>	<b>Review Goal</b>	<b>Goal</b>	<b>Actions* Completed</b>	<b>Percent on Time</b>	<b>Potential Range</b>
FDA to conduct requested post-CRL teleconferences on the FDA-proposed date	Within 30 calendar days of the receipt of the written request	90%	61 of 65	98%	91% to 98%
<b>Post-CRL Scientific Meetings</b>					
FDA to grant or deny post-CRL Scientific meeting requests	Within 14 calendar days of the request	90%	20 of 20	100%	100% to 100%
FDA to conduct or provide written response to post-CRL scientific meeting granted	Within 90 calendar days after the date the meeting is granted	90%	12 of 14	100%	86% to 100%
<b>DMF First Cycle Review Deficiency</b>					
FDA to strive to grant DMF first cycle review deficiency teleconferences	Within 30 calendar days	-	4 of 4	100%	100% to 100%
<b>Foreign Regulators</b>					
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 request	-	22 of 22	100%	100% to 100%
<b>Post-WL Meetings</b>					
FDA to grant, deny, or defer in favor of re-inspection a Post-WL Meeting	Within 30 calendar days from receipt of request	-	1 of 2	100%	50% to 100%
<b>Re-Inspection</b>					
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	0%	0% to 0%
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	-	2 of 4	100%	50% to 100%

\* "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.

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



## V. Additional Activities to Implement GDUFA Commitments

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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-Related Document Highlights

In FY 2023, FDA published many guidances for industry<sup>4</sup> and Manuals of Policies and Procedures (MAPPs)<sup>5</sup> 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 2023, FDA published the following guidances for industry and MAPPs:

- Draft guidance for industry: *Facility Readiness: Goal Date Decisions Under GDUFA* (October 2022)
- Draft guidance for industry: *Review of Drug Master Files in Advance of Certain ANDA Submissions under GDUFA* (October 2022)
- Final guidance for industry: *Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA* (October 2022)
- Final guidance for industry: *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2022)
- Final guidance for industry: *Information Requests and Discipline Review Letters Under GDUFA* (October 2022)
- Final guidance for industry: *Competitive Generic Therapies* (October 2022)
- Final guidance for industry: *Prior Approval Supplements under GDUFA* (October 2022)
- Draft guidance for industry: *Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs* (October 2022)
- Draft guidance for industry: *In Vitro Release Test Studies for Topical Products Submitted in ANDAs* (October 2022)
- Draft guidance for industry: *In Vitro Permeation Test Studies for Topical Products Submitted in Abbreviated New Drug Applications* (October 2022)
- Draft guidance for industry: *Topical Dermatologic Corticosteroids: In Vivo Bioequivalence* (October 2022)

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<sup>4</sup> FDA's guidance documents may be accessed at [www.fda.gov/regulatoryinformation/guidances/](https://www.fda.gov/regulatoryinformation/guidances/).

<sup>5</sup> These MAPPs may be accessed at [www.fda.gov/about-fda/center-drug-evaluation-and-research/cder-manual-policies-procedures-mapp](https://www.fda.gov/about-fda/center-drug-evaluation-and-research/cder-manual-policies-procedures-mapp).

- Final guidance for industry: *Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA* (October 2022)
- Draft guidance for industry: *Sameness Evaluations in an ANDA – Active Ingredients* (November 2022)
- Draft guidance for industry: *ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence)* (December 2022)
- Draft guidance for industry: *Statistical Approaches to Establishing Bioequivalence* (December 2022)
- Draft guidance for industry: *Controlled Correspondence Related to Generic Drug Development* (December 2022)
- Final guidance for industry: *Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe* (December 2022)
- Draft guidance for industry: *M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms* (January 2023)
- Draft guidance for industry: *Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA* (February 2023)
- Final guidance for industry: *Q13 Continuous Manufacturing of Drug Substances and Drug Products* (March 2023)
- Draft guidance for industry: *Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs* (April 2023)
- Draft guidance for industry: *Assessing Adhesion with Transdermal and Topical Delivery Systems for ANDAs* (April 2023)
- Final guidance for industry: *Cover Letter Attachments for Controlled Correspondence and ANDA Submissions* (June 2023)
- Final guidance for industry: *Assessing User Fees Under the Generic Drug User Fee Amendments of 2022* (June 2023)
- Final guidance for industry: *CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality* (July 2023)
- Final guidance for industry: *Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs)* (August 2023)
- Draft guidance for industry: *Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications* (September 2023)
- Draft guidance for industry: *Post-Warning Letter Meetings Under GDUFA* (August 2023)
- MAPP 5220.5 Revision 2: *Issuance of Information Requests and/or Discipline Review Letters for Abbreviated New Drug Applications* (October 2022)
- MAPP 5220.8 Revision 1: *Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings* (October 2022)
- MAPP 5200.12: *Communicating Abbreviated New Drug Application Review Status Updates with Industry* (October 2022)

- MAPP 5240.3 Revision 6: *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* (October 2022)
- MAPP 5220.1 Revision 1: *Receiving and Processing a Request for Voluntary Withdrawal of an Approved ANDA* (January 2023)
- MAPP 5210.4 Revision 3: *Assessment of Bioequivalence Studies with Clinical Endpoints in ANDAs* (May 2023)
- MAPP 5021.5: *Assessment of Facility-Based Deficiency Major-to-Minor Reclassification Requests* (June 2023)
- MAPP 5240.5 Revision 3: *ANDA Suitability Petitions* (September 2023)

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 October 2022, FDA published three draft guidances providing general recommendations for physiochemical and structural (Q3) characterization tests, in vitro release test studies (IVRT), and in vitro permeation test (IVPT) studies for topical generic drug products. These draft guidances are intended to assist applicants who are submitting ANDAs for liquid-based and/or other semisolid products applied to the skin.

The first draft guidance, *Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs*, includes recommendations for characterization tests that can be used to assess whether a proposed generic topical product and its reference product are the same dosage form to support a demonstration of pharmaceutical equivalence. This draft guidance also contains recommendations for characterization tests that can be used to describe properties of the drug product that may be critical to its performance to support a demonstration of bioequivalence (BE). The other two draft guidances provide general recommendations for IVRT studies and IVPT studies, comparing a proposed generic topical product and its reference standard to support a demonstration of BE. In addition to these three guidances, FDA published more than 80 Product-Specific Guidances (PSGs) for topical drug products that included recommendations on Q3 characterization tests, IVRT studies, and/or IVPT studies.

In FY 2023, 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 all significant performance goals and program enhancements under GDUFA III.

Notably, by the end of Year 1 of GDUFA III (i.e., FY 2023), FDA had published all the guidances and MAPPs delineated in Section IX of the GDUFA III Commitment Letter.

## 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.

In FY 2023, 14 suitability petitions were submitted to FDA. Consistent with the GDUFA III Commitment Letter, FDA accomplished the following in FY 2023:

- FDA enhanced its processes for reviewing and responding to suitability petitions. For example, the Agency published MAPP 5240.5 Revision 3: *ANDA Suitability Petitions* in September 2023, which generally describes how FDA’s Office of Generic Drugs (OGD) responds to suitability petitions, including enhancements to FDA’s tracking of and performance in responding to suitability petitions.
- FDA continued to review and respond to pending suitability petitions. In FY 2023, 102 suitability petitions were closed out.
- FDA contacted petitioners who submitted suitability petitions prior to FY 2023 to determine if they remained interested in a response.

## C. GDUFA Regulatory Science and Research Highlights

### 1. Outreach Highlights

In FY 2023, as shown in Table 10, FDA hosted or co-hosted numerous meetings, webinars, trainings, 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 10. FDA’s GDUFA-Related Meetings, Webinars, Trainings, and Public Workshops in FY 2023**

GDUFA-Related Meetings, Webinars, Trainings, and Public Workshops	Date Held
<a href="#">FDA and Center for Research on Complex Generics Co-Hosted Workshop: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development</a>	10/27/2022 – 10/28/2022

GDUFA-Related Meetings, Webinars, Trainings, and Public Workshops	Date Held
<p>This workshop discussed how to modernize approaches for efficiently demonstrating BE, to establish the role of quantitative methods and modeling in modern paradigms of generic drug development, and to explore and develop best practices for the use of modeling and simulation approaches in regulatory submissions and approval. This workshop engaged experts from regulatory agencies, the generic drug industry, consultants, academia, and others in the field of modeling and simulation to discuss the opportunities and best practices for incorporating modeling and simulation approaches into generic drug development programs and regulatory submissions. The workshop also identified commonalities in methodologies, workflows, or in silico models supporting alternative BE approaches and clarified how a model master file may be leveraged to advance drug product development, facilitate regulatory assessment, and streamline drug product approval.</p>	
<p><b><u>FDA and Center for Research on Complex Generics Co-Hosted Workshop: Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development</u></b></p> <p>This workshop discussed efficient, science-based BE approaches under development that may be useful for certain prospective generic products which are compositionally different compared to the reference standard. The approaches included sophisticated techniques to characterize the physicochemical, structural, sensorial, and thermodynamic properties of topical drug products applied on the skin, as well as in vivo cutaneous pharmacokinetics studies. The workshop provided an update on the progress of research activities funded by GDUFA, explored challenging issues that benefited from broader discussion, identified areas for further research, and discussed opportunities for coordination and collaboration between FDA, the generic industry, academic institutions, contract research organizations, consultants, and others involved in generic drug development.</p>	11/03/2022
<p><b><u>FDA and Center for Research on Complex Generics Co-Hosted Webinar: Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned</u></b></p> <p>This webinar provided an overview of the regulatory framework, scientific concepts, product-specific challenges, and best practices related to the development of complex generic drug products that are either required or recommended to have the same formulation as their respective reference listed drugs. The information presented and discussions during the webinar provided attendees with a better understanding of the considerations that go into developing appropriate formulations. The webinar also discussed best practices for the presentation of formulation information that can support an efficient formulation assessment by FDA and can reduce the time to potential product approval.</p>	12/06/2022
<p><b><u>SBIA Webinar: A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence</u></b></p> <p>This webinar provided a deeper look into FDA's draft guidance for industry <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-approaches-establishing-bioequivalence-0">Statistical Approaches to Establishing Bioequivalence</a> (available at <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-approaches-establishing-bioequivalence-0">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-approaches-establishing-bioequivalence-0</a>), which was published in December of 2022 and provides recommendations to sponsors and applicants who intend to use equivalence criteria when analyzing in vivo or in vitro BE studies for investigational new drugs, new drug applications, ANDAs, and supplements to these applications. This guidance discusses statistical approaches for BE comparisons and focuses on how to use these approaches generally, and in specific situations. The webinar provided an overview of the draft guidance for industry, described the major changes in the draft guidance relative to the prior version published in February of 2001, and clarified the rationale on selected topics to public comments.</p>	03/14/2023

GDUFA-Related Meetings, Webinars, Trainings, and Public Workshops	Date Held
<p><b><u>Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF</u></b></p> <p>This virtual forum afforded attendees the opportunity to hear from subject-matter experts in FDA who represented every part of the generic drug assessment process; these experts explained the ANDA assessment process in detail, presented case studies, and provided practical advice to current and prospective generic drug applicants. The presentations and discussions focused on the pre-ANDA program, generic drug metrics, post-market safety, pre-approval inspections, and global generic drug affairs. This year's theme was celebrating 10 years of the Generic Drugs Forum, and several presentations focused on hot topics such as GDUFA III updates, information and technology, and complex generics.</p>	04/12/2023 – 04/13-2023
<p><b><u>FDA and Center for Research on Complex Generics Co-Hosted Workshop: Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products</u></b></p> <p>This workshop (1) discussed scientific and regulatory perspectives for using in vitro, in vivo, and in silico studies as alternatives to comparative clinical endpoint BE studies and pharmacodynamic bioequivalence studies and (2) explored potential designs for alternative BE approaches that could address the particular challenges associated with establishing the equivalence of local drug delivery for suspension-based metered dose inhalers and dry powder inhalers. The workshop reflected on the successes, limitations, and challenges with BE approaches that include comparative clinical endpoint BE studies and pharmacodynamic BE studies.</p>	04/20/2023 – 04/21/2023
<p><b><u>SBIA Webinar: Navigating the First ICH Generic Drug Draft Guideline “M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms”</u></b></p> <p>This webinar provided a deeper look into the FDA draft guidance for industry <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms">M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms</a> (available at <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m13a-bioequivalence-immediate-release-solid-oral-dosage-forms</a>), which followed from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly's December 2022 endorsement of the draft ICH M13A guideline <b><i>M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms</i></b>. This guideline provides recommendations for conducting BE studies during the development and post-approval phases for orally administered immediate-release solid oral dosage forms designed to deliver drugs to the systemic circulation, such as tablets, capsules, and granules/powders for oral suspension. The webinar highlighted key aspects of the draft guidance, explained the ICH expert working group's current scientific thinking, and provided clarification on FDA's plans for the implementation of M13A.</p>	05/02/2023
<p><b><u>FDA and Center for Research on Complex Generics Co-Hosted Training: Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products</u></b></p> <p>This training discussed FDA's regulatory expectations and practices for the pre-ANDA assessment and ANDA review of generic drug-device combination products, especially those with complex device constituent parts. For these products, ANDAs include comparative analyses between the device user interfaces of the proposed generic product and its RLD product, as well as data supporting the quality and performance of the overall product. The discussions during the training explored how, as the complexity of drug-device combination products increases, challenges with product development and demonstration of substitutability may also increase.</p>	05/10/2023
<p><b><u>FY 2023 Generic Drug Science and Research Initiatives Public Workshop</u></b></p> <p>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</p>	05/11/2023 – 05/12/2023

GDUFA-Related Meetings, Webinars, Trainings, and Public Workshops	Date Held
under GDUFA III to develop an annual list of science and research initiatives specific to generic drugs. FDA considered the information from the public workshop when developing its FY 2024 GDUFA science and research priorities.	
<p><b><u>SBIA Webinar: A Deep Dive: GDUFA III Scientific Meetings</u></b></p> <p>This webinar provided a deeper look into new enhancements or changes under GDUFA III to the generic drug program's pre-ANDA and ANDA processes as they relate to scientific meetings to help provide clarity to prospective applicants looking to develop new generic drug products. This webinar took an in-depth look into the three types of scientifically focused meetings offered under GDUFA III: Pre-Submission Meetings; Post- CRL Scientific Meetings; and PSG teleconferences and Pre- and Post-submission PSG Meetings.</p>	05/15/2023
<p><b><u>2023 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments</u></b></p> <p>This was an annual public meeting and opportunity for public comment on "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments." This public meeting was intended to meet performance commitments included in PDUFA VII, BsUFA III, and GDUFA III. These user fee programs were reauthorized as part of the FDA User Fee Reauthorization Act of 2022. This meeting provided FDA the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VII, BsUFA III, and GDUFA III. FDA presented the 5-year financial plans for each of these programs and updated participants on the Agency's progress towards implementing resource capacity planning and modernizing its time reporting approach.</p>	06/08/2023
<p><b><u>FDA and Center for Research on Complex Generics Co-Hosted Workshop: Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generic Products</u></b></p> <p>This workshop discussed the risks of forming N-nitrosamine drug substance-related impurities (NDSRIs) in certain drug products, strategies to mitigate these risks, and considerations in assessing the safety risks of NDSRIs. The workshop also discussed approaches to prevent or mitigate the formation of such impurities, for example by adding a suitable antioxidant and/or pH modifier to drug products. Finally, the workshop discussed the potential impacts of such reformulations on the BE of generic products and some strategies to efficiently address these issues.</p>	06/15/2023
<p><b><u>SBIA Webinar: Advancing Generic Drug Development: Translating Science to Approval 2023</u></b></p> <p>This public workshop communicated how outcomes from FDA's GDUFA Science and Research Program guide and facilitate generic drug development, regulatory assessment, and approval. This workshop focused on common issues seen in ANDAs; provided GDUFA III updates; addressed GDUFA science and research on complex products and scientific issues and PSG development; discussed pre-ANDA and ANDA meetings; and examined various areas of innovative science and cutting-edge methodologies supporting generic drug development.</p>	09/13/2023 – 09/14/2023

## 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 223 research contracts and grants. A complete list of FY 2013 through FY 2023 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 by fiscal year is provided in Table 11.

**Table 11. 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

## **E. FY 2023 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 2023 GDUFA Science and Research Program included the following eight research areas that correspond to the eight GDUFA Science and Research Priority Initiatives for FY 2023.<sup>6</sup>

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

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<sup>6</sup> A detailed description of the FY 2023 GDUFA Science and Research Priority Initiatives can be found at [www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects](https://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.

## 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 2023 is provided in [Appendix B](#) of this report.

In addition, two examples are included below that illustrate how GDUFA science and research program accomplishments facilitate the development of complex generics and enhance patient access to high quality, affordable generic products.

### 1. *Impact Stories on GDUFA Science and Research*

On July 26, 2023, FDA posted the OGD-authored impact story titled “[FDA Shows Generic Lamotrigine Extended-Release Tablets Are Bioequivalent to Innovator Drug in Fully Replicated Crossover Bioequivalence Study.](#)”<sup>7</sup> FDA researchers conducted a study of the antiepileptic drug lamotrigine, comparing generic lamotrigine extended-release tablets and brand extended-release tablets in healthy subjects. Their confirmation that the generic and brand tablets were bioequivalent even when evaluated using a more complex BE study design than FDA recommends for this product supports generic-brand substitution of lamotrigine extended-release products for patients.

On September 19, 2023, FDA posted the OGD-authored Spotlight on CDER Science article titled “[Laboratory Study Shows Oral Antacid Drug Performs Differently When Mixed with Various Food Vehicles.](#)”<sup>8</sup> FDA researchers conducted a study of the antacid drug pantoprazole sodium delayed-release granules, evaluating the impact of food on the drug’s release. Their finding confirmed that an in vitro assessment can detect the effect of the food on drug performance.

## 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 11 to 12, 2023, FDA held the FY 2023 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

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<sup>7</sup> <https://www.fda.gov/drugs/regulatory-science-action/fda-shows-generic-lamotrigine-extended-release-tablets-are-bioequivalent-innovator-drug-fully>.

<sup>8</sup> Available at: <https://www.fda.gov/drugs/news-events-human-drugs/laboratory-study-shows-oral-antacid-drug-performs-differently-when-mixed-various-food-vehicles>.

FY 2024 research priorities. Information obtained during the public workshop and other inputs (e.g., comments to the public docket) were considered in developing the FY 2024 GDUFA Science and Research Priority Initiatives.<sup>9</sup>

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 2024 of certain details within the same eight priority areas mentioned above from FY 2023. 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 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 2024 on FDA's Generic Drug Research Priorities & Projects website.<sup>10</sup>

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<sup>9</sup> 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](https://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.

<sup>10</sup> See <https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects>.

## VI. Inspections Performance

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FDA is committed to ensuring consistency and transparency regarding inspections.

This section satisfies the annual reporting requirement created by the GDUFA III Commitment Letter for FY 2023 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 (preapproval inspection, surveillance, BE clinical and BE analytical) and facility type (finished dosage form, API);
2. Median time from beginning of the inspection to the issuance of Form FDA 483(483), *Inspectional Observations*<sup>11</sup>;
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

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<sup>11</sup> More information about 483s can be found at [www.fda.gov/ICECI/Inspections/ucm256377.htm](https://www.fda.gov/ICECI/Inspections/ucm256377.htm).

- If multiple applications were covered under one unique pre-approval inspection (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 a new drug application 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 (UL) issued only after an OAI inspection. A UL 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 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 12 reflects the number of FY 2023 inspections<sup>12</sup> 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 12. Inspection Type by Location Totals**

Inspection Type	Location		Total*	Number of 483s Issued
	Domestic	Foreign		
<b>PAI (API) †</b>	5	65	70	42
<b>PAI (API/FDF) †</b>	2	14	16	13
<b>PAI (FDF) †</b>	34	93	127	90
<b>PAI (Other) †</b>	10	25	35	22

<sup>12</sup> 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.

<b>Surveillance (API)</b>	17	87	104	63
<b>Surveillance (API/FDF)</b>	16	30	46	33
<b>Surveillance (FDF)</b>	79	108	187	130
<b>Surveillance (Other)</b>	50	28	78	45
<b>BE Clinical†</b>	8	75	83	18
<b>BE Analytical†</b>	4	13	17	5

\* 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 13 shows the median time (in calendar days) between the start of inspections and the issuance of a 483 in FY 2023.

**Table 13. Median Time from Beginning of Inspection to 483 Issuance in FY 2023**

<b>User Fee Program</b>	<b>FY 2023 Median Time (Calendar Days)</b>
GDUFA	6

Table 14 shows the median time (in calendar days) in FY 2023 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 14. Median Time from 483 Issuance to WL, IA, and Regulatory Meeting for Inspections with Final Classification of OAI (or Equivalent) (Calendar Days)**

<b>User Fee Program</b>	<b>FY 2023 Median Time FDA 483 to WL</b>	<b>FY 2023 Median Time FDA 483 to IA</b>	<b>FY 2023 Median Time 483 to Reg. Meeting</b>
GDUFA	169	156	178

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 2023. “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 (NAI), 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 15. Median Time from Date of WLs, IAs, and Regulatory Meetings to Resolution of OAI Status (Calendar Days)**

User Fee Program	FY 2023 Median Time OAI Finalized to Resolution	FY 2023 Median Time WL to OAI Resolution	FY 2023 Median Time IA to OAI Resolution	FY 2023 Median Time Reg. Meeting to OAI Resolution
GDUFA	1309	1310	1471	1206

During FY 2023, there were 28 facilities that were issued a WL, IA and/or had a Regulatory Meeting with an OAI resolution occurring in or after FY 2023, the beginning of the GDUFA III reporting period. Eleven of these facilities were issued a WL, two were issued an IA, and 17 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 NAI, 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.<sup>13</sup> In 2012, with the passage of the Food and Drug Administration Safety and Innovation Act,<sup>14</sup> Congress gave FDA the authority to enter into arrangements with a foreign

<sup>13</sup> See [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619435.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619435.htm).

<sup>14</sup> [www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf](https://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf).



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 agreements (MRAs)<sup>15</sup> 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 2023 by responding within 30 days of receipt to 26 requests for CGMP declarations. (Thirty total requests were received, and four requests did not fit the criteria for issuance.) 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 classifications database for the most recent inspection classification that is publicly available.

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<sup>15</sup> See [www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra](https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra).

The inspection classifications database provides the most recent classifications based on FDA's final assessments following an inspection of manufacturing facilities for routine surveillance purposes or sites conducting BE/bioavailability 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.

## VII. 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 16. 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 ( <a href="https://www.fda.gov/media/166677/download?attachment">https://www.fda.gov/media/166677/download?attachment</a> ) 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	The first update is due no later than the end of the second quarter of FY 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 <i>Federal Register</i> not later than 60 days before the start of the fiscal year	FDA implemented the CPA for FY 2024 fees and published a justification for the CPA taken in the fee-setting <i>Federal Register Notice</i> ( <a href="https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024">https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024</a> ) on July 28, 2023.
FDA will document in the annual GDUFA financial report how any CPA fee revenues are being utilized.	120 days after the end of the fiscal year	GDUFA financial report are published and posted at the following link: <a href="https://www.fda.gov/about-fda/user-fee-financial-reports/gdufa-financial-reports">https://www.fda.gov/about-fda/user-fee-financial-reports/gdufa-financial-reports</a> . The first GDUFA financial

		reporting that will contain updates on CPA fee revenues will be in the FY 2024 GDUFA financial report.
By the end of FY 2025, an independent contractor will 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.	By the end of FY 2025, the evaluation will be published	N/A

## A. Financial Transparency and Efficiency

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 17. 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 ( <a href="http://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans">www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans</a> ) 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 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 ( <a href="https://www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act">https://www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act</a> ) in June 2023.

## VIII. FY 2023 Performance Report Metrics

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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](https://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 18 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 18. Mean and Median Approval Times for Generic Drug Reviews**

GDUFA III	FY 2023
<b>Receipt Cohort</b>	
Mean Approval Time (Calendar Days)	287
Median Approval Time (Calendar Days)	294
First Cycle Mean Approval Time (Calendar Days)	287
First Cycle Median Approval Time (Calendar Days)	294
Mean Tentative Approval Time (Calendar Days)	311
Median Tentative Approval Time (Calendar Days)	311
First Cycle Mean Tentative Approval Time (Calendar Days)	311
First Cycle Median Tentative Approval Time (Calendar Days)	311
Mean Number of ANDA Assessment Cycles to Approval	1
Median Number of ANDA Assessment Cycles to Approval	1
Mean Number of ANDA Assessment Cycles to Tentative Approval	1
Median Number of ANDA Assessment Cycles to Tentative Approval	1
Missed Goal Date for Original ANDAs by More Than 6 months	1
Missed Goal Date for Original ANDAs by More Than 9 months	0
Missed Goal Date for Original ANDAs by More Than 12 months	0

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 19 and 20 summarize FDA's commitment to publish other metrics not already included in this report.

**Table 19. FY 2023 Fiscal Year Performance Report Metrics**

<b>GDUFA III</b>	<b>FY 2023</b>
<b>Application Receipt</b>	
Number of applications received	627
Number of applications refused to receive	33
Average time to receipt decision (i.e., number of calendar days)	39
<b>ANDA Review</b>	
Number of ANDA applications received by FDA for standard assessment	492
Number of ANDA applications received by FDA for priority assessment	135
Percentage of ANDA proprietary name requests reviewed within 180 days of receipt	92%
<b>Petitions</b>	
Number of suitability petitions submitted	14
Number of suitability petitions completed	102
Beginning in FY 2024, percent of suitability petitions completed within 6 months after FDA completes complete assessment along with the total submitted and completed	--
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
<b>DMF</b>	
Number of DMF First Adequate Letters issued status (or equivalent)	301
<b>DMF Email Exchanges</b>	
Number of initial (first cycle) email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in DMF deficiency letters	39
Number of follow-up email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in follow-up cycle DMF deficiency letters	8

**Table 20.**

<b>GDUFA III</b>		<b>FY 2023</b>
FDA to grant or deny <b>Product Development Meeting</b> Requests within 14 calendar days from receipt of request*	Meetings Requested	99
	Meetings Granted	71
	Meetings Denied	28
	Meetings Conducted	56
FDA to grant or deny <b>Pre-Submission Meeting</b> Requests within 30 calendar days from receipt of request*	Meetings Requested	9
	Meetings Granted	0
	Meetings Denied	9
	Meetings Conducted	0
FDA to grant or deny a meeting request for a <b>Pre-Submission PSG Meeting</b> if the applicant within 14 days after receipt of the request has not submitted an ANDA*	Meetings Requested	0
	Meetings Granted	0
	Meetings Denied	0
	Meetings Conducted	0
FDA to conduct granted <b>PSG teleconferences</b> within 30 days of receipt*	Teleconference Requested	2
	Teleconference Granted	2
	Teleconference Denied	0
	Teleconference Conducted	2
FDA to grant or deny a meeting request for a <b>Post-Submission PSG Meeting</b> if the applicant has submitted an ANDA within 14 days after receipt of the request*	Meetings Requested	0
	Meetings Granted	0
	Meetings Denied	0
	Meetings Conducted	0
FDA to grant or deny a meeting request for a <b>Mid-Cycle Review Meeting (MCRM)</b> *	Meetings Requested	1
	Meetings Granted	1
	Meetings Denied	0
	Meetings Conducted	1
FDA to conduct an <b>Enhanced Mid-Cycle Review Meeting (EMCRM)</b> within 90 calendar days after issuance of the last mid-cycle DRL*	Meetings Requested	1
	Meetings Granted	0
	Meetings Denied	1
	Meetings Conducted	0
FDA to provide a scheduled date for a requested <b>Post-CRL teleconference</b> within 14 calendar days of the request for a teleconference*	Teleconferences Requested	65
	Teleconferences Granted	54
	Teleconferences Denied	11
	Teleconferences Conducted	50
FDA to grant or deny <b>Post-CRL Scientific meeting</b> requests within 14 days after receipt of the request*	Meetings Requested	20
	Meetings Granted	14
	Meetings Denied	6
	Meetings Conducted	12
FDA to strive to grant <b>DMF first cycle assessment deficiency teleconferences</b>	Teleconferences Requested	4
	Teleconferences Granted	4
	Teleconferences Denied	0
	Teleconferences Conducted	0
	Email exchanges in lieu of Teleconferences	42 initial and 7 follow-up

GDUFA III		FY 2023
FDA to grant, deny, or defer in favor of re-inspection a <b>Post-WL Meeting</b> within 30 calendar days from receipt of request	Meetings Requested	3
	Meetings Granted	2
	Meetings Denied	1
	Meetings Conducted	1

\*

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.



## IX. Rationale for GDUFA Program Changes

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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 Commitment Letter, the Number of Remaining Vacancies, the Number of Full-time Equivalents (FTEs) Funded by Fees Collected Pursuant to Section 744B, and the Number of FTEs Funded by Budget Authority by Division Within CDER, the Center for Biological Evaluation**

**and Research (CBER), the Office of Regulatory Affairs (ORA), and the Office of the Commissioner (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 21. Number of Individuals Hired to Meet GDUFA III Commitments**

Center	Number Hired in FY 2022*	Number Hired in FY 2023	Change in Number Hired	Remaining Vacancies in FY 2022*	Remaining Vacancies in FY 2023	Change in Number of Remaining Vacancies
CDER	0	100	100	0	14	14
CBER	0	0	0	0	0	0
ORA	0	0	0	0	0	0
OC	0	5	5	0	8	8
<b>Total</b>	<b>0</b>	<b>105</b>	<b>105</b>	<b>0</b>	<b>22</b>	<b>22</b>

\* GDUFA III became effective in FY 2023; therefore, there were no GDUFA III hires in FY 2022.

FDA committed to hiring 128 individuals between FY 2023 and FY 2027. The Agency successfully hired 105 FTEs as of September 30, 2023.

*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 22 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 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 22. The

number of FTEs funded by budget authority for FY 2023 are those FTEs as of September 30, 2023.

**Table 22. Changes in the Number of FTEs Funded by GDUFA Fees and by Budget Authority**

Center and Office	Number of FTEs Funded by Budget Authority		Change in the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2022	FY 2023		FY 2022	FY 2023	
CDER						
Office of Communications	6.40	10.49	4.09	17.35	15.15	-2.20
Office of Compliance*	24.70	25	0.30	43.56	51.42	7.86
Office of the Center Director	4.60	5.95	1.35	8.62	6.09	-2.53
Office of Executive Programs	11.40	9.83	-1.57	16.56	18.41	1.85
Office of Generic Drugs	20.60	28.21	7.61	484.31	497.60	13.29
Office of Medical Policy	0.10	3.06	2.96	1.17	0.09	-1.08
Office of Management	9.50	11.61	2.11	50.35	46.51	-3.84
Office of New Drugs	1.90	1.53	-0.37	0.00	0.00†	0.00
Office of Pharmaceutical Quality	52.00	46.47	-5.53	591.66	625.02	33.36
Office of Regulatory Policy	6.10	4.44	-1.66	5.32	4.88	-0.44
Office of Surveillance and Epidemiology	5.40	19.02	13.62	85.21	64.35	-20.86
Office of Strategic Planning	4.40	17.49	13.09	60.99	56.32	-4.67
Office of Information Management and Technology	0.00		0.00			
Office of Translational Sciences	10.60	16.42	5.82	50.51	49.38	-1.13
Other Offices	0.20	1.08	0.88	1.71	1.54	-0.17
Working Capital Fund (WCF)*	27.30	29.64	2.34	92.19	87.13	-5.06
CBER						
Office of Biostatistics and Epidemiology / Office of Biostatistics and Pharmacovigilance‡	0.00	-0.97§	-0.97	0.00	0.97	0.97
Office of Blood Research and Review	1.29	0.18	-1.11	0.00	0.56	0.56
Office of Compliance and Biologics Quality	0.25	0.04	-0.21	0.08	0.45	0.37
Office of Tissues and Advanced Therapies / Office of Therapeutic Products#	0.00	0.00	0.00	0.00	0.00	0.00
Office of Vaccines Research and Review	0.00	0.00†	0.00	0.00	0.00†	0.00
Office of Communication Outreach and Development	0.08	0.01	-0.07	0.00	0.06	0.06

Office of the Center Director	0.09	0.00 <sup>†</sup>	-0.09	0.00	0.04	0.04
Office of Regulatory Operations <sup>¶</sup>	0.05	0.02	-0.03	0.00	0.05	0.05
Office of Management	0.17	0.05	-0.12	0.00	0.08	0.08
Office of Information Management and Technology	0.01	0.01	0.00	0.00	0.00	0.00
WCF	0.08	0.06	-0.02	0.18	0.00	-0.18
<b>OC</b>						
OC of the Commissioner - Immediate Office	0.20	0.29	0.09	4.19	5.68	1.49
Office of the Chief Counsel	1.20	1.45	0.25	28.40	28.61	0.21
Office of the Chief Scientist	0.00	0.04	0.04	0.34	0.83	0.49
Office of Clinical Policy and Programs	0.00	0.04	0.04	0.85	0.86	0.01
Office of Digital Transformation	0.00	0.01	0.01	0.31	0.26	-0.05
Office of Enterprise Management Services	0.00	0.75	0.75	14.56	14.75	0.19
Office of External Affairs	0.20	0.25	0.05	5.23	5.02	-0.21
Office of Global Policy and Strategy	0.40	0.83	0.43	10.46	16.34	5.88
Office of Operations	1.50	1.19	-0.31	21.55	23.50	1.95
Office of Policy, Legislation, and International Affairs	0.80	0.80	0.00	19.17	15.78	-3.39
WCF	5.29	2.64	-2.65	8.72	9.18	0.46
<b>ORA</b>						
Office of Pharmaceutical Quality Operations	14.00	29.00	15.00	257.70	257.08	-0.62
WCF	16.10	17.89	1.79	17.07	19.61	2.54

\* 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.

<sup>†</sup> FTEs are rounded to the hundredth decimal. Offices with fewer than 0.01 FTEs are shown as 0.00.

<sup>‡</sup> CBER's Office of Biostatistics and Epidemiology was reorganized to the Office of Biostatistics and Pharmacovigilance in FY 2023.

<sup>§</sup> 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.

<sup>#</sup> CBER's Office of Tissues and Advanced Therapies was reorganized to the Office of Therapeutic Products in FY 2023.

<sup>¶</sup> 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 an increase in overall FTEs funded by budget authority in FY 2023 compared to FY 2022. The increase in reported FTEs was attributable to a re-baselining of payroll distribution percentages between annual appropriations and GDUFA fees.

## 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 23 provides data for the GDUFA fee revenue amounts, the FY 2022 and FY 2023 total average cost per FTE in the generic drug review program, and the changes in these costs from FY 2022 to FY 2023.

In FY 2023, FDA had net collections of \$551,653,777 in human generic drug user fees, spent \$570,325,960 million in user fees for human generic drug activities, and carried a cumulative balance of \$120,195,906 million forward for future fiscal years. Detailed financial information for the GDUFA user fee program can be found in the FY 2023 GDUFA financial report.

For FY 2018 through FY 2022, the base revenue amounts used in calculating the total GDUFA fee revenues are established by GDUFA II. The fee revenue amount for FY 2023 for GDUFA III is \$582,500,000. Since this is the first fiscal year of the GDUFA III authorization period, there is no inflation adjustment. Applicable inflation adjustments will be made beginning with FY 2024.

Beginning with FY 2024, 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 fee 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 (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

In FY 2023, GDUFA review process costs had a small increase compared to FY 2022.

**Table 23. GDUFA Fee Revenue Amounts, the FY 2022 and FY 2023 Total Average Cost Per FTE, and the Changes in These Costs from FY 2022 to FY 2023**

Revenue/Cost	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Fee Revenue Amounts (Net Collections)	\$545,842,834	\$551,653,777	+1%
Cost of Activities	\$681,402,012	\$743,860,085	+9%
Changes in average total cost per FTE	\$188,471	\$200,059	+6%

### **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 24 provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2023.

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

**Table 24. Time Reporting Requirement for FY 2023**

Center	FTEs for Whom Time Reporting Is Required	FTEs for Whom Time Reporting Is Not Required
CDER	5739	0
CBER	1260	8
ORA	4592	0
OC	61	2606
Total	11,652	2,614

#### **D. Changes in the Average FTE Hours Required to Complete Review of Each Type of Abbreviated New Drug Application**

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.<sup>16</sup>

**Table 25. Average FTE Hours Required to Complete Review**

Application Type	Hours Required to Complete Application Reviews FY 2022	Hours Required to Complete Application Reviews FY 2023	Change from FY 2022 to FY 2023
Original ANDAs Submitted	1,276	1,265	-11
Total	1,276	1,265	-11

<sup>16</sup> 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.

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 2020 to FY 2022 and FY 2021 to FY 2023). The sum was then divided by the total number of applications over the same 3-year period.

## Appendix A: Definitions of Key Terms

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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. \mk' 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 pre-approval inspection 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** - 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 complete response 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 controlled correspondence (CC)** - GDUFA II Commitment Letter - means:
1. CC involving evaluation of clinical content;
  2. BE protocols for RLDs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU); or
  3. Requested evaluations of alternative BE approaches within the same study type (e.g., pharmacokinetic, in vitro, clinical).
- K. **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.
- L. **Complex Generic Product** - refers to a generic version of a Complex Product.
- M. **Controlled Correspondence (CC)** - GDUFA II Commitment Letter - is correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry, requesting information on a specific element of generic drug product development. See CDER's December 2020 guidance for industry *Controlled Correspondence Related to Generic Drug Development*.<sup>27</sup> CC does not include citizen petitions, petitions for reconsideration, or requests for stay.
- N. **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 tentative approval;
    - 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.
- O. **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 bioequivalence protocols for development and testing that involves human clinical trials for an ANDA where the RLD is subject to a REMS with 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 bioequivalence approaches (e.g., pharmacokinetic, in vitro, clinical); or

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<sup>27</sup> See [www.fda.gov/regulatory-information/search-fda-guidance-documents](https://www.fda.gov/regulatory-information/search-fda-guidance-documents).

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 II Commitment Letter - means a Major Amendment as described in CDER’s December 2001 guidance for industry: *Major, Minor and Telephone Amendments to Abbreviated New Drug Applications*.
- CC. **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.
- DD. **Minor Amendments** – GDUFA II Commitment Letter – means a minor amendment as described in CDER’s December 2001 guidance for industry *Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications*.
- EE. **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.
- FF. **Original ANDA** - The initial submission of an ANDA to CDER’s OGD or to CBER.
- GG. **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.
- HH. **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.<sup>28</sup>

- II. **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.<sup>29</sup>
- JJ. **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.
- KK. **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.
- LL. **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).<sup>30</sup>
- MM. **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.
- NN. **Standard** - means submissions not affirmatively identified as eligible for expedited assessment pursuant to the CDER Prioritization MAPP.
- OO. **Standard controlled correspondence** – GDUFA II Commitment Letter – controlled correspondence:
  - 1. As described in CDER's December 2020 guidance for industry *Controlled Correspondence Related to Generic Drug Development*<sup>31</sup> or
  - 2. Concerning post-approval submission requirements that are not covered by CDER's post-approval changes guidance and are not specific to an ANDA.

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<sup>28</sup> See section 744A(11) of the FD&C Act.

<sup>29</sup> See <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp>.

<sup>30</sup> See [www.fda.gov/regulatory-information/search-fda-guidance-documents](http://www.fda.gov/regulatory-information/search-fda-guidance-documents).

<sup>31</sup> Ibid.

- PP. **Submission** – refers to an ANDA, an amendment to an ANDA, a PAS to an ANDA, or an amendment to a PAS.
- QQ. **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).<sup>32</sup>
- RR. **Teleconference** - means a verbal communication by telephone, not a written response, unless otherwise agreed to by the applicant.
- SS. **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.
- TT. **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 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.
- UU. **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).

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<sup>32</sup> Ibid.

## Appendix B: Synopsis of FY 2023 GDUFA Science and Research Accomplishments

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Multiple sources of public input helped FDA identify eight [GDUFA Science and Research Priority Initiatives for Fiscal Year \(FY\) 2023](#)<sup>33</sup> 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 2023. More detailed information in all nine areas is provided in the FY 2023 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 2023. These outcomes include general guidances for industry and PSGs published in FY 2023 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 2023 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., NDSRIs), evaluating the risk of human exposure to these impurities, and developing methods for ANDA applicants to efficiently address the potential risks.

During FY 2023, FDA conducted internal research studies and funded external research collaborations to develop analytical procedures for the quantitation of N-nitrosamine impurities (small molecule nitrosamines and NDSRIs) in pharmaceuticals; assess the risk of forming these impurities; elucidate the toxicological risks associated with these impurities, if formed; explore strategies to prevent or mitigate the formation of N-nitrosamine impurities by reformulating drug products (potentially with suitable antioxidants or pH modifiers); and characterize whether such reformulations could be performed in a manner that would not alter the bioequivalence of approved generic products.

A notable outcome of this research indicated that small amounts (e.g., 1-2% w/w) of pH modifiers such as sodium bicarbonate or antioxidants such as ascorbic acid, alpha-tocopherol, propyl gallate, or cysteine hydrochloride added to a drug product may be sufficient to inhibit the potential formation of N-nitrosamine impurities. Furthermore, the research indicated that such antioxidants did not appear to alter the permeability across the intestinal membrane or the function of intestinal transporters for model drugs such

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<sup>33</sup> <https://www.fda.gov/media/162554/download?attachment>.

as ranitidine, atenolol, acyclovir, and cimetidine when evaluated in vitro. These results suggested that it may be feasible to make minor modifications to the formulation of an approved generic drug product that prevent the formation of N-nitrosamine impurities without altering its bioavailability or bioequivalence. This research supported the development of efficient approaches by which ANDA applicants could address health risks associated with N-nitrosamine impurities, potentially without necessitating new in vivo studies to confirm the bioequivalence of their reformulated generic product.

## **B. Complex Active Ingredients**

The advancement of research in this area during FY 2023 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 bioequivalence and pharmaceutical equivalence approaches.

During FY 2023, FDA conducted internal research studies and funded external research collaborations to characterize complex API drug products with an emphasis on peptide, oligonucleotide, and other polymeric APIs. The research on peptides involved the development of analytical techniques that characterized the sequence of their component amino acids and assessed how that influenced the folding and three-dimensional shape of peptides such as glucagon, calcitonin salmon, icatibant, and leuprolide. This was important because differences in the way a peptide may fold in a prospective generic product can alter its receptor binding, expose immunogenic epitopes, and give rise to aggregation. The research on oligonucleotides focused on understanding how complex molecular structures such as diastereomeric compositions and impurity profiles for these APIs may be different in a prospective generic product and identifying ways to ensure that a generic oligonucleotide product would be bioequivalent to its reference listed drug (RLD) product.

A notable outcome of research with additional peptide drugs indicated that the primary species of liraglutide in its formulation could be either a pentamer or a hexamer. Similarly, the primary species of semaglutide was predicted to be either a dimer or a trimer. These results demonstrated how prospective generic peptide drug developers can characterize the complexity of the RLD product and ensure that the processes utilized to develop their prospective generic product produces an API that is identical in all critical attributes. This research also expanded our understanding of the ways in which a prospective generic peptide or oligonucleotide product would need to be matched to its RLD product and illustrated how novel analytical approaches could support a demonstration of bioequivalence for these complex generic products.



## **C. Complex Dosage Forms and Formulations**

The advancement of research in this area during FY 2023 focused on improving efficient characterization-based (in vitro) bioequivalence approaches for long-acting injectable, insertable, or implantable (collectively, 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 2023, FDA conducted internal research studies and funded external research collaborations to investigate LAI products, including those utilizing poly (lactide-co-glycolide) polymers and nanomaterials, including lipid nanoparticles and colloidal iron-carbohydrate complexes. The research on LAI products included developing new analytical tools for separating and characterizing poly (lactide-co-glycolide) polymer mixtures; investigating the impact of raw materials and manufacturing parameters on formulation performance; and exploring in vitro-in vivo correlations using advanced imaging tools. The research on nanomaterial products elucidated the impact of API impurities, lipid sources, and manufacturing processes on the performance and quality of lipid nanoparticles.

A notable outcome of this research was the development of a novel method using scanning electron Raman cryo-microscopy, which can characterize the morphology, particle size, and composition of a nanomaterial. Using an albumin-bound paclitaxel nanoparticle formulation as a model drug product, FDA scientists optimized a sample fixation method for scanning electron cryo-microscopy and integrated a Raman structural and chemical analyzer unit that provided detailed chemical information for structural features. The novel cryo-microscopy approach was able to confirm the chemical composition of particles observed in cryo-fixed samples, providing a practical way to characterize and compare critical features of albumin-based nanoparticles in RLD and prospective generic drug products, which could support a demonstration of bioequivalence for these complex generic products.

## **D. Complex Routes of Delivery**

The advancement of research in this area during FY 2023 focused on improving efficient characterization-based bioequivalence 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 2023, 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 products improved in vitro methods and developed a predictive in silico model to support demonstrations of bioequivalence. The research on inhalation products developed a computational fluid dynamic (CFD) model to predict the deposition of inhaled beclomethasone dipropionate in different regions of the lung, and research on the features of nasal products that influence where drug is deposited suggested that the cone angle and plume ovality of the nasal spray had the most substantial impact. The research on ophthalmic and otic products identified and characterized CQAs in these products that can affect in vitro, ex vivo, and in vivo performance, and utilized in silico models to elucidate the relationship between these CQAs and the pharmacokinetics and/or pharmacodynamics of the product. The research on topical products investigated how small differences in the ingredients or CQAs of a topical semisolid product might (or might not) alter its performance and advanced the development of multiple methods by which to establish whether specific differences would impact the bioequivalence of a prospective generic product to its RLD product.

A notable outcome of the research on lorazepam inhalation powder was evidence that the flow rate can be a critical factor, with higher flow rates generating smaller particles, and that certain methods for characterizing particle size distributions have limitations that may preclude their use to support a demonstration of bioequivalence. A notable outcome of the research on ophthalmic products was the expansion and validation of a popular commercial in silico modeling platform, enhancing its ability to predict human ocular pharmacokinetics and pharmacodynamics by extrapolating data from animals such as rabbits. This enhanced model was successfully able to predict the pharmacokinetics in humans for drug products such as levofloxacin, moxifloxacin, and gatifloxacin ophthalmic solutions. A notable outcome of the research on topical products was a demonstration that non-invasive spectroscopic methods could characterize the epidermal pharmacokinetics of topically applied metronidazole or tazarotene. These studies, which compared multiple comparator products or formulations of each drug, illustrated that Raman spectroscopy-based methods can provide reproducible and sensitive comparisons of the rate and extent to which topically applied drugs become available at a site of action in the epidermis from different products. Research in these areas supported the development of efficient approaches to comprehensively characterize RLD products so that prospective generic products could be designed with CQAs that are matched as closely as possible and so that bioequivalence could be ensured by using novel in vitro, in silico, and/or in vivo approaches.

## **E. Complex Drug-Device Combination Products**

The advancement of research in this area during FY 2023 focused on enhancing the efficiency of equivalence approaches for complex drug-device combination products (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 2023, FDA conducted internal research studies and funded external research collaborations to develop methods by which to categorize and evaluate user interface differences in prospective generic DDCPs. The research refined an approach that integrates risk management elements and human factor engineering elements to assess and categorize design differences. That approach was implemented in the assessment of dry powder inhalers and autoinjectors, which have different use populations, indications, and design elements. Research to develop a taxonomy for DDCPs continued, progressively organizing and creating a shared vocabulary for DDCPs. The visual taxonomy system developed utilizes principles of task analyses, use error analyses, and risk assessments to associate the user interface design elements to corresponding risks.

A notable outcome of the research was the insight gleaned on patient and caregiver perspectives about the substitution of complex DDCPs, such as dry powder inhalers or autoinjectors, with generic versions that may contain certain design differences. In general, patients and caregivers expressed positive feelings about the financial savings associated with their prescription being filled with a substituted generic DDCP. This was true for both the dry powder inhalers and the autoinjectors. Interestingly, patients reported that some design features of the generic DDCP were better than or equal to the RLD DDCP. However, there was also some anxiety reported about the uncertainty of whether they would understand how to use the device constituent of the generic DDCP. Most patients expressed a desire to participate in discussions with their healthcare provider about decisions relating to the substitution of their dry powder inhaler with a generic product. Research in these areas supported the development of enhanced approaches to classify and compare identified differences in the user interface of a prospective generic DDCP product compared to its RLD product so that prospective generic DDCP developers can better understand how to incorporate design elements that are matched as closely as possible to those of the RLD product and so that the bioequivalence of a prospective generic DDCP can be ensured even when certain design differences may exist.

## **F. Oral and Parenteral Generic Products**

The advancement of research in this area during FY 2023 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 Biopharmaceutics Classification System-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 2023, FDA conducted internal research studies and funded external research collaborations to develop biorelevant and bio-predictive in vitro testing, evidence from which may be incorporated in physiologically based pharmacokinetic (PBPK) models to predict the impact of formulation excipients, food, and other factors on bioequivalence assessments. For example, the research characterized the effect of different formulation excipients in selected generic products and their RLD products on the bioavailability of rasagiline mesylate tablets, acyclovir capsules, atenolol tablets, and hydroxychloroquine sulfate tablets. Other research measured the release rate of glipizide in different gastrointestinal tract regions using an incubation tube and a smart pill to record physiologically relevant parameters (e.g., pH and pressure). In parallel, drug concentrations in the plasma were also analyzed to help characterize how differences in the in vitro dissolution of a product may be associated with variable absorption in vivo. The research on injectable products developed methods for characterizing CQAs and assessing the impact of manufacturing processes on injectable drug substance suspension and thermodynamically stable microemulsion products.

A notable outcome of the research with pantoprazole sodium delayed-release products, which served as model drug products for patients who may have difficulty swallowing whole tablets or capsules, was that when the granules were sprinkled on high pH food vehicles with a long contact time (e.g., 2 hours), it caused premature drug release and led to drug degradation, as expected. The results showed that food pH, and the interaction between food pH and drug-food contact time, were significant factors affecting the in vitro dissolution of pantoprazole sodium granules. The results also demonstrated that the in vitro methodology was capable of discriminating differences in the performance of the product under labeled-use conditions and under other conditions of use not approved in the labeling. Research in these areas supported the development of efficient approaches to assess the impact of formulation excipients, food, and other factors on the bioavailability and bioequivalence of prospective generic oral drug products. A notable outcome of the research with phytonadione injection, which can form a thermodynamically stable microemulsion, was that manufacturing and formulation factors (e.g., mixing, temperature, surfactant to oil ratio) could impact the initial dispersion state, producing macro-, nano-, or micro-emulsions. This research provided insights about critical formulation attributes and drug release kinetics that are particularly helpful as FDA continues to explore in vitro characterization based bioequivalence approaches for this class of injectable suspension products.

## **G. MIE of Bioequivalence**

The advancement of research in this area during FY 2023 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 formulations 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 2023, FDA conducted internal research studies and funded external research collaborations to develop mechanistic in silico tools in coordination with in vitro tests to predict local drug concentrations at the site of administration; improve the validation of CFD model predictions of regional deposition from metered dose inhalers and dry powder inhalers, and further develop an existing lung PBPK model; enhance CFD and PBPK models to accurately predict nose-to-brain drug delivery; advance the development of preclinical ocular PBPK and pharmacodynamic models to predict the performance of ophthalmic products by extrapolating evidence from preclinical models to humans; expand the utility of oral absorption models; advance population pharmacokinetics modeling for drugs with high variability or long half-lives; develop ML approaches to aid the selection of population pharmacokinetics models; and establish best practices for the development of alternative study designs and analysis methods for a wide range of products, including LAI, oncology, and opioid products, as well as others for which only sparse sampling is feasible when conducting clinical studies.

A notable outcome of the PBPK modeling research with orally inhaled products was the development of a CFD regional deposition model that can evaluate the impact of formulation differences and inter-subject variability on oral airway and lung deposition for beclomethasone dipropionate inhalation metered aerosol. This research suggested that differences in formulation and differences in the anatomy of the lung (e.g., healthy versus asthmatic lung geometries) can both substantially impact the fraction of drug that deposits in the oral airway versus the lung. Similarly, for ophthalmic products, a tear film dynamic model was developed to mimic the dynamic response of the tear film volume to the sudden addition of an eyedrop, which provided insights about how long a drug would remain on the surface of the eye after topical administration of an ophthalmic solution. A notable outcome of the research on oral absorption models was a demonstration that it was feasible to predict both positive and negative food effects for amorphous solid dispersion formulations of itraconazole, and for ibuprofen as well,

which demonstrated the generalizability of this approach. A notable outcome of the quantitative clinical pharmacology research was an illustration that a novel model-based two one-sided test procedure could assess bioequivalence using data from pharmacokinetics-based bioequivalence studies with sparse sampling, provided that the pharmacokinetics model was correctly specified. These diverse research projects are establishing how MIE approaches can be utilized in a complementary manner with evidence from in vitro product characterization tests and in vivo studies to overcome constraints that otherwise made it unfeasible to develop generic products in several situations, each with unique challenges.

## **H. AI and ML Tools**

The advancement of research in this area during FY 2023 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 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 GDUFA commitments.

During FY 2023, FDA conducted internal research studies and funded external research collaborations to develop a user-friendly automation tool, called “BE Assessment Mate,” to streamline labor-intensive collation of key information during the ANDA assessment process. In FY 2023, this tool completely operated in the cloud environment to enhance the tool usage and user experience and served as the data engine integrated with OGD’s structured assessment tool (i.e., the Generic Drug Structured Assessment) to facilitate regulatory assessment efficiency in FDA. Other research innovated an ML-assisted tool to facilitate the assessment of PLG formulations and developed an ML-assisted method to aid the analysis of PLG-based LAI formulations that established a correlation between material attributes, processing conditions, and product quality and performance. This ML-assisted tool can improve the efficiency of formulation development and optimization for prospective generic LAI products.

A notable outcome of the research involving natural language processing was the development of a trained model optimized for the uniqueness and technical sophistication of language used in drug labeling that outperforms other specialized Bidirectional Encoder Representations from Transformers models such as ClinicalBERT and BioBERT, which have exhibited exceptional performance in text-based information extraction. Using these tools, it is possible to automate and accelerate access to information relevant to regulatory assessments, including information about such things as adverse reactions to drugs, drug-drug interactions, or pharmacokinetic information in drug labeling. These AI/ML tools have the potential to streamline the assessment of

pertinent information and improve the efficiency with which PSGs can be developed, for example.

## **I. Other Generic Drug Science and Research**

Other generic drug science and research during FY 2023 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 helps address current public health needs related to opioid products, particularly related to the treatment of addiction and for rescue from overdose. During FY 2023, FDA completed research designed to evaluate and address patient perceptions about the substitutability of generic drug products, which involved conducting clinical studies in patients or in healthy subjects, analyzing clinical databases on the utilization and substitution of generic drugs, and assessing perceptions held by patients and healthcare providers. This research involved the lamotrigine extended-release tablet RLD and generic products as well as the tacrolimus oral capsule RLD and generic products. Other research related to post-marketing surveillance of generic drugs assessed the substitutability of generic mixed amphetamine sulphate products for the treatment of attention-deficit/hyperactivity disorder. In addition, FDA evaluated the nasal bioavailability of different formulations and delivery device systems that may be utilized for a prospective generic naloxone nasal spray, indicated for the emergency treatment of opioid overdose reversal.

A notable outcome of the research on RLD substitution with generic lamotrigine extended-release tablets was that the generic product was confirmed to be bioequivalent to the RLD product even when evaluated using a bioequivalence study design that was more complex than FDA recommends for this product. Additionally, in silico modeling that simulated the steady state plasma concentrations of lamotrigine from the RLD and generic products after repeated dosing (which is relevant for this chronic use medication) predicted equivalent pharmacokinetics for both generic and RLD products. The outcomes of this research supported the appropriateness of FDA's recommendation to conduct an efficient two-way, crossover study to demonstrate the bioequivalence of lamotrigine extended-release tablets. These results also provided comprehensive evidence to reinforce patient, caregiver, and prescriber confidence in approved generic lamotrigine extended-release tablets. Collectively, the research projects with lamotrigine and tacrolimus drug products ensured that bioequivalence standards and regulatory decision making for generic products are evidence-based and continually aligned with current scientific thinking.

## Appendix C: Analysis of Performance in Meeting Goals

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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 complete response letters, determining the causes affecting the agency’s ability to meet performance goals, and issuing corrective action reports on FDA’s efforts to improve its meeting 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 2022 Final Performance by Goal Type**

Goal Type	Review Goal	Received	Received with Goal Post FY 2022	Approved	Tentatively Approved	Complete Response	Missed Goal*	Percent on Time†	Potential Range†	On Time Imminent Approval†	Imminent Approval Potential Range†
<b>I. Original ANDA Review Goals</b>											
Standard Original ANDA Applications	10 months	593	548	89	15	433	42	93%	87% to 93%	95%	89% to 96%
Priority Original ANDA Applications (if applicant meets requirements of a PFC)	8 months	37	24	6	0	31	2	95%	95% to 95%	98%	98% to 98%
Priority Original ANDA Applications (if the applicant does not meet the requirements of a PFC)	10 months	173	162	40	2	120	13	92%	88% to 94%	97%	92% to 97%
<b>II. Amendment Review Goals</b>											
Standard Major ANDA Amendments (if preapproval inspection is not required)	8 months	797	535	155	35	585	77	90%	90% to 90%	94%	94% to 94%
Standard Major ANDA Amendments (if preapproval inspection is required)	10 months	72	67	19	1	41	13	88%	82% to 89%	90%	83% to 90%
Priority Major ANDA Amendments (if pre-approval inspection is not required)	6 months	131	70	28	6	95	10	92%	92% to 92%	98%	98% to 98%
Priority Major ANDA Amendments (if preapproval inspection is required and applicant meets the requirements of a PFC)	8 months	-	-	-	-	-	-	-	-	--	--
Priority Major ANDA Amendments (if preapproval inspection is required and applicant does not meet the requirements of a PFC)	10 months	14	12	6	0	7	3	79%	79% to 79%	93%	93% to 93%

Goal Type	Review Goal	Received	Received with Goal Post FY 2022	Approved	Tentatively Approved	Complete Response	Missed Goal*	Percent on Time†	Potential Range†	On Time Imminent Approval†	Imminent Approval Potential Range†
Standard and Priority Minor ANDA Amendments	3 months	810	230	424	116	265	129	84%	84% to 84%	96%	96% to 96%

\* 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 2023 Preliminary 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†
<b>I. Original ANDA Review</b>											
Standard Original ANDA Submissions	10/30 months	489	436	11	2	41	6	93%	15% to 99%	100%	15% to 100%
Priority Original ANDA Submissions	8/10/30 months	130	111	4	0	14	2	93%	19% to 99%	100%	19% to 100%
<b>II. Amendment Review</b>											
Standard Major ANDA Amendments	8/10 months	766	528	56	7	172	25	90%	30% to 97%	96%	30% to 99%
Priority Major ANDA Amendments	6/8/10 months	130	70	11	2	47	4	94%	45% to 97%	95%	45% to 98%
Standard and Priority Minor ANDA Amendments	3 months	716	226	283	66	144	63	88%	62% to 91%	97%	68% 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 GDUFA III (i.e., currently 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 2023 Performance Enhancement Goals**

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
<b>Pre-ANDA</b>				
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	<a href="https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development">https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development</a>
Update the Inactive Ingredient Database on an ongoing basis and post quarterly notice of updates made.	Quarterly	Y	Quarterly	<a href="http://www.fda.gov/drugs/drug-approvals-and-databases/most-recent-changes-iid-database">www.fda.gov/drugs/drug-approvals-and-databases/most-recent-changes-iid-database</a>
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 5/11/2023 – 5/12/2023	<a href="https://www.fda.gov/drugs/fiscal-year-2023-generic-drug-science-and-research-initiatives-public-workshop-05112023">https://www.fda.gov/drugs/fiscal-year-2023-generic-drug-science-and-research-initiatives-public-workshop-05112023</a>
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.	<a href="https://www.fda.gov/drugs/generic-drugs/generic-drug-research-related-guidances-reports">https://www.fda.gov/drugs/generic-drugs/generic-drug-research-related-guidances-reports</a>
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 08/30/2023 Second Meeting held 11/17/2023	<a href="http://www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects">www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects</a>
<b>Continued Enhancement of User Fee Resource Management</b>				
Publish a GDUFA Five-Year Financial Plan no later than the second quarter of FY 2023.	3/31/2023	N	4/12/2023	FDA published the FY 2023 GDUFA Five-Year Financial Plan update in April 2023. <a href="https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans">https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans</a>

Publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be utilized during GDUFA III.	3/31/2023	Y	3/29/2023	<a href="https://www.fda.gov/media/166677/download?attachment">https://www.fda.gov/media/166677/download?attachment</a>
Hire 128 staff for the generic drug review program in FY 2023.	9/30/2023	N	TBD	<a href="#">We hired 105 out of 128</a>
<b>Guidances and MAPPs</b>				
Revise MAPP 5200.12, <i>Communicating Abbreviated New Drug Application Review Status Updates with Industry</i> , to include communications related to imminent actions.	4/30/2023	Y	10/5/2022	<a href="https://www.fda.gov/media/108418/download">https://www.fda.gov/media/108418/download</a>
Issue a <i>Federal Register</i> notice to solicit public comment on the content of Appendix A in the guidance for industry <i>ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA</i> (July 2018).	4/30/2023	Y	8/15/2022	<a href="https://www.federalregister.gov/documents/2022/08/15/2022-17414/soliciting-public-comment-on-appendix-a-of-the-food-and-drug-administrations-july-2018-guidance">https://www.federalregister.gov/documents/2022/08/15/2022-17414/soliciting-public-comment-on-appendix-a-of-the-food-and-drug-administrations-july-2018-guidance</a>
<b>Performance Reporting</b>				
Publish monthly reporting metrics set forth under section X(A) of the GDUFA III Commitment Letter.	Monthly	Y	Monthly	<a href="https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report">https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report</a>
Publish quarterly reporting metrics set forth under section X(B) of the GDUFA III Commitment Letter.	Quarterly	Y	Quarterly	<a href="https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report">https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report</a>
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 2023 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	<a href="https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-2023-fiscal-year-web-posting">https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-2023-fiscal-year-web-posting</a>

## 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 II Commitment Letter.

In addition to the causes and trends initially identified in last year's report, Table C-4 represents FDA's FY 2022 updated performance results.

**Table C-4. FY 2022 GDUFA II Updated Performance Results**

Cause or Trend	Impact on FDA's Ability to Meet Goals
<b>Performance Goals</b>	In last year's report, the Agency could not fully report on this category because some submissions received in FY 2022 had associated review goals that fell within the subsequent fiscal year (i.e., FY 2023). FDA did not meet some FY 2022 assessment review goals. However, all the FY 2022 assessment review goals surpassed the 90-percent metric when imminent approval (now called imminent action) was considered. FDA did not meet the FY 2022 review goal for clarification of ambiguities in CC response due to receipts of requests on Fridays and lost time due to weekends and holidays. The performance period for this review goal was lengthened in GDUFA III.
<b>Program Enhancement Goals</b>	In last year's report, the Agency could not fully report on this category because some submissions received in FY 2022 had associated review goals that fell within the subsequent fiscal year (i.e., FY 2021). FDA did not meet the FY 2022 review program enhancement goal "FDA will provide a scheduled date for a requested post-CRL teleconference within 10 calendar days of the request for a teleconference" due to receipts of requests on Fridays and lost time due to weekends and holidays. The performance period for this review program enhancement goal was lengthened in GDUFA III.
<b>Pre-ANDA Program Goals</b>	In last year's report, the Agency could not fully report on this category. As promised in last year's report, the Agency is now able to fulfill the commitment to fully report its pre-ANDA program goals. FDA met the FY 2022 pre-ANDA program goals.

Table C-5 represents FDA’s FY 2023 preliminary performance results.

**Table C-5. FY 2023 GDUFA III Preliminary Performance Results.**

Cause or Trend	Impact on FDA’s Ability to Meet Goals
<b>Performance Goals</b>	Because some submissions received in FY 2023 have associated performance goals that fall within subsequent fiscal years (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 performance goals. FDA will provide an update next year.
<b>Program Enhancement and Other Goals</b>	Because some submissions received in FY 2023 have associated program enhancement goals that fall within subsequent fiscal years (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 program enhancement and other goals. FDA will provide an update next year.

## Appendix D: FY 2022 Corrective Action Report

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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.<sup>34</sup>

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 2022 (GDUFA II) Performance Results

Table D-1 represents FDA's FY 2022 updated performance results for goal types that the Agency was not able to fully report on in last year's report. If a goal type is not listed in this table for FY 2022, then the Agency fully reported on it in last year's report.<sup>35</sup>

**Table D-1. FY 2022 GDUFA II 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
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<sup>34</sup> Section 744C(c)(1) of the FD&C Act (21 U.S.C. 379j-43(c)(1)).

<sup>35</sup> See [www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports](https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports).

<b>Performance Goals</b>	Clarification of ambiguities in CC response within 14 days was missed due to receipts of requests on Fridays and lost time due to weekends and holidays.	No corrective action plan is needed. The goal was renegotiated in GDUFA III to 21 days, which will allow FDA to avoid the issues posed by the previous time frame for requests that come in close in time to weekends or holidays.
	Standard Major ANDA Amendments (if PAI is required) due to open reviews at the goal date as FDA worked through the goal date rather than issuing CRLs on the goal date in an effort to instead issue an imminent action as described in the GDUFA III Commitment Letter.	No corrective action plan is needed. Working through goal dates because in FDA's judgment the continued work would likely result in an imminent action as described in the GDUFA II Commitment Letter.
	Priority major ANDA amendments (if PAI is required and applicant does not meet the requirements of a PFC) due to open reviews at the goal date as FDA worked through the goal date rather than issuing CRLs on the goal date in an effort to instead issue an imminent action as described in the GDUFA III Commitment Letter.	No corrective action plan is needed. Working through goal dates because in FDA's judgment the continued work would likely result in an imminent action as described in the GDUFA II Commitment Letter.
	Standard and priority minor ANDA amendments was missed due to open reviews at the goal date as FDA worked through the goal date rather than issuing CRLs on the goal date in an effort to instead issue an imminent action as described in the GDUFA III Commitment Letter.	No corrective action plan is needed. Working through goal dates because in FDA's judgment the continued work would likely result in an imminent action as described in the GDUFA II Commitment Letter.
<b>Program Enhancement Goals</b>	FDA will provide a scheduled date for a requested post-CRL teleconference within 10 calendar days of the request for a teleconference; this goal was missed due to receipts of requests on Fridays and lost time due to weekends and holidays	No corrective action plan is needed. The goal was renegotiated in GDUFA III to 14 days, which will allow FDA to avoid the issues posed by the previous 10-calendar day time frame for requests that come in close to weekends or holidays.
<b>Pre-ANDA Program Goals</b>	All FY 2022 goals were met.	No corrective action plan needed.



## 2. FY 2023 (GDUFA III) Performance Results

Table D-2 represents FDA's FY 2023 preliminary performance results.

**Table D-2. FY 2023 Preliminary Performance Results**

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
<b>Performance Goals</b>	It is too soon to determine.	Because some submissions received in FY 2023 have associated performance goals that may fall within subsequent fiscal years (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 performance goals. FDA will provide a full evaluation next year.
<b>Program Enhancement and Other Goals</b>	It is too soon to determine.	Because some submissions received in FY 2023 have associated program enhancement goals that fall within a subsequent fiscal year (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 program enhancement goals. FDA will provide a full evaluation next year.
<b>Performance Enhancement Goal: Pre-ANDA</b>	All FY 2023 goals were met.	No corrective action plan is needed.
<b>Performance Enhancement Goal: Facilities</b>	All FY 2023 goals were met.	No corrective action plan is needed.
<b>Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management</b>	FDA's publication of the annual update to the GDUFA Five-Year Financial Plan did not occur by the second quarter of FY 2023.  105 of 128 staff were hired in FY 2023.	FDA is reviewing its processes to ensure the GDUFA Five-Year Financial Plan is published on time going forward.  CDER is partnering with the Office of Talent Solutions and the hiring managers to expand its outreach capacity and recruitment strategies to mitigate the challenges faced with finding and selecting candidates. ORA is working to increase its use of Title 21 to recruit and retain investigatory staff. FDA will fill the remaining GDUFA III positions allocated for FY 2023 and will continue to track hiring progress until all 128 are on board.
<b>Performance Enhancement Goal: Guidance and MAPPs</b>	All FY 2023 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 2022 and 2023 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 2022 Performance Goal Performance*

#### **Summary of Performance**

FDA did not meet the FY 2022 performance goal for clarification of ambiguities in CC response within 14 days.

#### **Justification**

This performance goal was affected by the receipt of requests to clarify ambiguities in CC on Fridays and lost time due to weekends and holidays.

#### **FY 2022 Corrective Actions**

No corrective action plan is needed. The performance period for this performance goal was lengthened in GDUFA III, which will allow FDA to avoid the issues posed by the previous time frame for requests that come in close in time to weekends or holidays.

#### **Summary of Performance**

FDA did not meet the FY 2022 performance goal for priority major ANDA amendments (if PAI is required and applicant does not meet the requirements of a PFC).

#### **Justification**

This performance goal was affected by open reviews at the goal date as FDA worked through the goal date rather than issuing CRLs on the goal date in an effort to instead issue an imminent action as described in the GDUFA III Commitment Letter.

### **FY 2022 Corrective Actions**

No corrective action plan is needed. Working through goal dates because in FDA's judgment the continued work would likely result in an imminent action as described in the GDUFA II Commitment Letter.

### **Summary of Performance**

FDA did not meet the FY 2022 performance goal for standard and priority minor ANDA amendments.

### **Justification**

This performance goal was affected by open reviews at the goal date as FDA worked through the goal date rather than issuing CRLs on the goal date in an effort to instead issue an imminent action as described in the GDUFA III Commitment Letter.

### **FY 2022 Corrective Actions**

No corrective action plan is needed. Working through goal dates because in FDA's judgment the continued work would likely result in an imminent action as described in the GDUFA II Commitment Letter.

## **2. *FY 2023 Performance Goal Performance***

### **Summary of Performance**

Because some submissions received in FY 2023 have associated performance goals that fall within subsequent fiscal years (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 performance goals. FDA will provide a full evaluation next year.

### **Justification**

It is too soon to determine the justification.

### **FY 2023 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 2022 and FY 2023.

This section presents non-review performance enhancement goals cited in the GDUFA II Commitment Letter with specified completion dates in FY 2022 and in the GDUFA III Commitment Letter with specified completion dates in FY 2023. For the purposes of this report, "performance enhancement goals" are defined as any non-review performance goal with a specified deadline in the GDUFA II or GDUFA III Commitment Letters.

### 1. *FY 2022 Program Enhancement and Other Goals*

#### **Summary of Performance**

FDA did not meet the FY 2022 review program enhancement goal "FDA will provide a scheduled date for a requested post-CRL teleconference within 10 calendar days of the request for a teleconference."

#### **Justification**

This goal was affected by the receipt of post-CRL teleconference requests on Fridays and lost time due to weekends and holidays.

#### **FY 2023 Corrective Actions**

No corrective action is needed because the period for this program enhancement goal was lengthened to 14 calendar days in GDUFA III, which will allow FDA to avoid the issues posed by the previous 10-calendar-day time frame for requests that come in close to weekends or holidays.

### 2. *FY 2023 Program Enhancement and Other Goals*

#### **Summary of Performance**

Because some submissions received in FY 2023 have associated program enhancement goals that fall within a subsequent fiscal year (e.g., FY 2024), FDA cannot yet evaluate the entire performance for FY 2023 review program enhancement goals. FDA will provide a full evaluation next year.

### **Justification**

It is too soon to determine the justification.

### **FY 2023 Corrective Actions**

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

## **3.     *FY 2023 Performance Enhancement Goal: Pre-ANDA***

### **Summary of Performance**

All FY 2023 goals were met.

### **Justification**

No justification is needed.

### **FY 2023 Corrective Actions**

No corrective action is needed.

## **4.     *FY 2023 Performance Enhancement Goal: Facilities***

### **Summary of Performance**

All FY 2023 goals were met.

### **Justification**

No justification is needed.

### **FY 2023 Corrective Actions**

No corrective action is needed.

## **5.     *FY 2023 Performance Enhancement Goal: Continued Enhancement of User Fee Resource Management***

## **Summary of Performance**

FDA failed to publish an update to the GDUFA Five-Year Financial Plan no later than the second quarter of FY 2023.

FDA missed the GDUFA III goal for hiring in FY 2023. As of September 29, 2023, 105 of 128 FTEs had been hired.

## **Justification**

Of the 23 of 128 FTE positions that had not been filled, three candidates received final offers and were set to enter on duty. Seven additional candidates were identified as of September 29, 2023.

For the remaining vacancies, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.

## **FY 2023 Corrective Actions**

FDA is reviewing its processes to ensure the GDUFA Five-Year Financial Plan is published on time going forward. CDER is partnering with the Office of Talent Solutions and the hiring managers to expand its outreach capacity and recruitment strategies to mitigate the challenges faced with finding and selecting candidates. ORA is working to increase its use of Title 21 to assist with the recruitment of investigators. FDA will fill the remaining GDUFA III positions allocated for FY 2023 and will continue to track hiring progress until all 28 are on board.

### **6. *FY 2023 Performance Enhancement Goal: Guidance and MAPPs***

## **Summary of Performance**

All FY 2023 goals were met.

## **Justification**

No justification is needed.

## **FY 2023 Corrective Actions**

No corrective action is needed.

7. *FY 2023 Performance Enhancement Goal: Performance Reporting*

**Summary of Performance**

All FY 2023 goals were met.

**Justification**

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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